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Exhibit 10.37

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

LICENSING AND COMMERCIALIZATION AGREEMENT

BY AND BETWEEN

SPARK THERAPEUTICS, INC.

AND

NOVARTIS PHARMA AG

January 24, 2018

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LICENSING AND COMMERCIALIZATION AGREEMENT

This Licensing and Commercialization Agreement (“Agreement”) is entered into as of January 24, 2018 (the “Effective Date”) by and between Spark Therapeutics, Inc., a Delaware corporation, with offices at 3737 Market Street, Suite 1300, Philadelphia, PA 19104, USA (“Spark”) and Novartis Pharma AG, a Swiss company, with offices at Lichtstrasse 35, CH-4056 Basel, Switzerland (“Novartis”).

INTRODUCTION

1. Spark is currently developing Luxturna (as defined below) and Commercializing Luxturna in the United States, for use in the treatment of inherited retinal disease;
2. Novartis is in the business of developing, manufacturing, marketing, promoting and selling pharmaceutical products throughout the world;
3. Spark desires to enter into an arrangement with respect to the development, manufacturing, marketing, promotion and sale of Luxturna outside of the United States; and
4. Spark and Novartis believe that an agreement between the Parties regarding Luxturna would be desirable.

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, Spark and Novartis hereby agree as follows:

ARTICLE 1

DEFINITIONS; INTERPRETATION

1.1 Definitions. As used in this Agreement, the following terms shall have the meanings set forth below:

1.1.1 “Accounting Standards” mean, with respect to Spark, U.S. GAAP (United States Generally Accepted Accounting Principles) and, with respect to Novartis, IFRS (International Financial Reporting Standards), in each case, as generally and consistently applied for accounting and financial reporting purposes throughout the Party’s organization. Each Party may change the accounting standards that it uses throughout such Party’s organization, in which case such Party shall promptly notify the other Party in writing of such change and “Accounting Standards” shall be modified as to such Party accordingly, it being understood that each Party may only use internationally recognized accounting principles (e.g., IFRS, U.S. GAAP, or successor standards thereto).

1.1.2 “Affiliate” means with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, “control” or “controlled” means direct or indirect ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors in the case of a corporation or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity; status as a general partner in any partnership; or any other arrangement whereby the Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity or the ability to cause the direction of the management or policies of a corporation or other entity. The Parties acknowledge that in the case of entities organized under the laws of certain countries where the maximum percentage ownership permitted by law for a foreign investor is less than fifty percent (50%), such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. Notwithstanding the foregoing, The Children’s Hospital of Philadelphia shall be deemed to not be an Affiliate of Spark.

1.1.3 “Base Royalty Term” means, with respect to a Royalty Region, the period beginning on the Effective Date and continuing until twelve (12) years after the date of the First Commercial Sale of Luxturna in such Royalty Region, provided that if, on a country-by-country basis, the Base Royalty Term would otherwise expire before the expiration of Regulatory Exclusivity in such country, then the Base Royalty Term shall be extended until the expiration of Regulatory Exclusivity in such country (but not in the remainder of the applicable Region).

1.1.4 “Business Day” means a day other than (a) a Saturday or a Sunday, (b) a bank or other public holiday in New York, New York, Fort Worth, Texas, East Hanover, New Jersey, or Basel, Switzerland, or (c) the nine (9) consecutive days beginning on December 24th and continuing through January 1st to the extent not already covered in (a) or (b).

1.1.5 “Calendar Quarter” means each of the three (3) calendar month periods ending on March 31, June 30, September 30 and December 31 of any Calendar Year; provided that the first Calendar Quarter shall commence on the Effective Date and end on March

31, 2018 and, unless otherwise agreed between the Parties, the last Calendar Quarter shall end on the effective date of expiration or termination of the Term.

1.1.6 “Calendar Year” means each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided that the first year of the Term shall begin on the Effective Date and end on December 31, 2018 and the last year of the Term shall begin on the first day of such year and end on the last day of the Term.

1.1.7 “Claims” means all Third Party demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, reasonable legal costs and other reasonable expenses of any nature whatsoever.

1.1.8 “Combination Product” means a commercial product comprising Luxturna plus another Gene Therapeutic or other therapeutically active ingredient, whether coformulated or copackaged.

1.1.9 “Commercialization” or “Commercialize” means activities directed to obtaining pricing and reimbursement approvals, marketing, promoting, distributing, importing, exporting, offering to sell or selling a product, including pre-launch activities undertaken in preparation for a product launch and post-launch activities. Commercialization does not include Development or Manufacturing.

1.1.10 “Continued Royalty Term” means, with respect to a Royalty Region (or any country thereof for which the Base Royalty Term was extended due to Regulatory Exclusivity in such country), the period beginning upon the expiration of the Base Royalty Term applicable to such Region (or country) and ending (a) on December 31 of the Calendar Year in which a Royalty Termination Event described in Section 1.1.51(a) occurs, or (b) on the date a Royalty Termination Event described in Section 1.1.51(b) occurs, in each case ((a) and (b)) with respect to such Royalty Region (or country).

1.1.11 “Control” or “Controlled” means, with respect to any Intellectual Property right, Trademark or other intangible property, the possession by a Party (whether by license from an Affiliate or a Third Party, ownership, or control over an Affiliate having such possession by license or ownership) of the ability to grant to the other Party access or a license or sublicense as provided herein without violating the terms of any agreement with any Third Party.

(a) Subject to Section 3.1.6, Intellectual Property licensed by Spark from Third Parties under the Existing Spark Agreements that Spark is permitted to sublicense to Novartis as provided herein without violating the terms of such Existing Spark Agreements shall be deemed to be Controlled by Spark.

(b) Notwithstanding the foregoing, Spark shall not be considered to Control any Intellectual Property that it licenses from a Third Party under a license agreement other than an Existing Spark Agreement if (i) Spark would be required to make any payment in connection with the grant of, or Novartis’ exercise of rights under, a sublicense to such Intellectual Property hereunder, and (ii) Novartis does not agree, subject to Novartis’ right to offset a portion of such

payments against the royalties payable to Spark hereunder pursuant to Section 3.2.4, in writing to make any such payment to Spark or its designee.

(c) Notwithstanding the foregoing, Novartis shall not be considered to Control any Intellectual Property that it licenses from a Third Party if (i) Novartis would be required to make any payment in connection with the grant of, or Spark's exercise of rights under, a sublicense to such Intellectual Property hereunder, and (ii) Spark does not agree in writing to make any such payment to Novartis or its designee.

1.1.12 "Cover", "Covering" or "Covered" means, as to any subject matter and Patent Right, that, in the absence of a license granted under, or ownership of, such Patent Right, the making, using, selling, offering for sale, importation or other practice of such subject matter would infringe such Patent Right or, as to a pending claim included in such Patent Right, the making, using, selling, offering for sale, importation or other practice of such subject matter would infringe such Patent Right if such pending claim were to issue in an issued patent without modification, in each case, without regard to the validity or enforceability of such Patent Right.

1.1.13 "Development" or "Develop" means non-clinical and clinical research and drug development activities, including discovery activities, toxicology, pharmacology and other research and pre-clinical efforts, statistical analysis, clinical studies, regulatory affairs, and the preparation, filing and prosecution of Regulatory Approval and clinical study regulatory activities (but excluding all Manufacturing activities directed to the production of commercial supply other than any activities to be conducted by Spark pursuant to Section 4.1.2). Development does not include Technical Development.

1.1.14 "Development Plan" means the high-level plan, as updated on [**] basis and as amended from time to time in accordance with the terms of this Agreement, for (i) Development efforts with respect to Luxturna Development in the Novartis Territory proposed by Novartis pursuant to Section 4.2, including clinical, regulatory activities and milestones and Post-Approval Commitments, (ii) Technical Development as proposed by Spark pursuant to Section 4.2.1, and (iii) Technical Development as proposed by both Parties for life cycle management pursuant to Section 4.2.1.

1.1.15 "Diligent Efforts" means, with respect to the efforts to be expended by Novartis with respect to Development and Commercialization of Luxturna, such efforts shall be substantially equivalent to the efforts and resources commonly used by Novartis for products [**] owned by it or to which it has rights, which product is of similar market and economic potential as Luxturna, and at a similar stage in its Development or product life as Luxturna, taking into account the efficacy, safety, approved labeling, present and future market potential, and market exclusivity and other proprietary position of Luxturna as well as competitiveness thereof, the likelihood of Regulatory Approval of Luxturna given the regulatory structure involved and any jurisdictional-specific regulatory or clinical development requirements, the profitability to Novartis of Luxturna, and the costs, liabilities and external and internal resources required to achieve the relevant objective. For the avoidance of doubt, where Novartis has an obligation to use Diligent Efforts, the efforts of Novartis and its Affiliates and Sublicensees shall be considered in determining whether Novartis has satisfied such obligation.

1.1.16 “Distributor” means any Third Party appointed by Novartis or any of its Affiliates or its or their Sublicensees to distribute, market and sell Luxturna, with or without packaging rights, in one or more countries in the Novartis Territory, in circumstances where (a) the Third Party purchases Luxturna from Novartis or its Affiliates or its or their Sublicensees but does not otherwise make any upfront, royalty or other payment (separate from a payment for supply of Luxturna) to Novartis or its Affiliates or its or their Sublicensees with respect to Luxturna and (b) the Third Party does not engage in any material promotional activity with respect to Luxturna. If a Third Party has been appointed by Novartis or any of its Affiliates or its or their Sublicensees to distribute, market and sell Luxturna, with or without packaging rights, in one or more countries in the Novartis Territory, in circumstances where (a) the Third Party purchases Luxturna from Novartis or its Affiliates or its or their Sublicensees and otherwise makes an upfront, royalty or other payment (separate from a payment for supply of Luxturna) to Novartis or its Affiliates or its or their Sublicensees with respect to Luxturna or (b) the Third Party engages in material promotional activity with respect to Luxturna, such Third Party, each, a “Deemed Sublicensee Distributor,” shall be deemed a Sublicensee for purpose of Net Sales and corresponding royalty calculations.

1.1.17 “EMA” means the European Medicines Agency or any successor agency thereto.

1.1.18 “EU Regulatory Approval” means, if a conditional Regulatory Approval has been issued by EMA, the Regulatory Approval granted following satisfaction of all conditions in the conditional Regulatory Approval that are required to be satisfied to permit Novartis to Commercialize Luxturna within the EU and, if a conditional Regulatory Approval has not been issued, the Regulatory Approval of Luxturna by EMA.

1.1.19 “European Union” or “EU” means (a) the economic, scientific and political organization of member states of Europe as constituted as of the Effective Date, namely Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom of Great Britain and Northern Ireland, (b) any member country of the European Economic Area that is not otherwise a member of the European Union, (c) any country not otherwise included in clauses (a) or (b) that participates in the unified filing system under the auspices of the EMA and (d) Switzerland. For clarity, the European Union will at all times be deemed to include each of France, Germany, Italy, Spain and the United Kingdom, whether or not the United Kingdom remains a member state of the European Union, except as expressly noted within this Agreement.

1.1.20 “Executive Officers” means the Chief Executive Officer of Spark and the Chief Executive Officer of Novartis Pharma or, in either case, the designee of such officer.

1.1.21 “Existing Spark Agreements” means the license agreements set forth on Exhibit 1.1.21, as well as any future amendments thereto, which shall automatically be incorporated into and become a part of Exhibit 1.1.21.

1.1.22 “Field” means the treatment, prevention, cure or control of RPE65-mediated retinal disease in humans, [**].

1.1.23 “First Commercial Sale” means, with respect to Luxturna in a given Royalty Region, the first *bona fide* arm’s length sale by or on behalf of Novartis or its Sublicensees to a Third Party for use or consumption of Luxturna in the first country in such Royalty Region, after all necessary Regulatory Approvals for Luxturna have been obtained in such country.

1.1.24 “Gene Therapeutic” means any product incorporating a gene-based approach utilizing a gene therapy, [**].

1.1.25 “Good Clinical Practice” means the current good clinical practice under applicable Law, to the extent such standards are not less stringent than the U.S. current good clinical practice.

1.1.26 “Good Laboratory Practice” means the current good laboratory practice under applicable Law, to the extent such standards are not less stringent than the U.S. current good laboratory practice, including 21 C.F.R. Part 58.

1.1.27 “Governmental Authority” means any federal, state, national, regional, provincial or local government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.1.28 “Handle” or “Handling” means, with respect to a Patent Right, to prepare, file, prosecute, maintain or defend such Patent Right. For clarity, Handling does not include initiating any claim or action to enforce Patent Rights against actual or alleged infringers.

1.1.29 “HHMI” means the Howard Hughes Medical Institute, a not-for-profit institution located at 4000 Jones Bridge Road, Chevy Chase, MD 20815-6789, United States, a Third Party identified as a third party beneficiary of the CHOP Agreement.

1.1.30 “Insolvency Event” means, in relation to either Party, any one of the following: (a) that Party becomes insolvent; (b) that Party is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against such Party (except for involuntary bankruptcy proceedings which are dismissed within sixty (60) days); (c) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator or similar officer is appointed in respect of that Party; (d) a notice shall have been issued to convene a meeting for the purpose of passing a resolution to wind up that Party, or such a resolution shall have been passed other than a resolution for the solvent reconstruction or reorganization of that Party; (e) a resolution shall have been passed by that Party or that Party’s directors to make an application for an administration order or to appoint an administrator; or (f) that Party proposes or makes any general assignment, composition or arrangement with or for the benefit of all or some of that Party’s creditors or makes or suspends or threatens to suspend making payments to all or some of that Party’s creditors.

1.1.31 “Intellectual Property” means Patent Rights, utility models, registered designs, unregistered design rights, registered and unregistered copyrights, Know-How,

Confidential Information, database rights, any rights in clinical study results, applications for and the right to apply for any such rights, and any similar or analogous rights anywhere worldwide. Intellectual Property does not include Trademarks.

1.1.32 “Know-How” means all clinical data, technical information, know-how, data and materials, including inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, cell banks and other cellular materials, expertise and other technology applicable to compounds, molecules, cell lines, formulations, compositions, products or to their manufacture, development, registration, use or commercialization or methods of assaying or testing them or processes for their manufacture, formulations containing them, compositions incorporating or comprising them and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, and regulatory data rights, and instructions, processes, formulae, expertise and information, regulatory filings and copies thereof, relevant to the development, manufacture, use or commercialization of and/or which may be useful in studying, testing, development, production or formulation of products, or intermediates for the synthesis thereof.

1.1.33 “Law” means all laws, statutes, rules, regulations, orders, judgments, injunctions or ordinances of any Governmental Authority.

1.1.34 “Luxturna” means Spark’s proprietary Gene Therapeutic, *voretigene neparvovec*, which is known in the U.S. by the trade name *Luxturna*™.

1.1.35 “Manufacturing” or “Manufacture” means activities directed to producing, manufacturing, processing, sourcing of materials, filling, finishing, packaging, labeling, quality assurance testing and release, shipping, storage, quality control testing (including in-process, release and stability testing), supplying, shipping and release thereof.

1.1.36 “Net Sales” means the gross sales amounts invoiced by Novartis or any of its Affiliates or Sublicensees for Luxturna sold to Third Parties (including to Distributors, but excluding to Deemed Sublicensee Distributors) in *bona fide*, arms-length transactions, as determined in accordance with Novartis’ Accounting Standards as consistently applied, less a deduction of [**] percent ([**]%) for direct expenses related to the sale of Luxturna for distribution and warehousing expenses and for uncollectible amounts on previously-sold products and the following deductions booked on an accrual basis by Novartis and its Affiliates under the applicable Accounting Standards:

- (a) normal and customary trade and cash discounts, actually allowed and properly taken, directly with respect to sales of Luxturna;
- (b) amounts repaid or credited by reasons of defects, rejections, recalls or returns;
- (c) rebates and chargebacks to customers and Third Parties (including, without limitation, Medicare, Medicaid, Managed Healthcare and similar types of rebates);

- (d) amounts provided or credited to customers through coupons and other discount programs;
- (e) delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates or retroactive price reductions;
- (f) customary fee for service payments paid to Distributors for maintaining agreed inventory levels and providing information; and
- (g) other reductions or specifically identifiable amounts deducted for reasons substantially similar to those listed above in accordance with Novartis' Accounting Standards.

In the case of any sale or other disposal of Luxturna between or among Novartis and its Affiliates or Sublicensees, for resale, Net Sales shall be calculated only on the value charged or invoiced on the first arm's length sale thereafter to a Third Party.

In the case of any sale which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time all the revenue recognition criteria required by Novartis's Accounting Standards are met.

In the case of any sale or other disposal for value, such as barter or counter-trade, of Luxturna, or part thereof, other than in an arm's length transaction exclusively for money, Net Sales shall be calculated on the value of the non-cash consideration received or the fair market price (if higher) of Luxturna in the country of sale or disposal.

For the avoidance of doubt, sales between Novartis, its Affiliates and Sublicensees shall not be considered Net Sales (unless such Person is the end user of Luxturna), but subsequent sales by Novartis, its Affiliates and Sublicensees to Third Party customers shall be included in the calculation of Net Sales.

In the event Luxturna is sold as a Combination Product, the calculation of Net Sales for Luxturna will be agreed by the Parties based on the [**].

1.1.37 “Novartis IP” means Intellectual Property in any country of the world that is: (i) Controlled by Novartis as of the Effective Date or thereafter during the Term; and (ii) conceived, reduced to practice, authored, created, developed or in-licensed by Novartis in the performance of its obligations under this Agreement or used by Novartis in exercise of Novartis' rights under this Agreement in the Novartis Territory; and (iii) reasonably necessary or useful for the Development or Commercialization of Luxturna in the Field. The term Novartis IP shall not include Novartis' rights in the Joint IP.

1.1.38 “Novartis Territory” means the entire world, excluding the Spark Territory.

1.1.39 “Parties” means Spark and Novartis.

1.1.40 “Party” means either Spark or Novartis.

1.1.41 “Patent Rights” means patents and patent applications, including all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations, additions, renewals, registrations, utility models, design patents and extensions (including supplemental protection certificates) thereof, and all counterparts thereof in any country.

1.1.42 “Person” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.

1.1.43 “Post-Approval Commitments” means, with respect to a country, clinical studies, other clinical activities or other activities that either Party is required by the applicable Regulatory Authority or otherwise commits to perform after obtaining Regulatory Approval for Luxturna in such country.

1.1.44 “Product Trademark” means (a) the “*Luxturna*” Trademark and (b) any other Trademark that is approved by Novartis, after consultation with but not approval by the JSC, for use in connection with the Commercialization of Luxturna in the Novartis Territory. The term Product Trademark shall not include the corporate names or logos of either Party.

1.1.45 “Regulatory Approval” means the approval of the applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical product in a country (including, without limitation, the grant of manufacturing authorizations approval of all sites at which Luxturna will be Manufactured by or for Spark) by the relevant Regulatory Authority, excluding separate pricing or reimbursement approvals that may be required, as it may be amended or updated from time to time.

1.1.46 “Regulatory Authority” means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing and sale of a pharmaceutical product in a country.

1.1.47 “Regulatory Exclusivity” means, with respect to any country in the Novartis Territory, an additional market protection, other than patent protection, granted by a Regulatory Authority in such country which confers an exclusive Commercialization period during which Novartis, its Affiliates or sublicensees have the exclusive right to market and sell Luxturna in such country or other jurisdiction through a regulatory exclusivity right (*e.g.*, new biologic entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity, or any applicable data exclusivity).

1.1.48 “Related Agreements” means any additional agreements that the Parties enter into relating to this Agreement, including the Supply Agreement, the Quality Agreement, the Pharmacovigilance Agreement and any agreements related thereto.

1.1.49 “Royalty Region” means each of the following [**] geographical regions, without duplication: [**].

1.1.50 “Royalty Term” means, with respect to a Royalty Region, the Base Royalty Term plus the Continued Royalty Term.

1.1.51 “Royalty Termination Event” means, with respect to a Royalty Region, and after expiration of the Base Royalty Term in such Royalty Region (without regard to the extension of Regulatory Exclusivity within an individual country in such Royalty Region), (a) the first occurrence of aggregate Net Sales in such Royalty Region falling below \$[*] per Calendar Year or (b) a Supply Transition Event (as defined in the Supply Agreement), and a subsequent transition of Manufacturing rights to Novartis pursuant to Article 9 of the Supply Agreement as a consequence of such Supply Transition Event, occurs. For clarity, following a Royalty Termination Event, any Continued Royalty Term terminated thereby with respect to an applicable Royalty Region shall be fully exhausted and shall not be subject to reinstatement.

1.1.52 “Spark Change in Control” means any transaction or series of related transactions in which a Third Party (or group of Third Parties acting in concert) (a) acquires or becomes the beneficial owner of more than fifty percent (50%) of the outstanding voting securities of Spark, (b) becomes the surviving entity in any merger, consolidation, reorganization, tender offer or similar transaction to which Spark is a party, or as a result of which more than fifty percent (50%) of the total voting power of the stock outstanding of the surviving entity normally entitled to vote in elections of directors is not held by the Persons holding at least fifty percent (50%) of the outstanding shares of Spark preceding such transaction, or (c) acquires or otherwise receives the benefit of all or substantially all of the assets of Spark, including the rights to Luxturna for the Spark Territory.

1.1.53 “Spark IP” means the Intellectual Property that is Controlled by Spark as of the Effective Date or during the Term and reasonably necessary or useful for the Development or Commercialization of Luxturna in the Field in the Novartis Territory. The term Spark IP shall not include any Spark Manufacturing IP.

1.1.54 “Spark Manufacturing IP” means the Intellectual Property that is Controlled by Spark and reasonably necessary or useful for the Manufacture of Luxturna.

1.1.55 “Spark Territory” means the United States.

1.1.56 “Sublicensee” means any Person, other than an Affiliate or a distributor, to which a Party grants a sublicense of any right granted to such Party hereunder.

1.1.57 “Supply Agreement” means an agreement between the Parties entered into as of the Effective Date pursuant to which Spark shall Manufacture Luxturna and related products (e.g., diluent) for Commercialization by Novartis.

1.1.58 “Technical Development” means technical and CMC-related activities, including, without limitation, test method development and stability testing, assay development, process development (including life cycle management activities), formulation development, quality assurance and quality control development, validation and other testing,

packaging development, as well as record-keeping, data and database development, management, storage and retention activities relating to any of the foregoing.

1.1.59 “Third Party” means any Person other than a Party or any of its Affiliates.

1.1.60 “Third Party IP” means Intellectual Property owned or controlled by any Third Party relating to the subject matter of this Agreement as of the Effective Date or thereafter during the Term.

1.1.61 “Trademark” means any and all trademarks of every kind and nature, however designated, whether arising by operation of law, contract, license or otherwise, whether or not registered or unregistered, including product names, trade names, service marks, logos, program names, taglines, slogans, trade dress, and any other indicia of origin, including all related rights thereto, such as copyrights and design rights (including design patents rights) in pictures, logos, icons, drawings and the like, and any similar or analogous rights anywhere worldwide.

1.1.62 “United States” or “U.S.” means the United States of America and its territories and possessions.

1.2 Additional Definitions. The definition of each of the following terms is set forth in the Section of this Agreement or the Supply Agreement as indicated below:

Term	Section
1974 Convention	12.1
Agreement	Preamble
Alliance Manager	2.2
Auditor	6.5
Breaching Party	10.2
Capacity Plan	Supply Agreement
CDA	12.5
CHOP Agreement	Exhibit 1.1.21
Code	3.3
Confidential Information	8.1
Created	7.1.2(a)
Deemed Sublicensee Distributor	1.1.16
Effective Date	Preamble
Existing Luxturna Clinical Program	4.3.1
Indemnification Claim Notice	9.11.3(a)
Indemnified Party	9.11.3(a)
Indemnifying Party	9.11.3(a)
Independent Patent Counsel	7.4
Invalidity Claim	7.3.7
Joint IP	7.1.2(b)

Term	Section
Joint Patent Rights	7.2.3
JSC	2.1.1
NIH Agreement	Exhibit 1.1.21
Non-Breaching Party	10.2
Notice of Dispute	11.1.1
Novartis	Preamble
Novartis Indemnified Parties	9.11.1
Novartis Patent Rights	7.2.1
Novartis Territory	5.1
Pharmacovigilance Agreement	4.5.1
Product(s)	Supply Agreement
Promotional Materials	5.3
Quality Agreement	5.6
Severed Clause	12.4
Spark	Preamble
Spark Indemnified Parties	9.11.2
Spark Patent Rights	7.2.2
Status Report	2.1.5
Supply Agreement	5.6
Supply Transition Event	Supply Agreement
Term	10.1
Terminated Country	4.1.1
UPenn Agreement	Exhibit 1.1.21

1.3 Interpretation. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The word “will” shall be construed to have the same meaning and effect as the word “shall.” The headings contained in this Agreement or any Exhibit and in the table of contents to this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. All dollar (\$) amounts specified in this Agreement are United States dollar amounts. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth therein); (b) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (c) the word “extent” in the phrase “to the extent” means the degree to which a subject or other thing extends and such phrase does not mean simply “if”; (d) the word “or” shall be inclusive and not exclusive (i.e., “and/or”); (e) any reference to any Law refers to such Law as from time to time enacted, repealed or amended; (f) the word “notice” shall mean notice in writing (whether or not specifically stated) and shall include notices, consents,

approvals and other written communications contemplated under this Agreement; (g) provisions that require that a Party or the Parties hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (h) words using the singular or plural number also include the plural or singular number, respectively; and (i) all references herein to ARTICLES, Sections or Exhibits shall be construed to refer to ARTICLES, Sections and Exhibits of this Agreement. All Exhibits attached hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any capitalized terms used in the Exhibits attached hereto but not otherwise defined therein shall have the meaning as defined in this Agreement. In the event of an ambiguity or a question of intent or interpretation, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring either Party by virtue of the authorship of any provision of this Agreement.

ARTICLE 2 GOVERNANCE

2.1 Joint Steering Committee.

2.1.1 Formation; Purposes and Principles. Within [**] after the Effective Date, Spark and Novartis shall establish a joint steering committee (the “JSC”), which shall serve as a forum for the Parties to coordinate their respective activities and exchange appropriate information regarding their respective regulatory, Development, Commercialization and Manufacturing activities with respect to Luxturna. For clarity, the role of the JSC will be limited to coordination and exchange of information, and it shall have no decision-making power or authority except as expressly provided in Section 2.1.3. The JSC may, in its discretion, form sub-teams or subcommittees to address any of the issues within its purview.

2.1.2 Membership. The JSC shall be composed of three (3) representatives and an Alliance Manager appointed by each of Spark and Novartis who are [**] sufficient authority, relevant knowledge and expertise in the Development, Commercialization and Manufacturing activities of Luxturna. The initial members of the JSC from each Party shall be selected and identified to the other Party within [**] after the Effective Date or such later date as the Parties may agree. Each Party may replace any of its JSC representatives at any time upon written notice (e.g., by e-mail) to the other Party.

2.1.3 Consultative Purview of the JSC. The Parties agree that the JSC is not intended to and does not have any approval right and/or power over a Party’s activities or decisions related to the territory of such Party except as expressly detailed below. It is intended to be a consultative forum for coordination and exchange of certain information. The JSC shall discuss and coordinate on the following topics:

- (a) the general strategy for seeking and obtaining Regulatory Approval in the Novartis Territory;

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- (b) the general strategy for pricing and reimbursement approval and the general strategy for discounting of Luxturna in the Parties' respective territories;
- (c) each Party's free goods and compassionate use policy with respect to Luxturna for its respective territory, and such Party's implementation of such policy;
- (d) the Luxturna positioning and branding strategy for each Party's Territory, including such Party's strategies with respect to regional or local publications and Product Trademarks;
- (e) the Development Plan and substantive updates or amendments thereof, including Technical Development conducted by the Parties pursuant to Section 4.1.2;
- (f) pharmacovigilance matters pursuant to the Pharmacovigilance Agreement;
- (g) each Party's plans and strategies with respect to such Party's presence at international congresses and conventions and other medical education activities; and
- (h) joint activities, or activities of one Party to support activities of the other Party, under the Development Plan.

Without limiting the foregoing, the Parties acknowledge and agree that certain issues may have an impact on both the Novartis Territory and the Spark Territory. The following three items (x), (y) and (z) may be discussed at meetings of the JSC, but, in the event that the JSC is unable to resolve any such issue to the satisfaction of the Parties within [**], such issue shall be treated as a dispute and either Party may evoke the dispute resolution procedures set forth in ARTICLE 11.

(x) Issues arising with respect to obtaining the EU Regulatory Approval and the Parties' obligations pursuant to Section 4.4.1(a).

(y) Issues arising under the Supply Agreement, including, without limitation, disagreements regarding supply price increases (including the Fixed Facility Fee), the annual review of numbers of Resulting Vials of Drug Product from each Batch of Drug Substance (as such capitalized terms are defined in the Supply Agreement) for the previous calendar year, as required by Section 2.5 of the Supply Agreement, capacity restrictions leading to supply shortages and, for a period of [**] following the Effective Date, review of the Capacity Plan.

(z) *Bona fide* scientific or safety concerns of a Party [**].

Notwithstanding the foregoing, neither Party shall have final decision-making authority with respect to the interpretation of, or either Party's rights or obligations under, this Agreement or the Supply Agreement.

2.1.4 Meetings of the JSC. The JSC shall hold meetings at such times as the Parties shall mutually determine, but in no event shall such meetings of the JSC be held less

frequently than [**] during the Term. Other representatives of each Party or of Third Parties involved in the Development or Commercialization of Luxturna may attend meetings of the JSC as observers with the consent of each Party. Meetings of the JSC may be held in person, or by audio or video teleconference, as may be agreed by the Parties. Each Party shall be responsible for all of its own expenses of participating in the JSC.

2.1.5 Status Reports. At least [**] prior to each semiannual JSC meeting, each Party shall submit to the JSC a status report summarizing its contemplated and completed Development and Commercialization activities with respect to Luxturna in the applicable territory in the period following the previously-held JSC (each, a “Status Report”). Such Status Report shall include, at a minimum, information reasonably necessary to enable the JSC to discuss the matters set forth in Section 2.1.3. The JSC shall review and discuss, and may provide comments on, each Status Report, and the preparing Party shall reasonably consider all such comments.

2.1.6 Dissolution. Notwithstanding anything herein to the contrary, at any time following [**]. In the event that [**], the Parties will [**]. In any event, [**].

2.2 Alliance Managers. Each Party shall designate a single alliance manager for all of the activities contemplated under this Agreement (each, an “Alliance Manager”) who shall have sufficient seniority, experience and knowledge appropriate for managers with such project management responsibilities. Such Alliance Managers will be responsible for the day-to-day worldwide coordination of the collaboration contemplated by this Agreement and will serve to facilitate communication between the Parties. In addition, the Alliance Managers shall be responsible for calling JSC meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting. Each Party may change its designated Alliance Manager from time to time upon notice (e.g., by e-mail) to the other Party.

ARTICLE 3 LICENSES; OPTIONS; OTHER RIGHTS

3.1 Grants by Spark.

3.1.1 Development and Commercialization License. Subject to the terms and conditions of this Agreement, Spark hereby grants to Novartis (i) an exclusive (even as to Spark and its Affiliates) right and license, with the right to grant sublicenses as set forth in Section 3.1.5 and 3.1.6, under the Spark IP and Spark’s interest in the Joint IP, to Develop, have Developed, Commercialize and have Commercialized Luxturna in the Field for the Novartis Territory, and (ii) a non-exclusive right and license under the Spark Manufacturing IP and Spark’s interest in the Joint IP to perform Technical Development activities with respect to life cycle management pursuant to Section 4.1.2(a)(iii) for the Development and Commercialization of Luxturna in the Field for the Novartis Territory. For the avoidance of doubt, except (a) following a Supply Transition Event and a subsequent transition of Manufacturing rights to Novartis pursuant to Article 9 of the Supply Agreement as a consequence of such Supply Transition Event or (b) with respect to Novartis’ packaging rights and responsibilities set forth in the Supply Agreement, the license granted to Novartis hereunder does not include any Manufacturing rights directed towards Manufacturing Drug Substance (as defined under the Supply Agreement); however, following a Supply Transition

Event and a subsequent transition of Manufacturing rights to Novartis pursuant to Article 9 of the Supply Agreement as a consequence of such Supply Transition Event, such license automatically shall be expanded, without further action of the Parties, to include the right and license (such license to be commensurate in scope with the license grant set forth in the first sentence of this section), under the Spark Manufacturing IP, to Manufacture Luxturna for sale in the Novartis Territory.

3.1.2 Study Data License. Subject to the terms and conditions of this Agreement, Spark hereby grants to Novartis an exclusive (even as to Spark and its Affiliates) right and license, with the right to grant sublicenses as set forth in Section 3.1.5, under Spark's rights in study data Controlled by Spark from any clinical trials of Luxturna, solely to use such study data to Develop and Commercialize Luxturna in the Field for the Novartis Territory (including the right to cross reference or include such study data in regulatory filings made with Regulatory Authorities for the Novartis Territory). In addition, Novartis shall have the right to use any information concerning any adverse events, and any product quality and product complaints involving adverse events, related to Luxturna, to enable Novartis (or its applicable Affiliate or Sublicensee) to comply with its legal and regulatory obligations.

3.1.3 Post-Royalty Term License. Each license granted in Section 3.1.1 and 3.1.2 shall automatically convert, on a Royalty Region-by-Royalty Region basis, to a fully paid-up, non-royalty bearing, perpetual, non-exclusive license upon the expiration of the Royalty Term applicable to such Royalty Region (but not upon an earlier termination of this Agreement). For the avoidance of doubt, as to any country for which the Base Royalty Term is extended because of Regulatory Exclusivity in such country, the license granted in this Section 3.1.3 shall not take effect prior to the expiration of the Base Royalty Term in such country.

3.1.4 Trademark License. Subject to the terms and conditions of this Agreement, Spark hereby grants to Novartis an exclusive right and license, with the right to grant sublicenses as set forth in Section 3.1.5, to use any Product Trademark Controlled by Spark in connection with Developing and Commercializing Luxturna in the Field for the Novartis Territory.

3.1.5 Sublicenses. Novartis may, subject to Section 3.1.6, sublicense the rights granted to it by Spark under this Agreement at any time at its sole discretion. In any sublicense granted by Novartis, Novartis will include provisions that require the Sublicensee to satisfy the obligations under the Existing Spark Agreements specified in Section 3.1.6 and all applicable obligations under future Spark in-license agreements under which Novartis elects to receive sublicenses pursuant to Section 3.2.4. Novartis shall notify Spark in writing of the identity of each Sublicensee within [**] following the grant of any sublicense hereunder, and shall notify Spark in writing of the termination of any sublicense agreement within [**] following such termination. In addition, as provided in more detail in Section 12.8, Novartis may subcontract to Third Parties the performance of Novartis' tasks and obligations with respect to the Development and Commercialization of Luxturna (and, subject to the applicable terms of the Supply Agreement, the Manufacture of Luxturna following a Supply Transition Event) as Novartis deems appropriate.

3.1.6 Third Party Licenses. The licenses granted by Spark hereunder may include sublicenses under the Existing Spark Agreements. Spark has, prior to the Effective Date, provided Novartis with copies of the Existing Spark Agreements. Novartis acknowledges that its

rights with respect to such Spark IP are subject to the terms and conditions of the applicable Existing Spark Agreements, including rights reserved to Third Parties set forth therein. However, the Parties agree that no such in-licensed Spark IP or Spark Manufacturing IP shall be licensed to Novartis, and the provisions of this Section 3.1.6 shall not apply to Novartis with respect thereto, until such time as Spark provides to Novartis a written description of the Spark IP and Spark Manufacturing IP, as applicable, in-licensed pursuant to each Existing License Agreement and Novartis accepts in writing that it desires to receive a sublicense to such Spark IP and Spark Manufacturing IP, as applicable.

(a) Novartis acknowledges that the licenses granted to Spark under the NIH Agreement are non-exclusive. Novartis shall comply with, and shall require its Sublicensees to comply with, the terms and conditions of such Existing Spark Agreements that are applicable to Novartis and its Sublicensees thereunder, including: (a) Sections 1.3, 1.4, 1.5, 4.3, 4.4, 6.5, 6.6 and 10 of the UPenn Agreement and (b) Sections 4.2, 4.4, 5.1-5.2, 8.1, 10.1, 10.2, 12.5, and 13.7-13.9 of the NIH Agreement, the text of which Sections are set forth on Exhibit 3.1.6 in compliance with Section 4.3 of the NIH Agreement.

(b) In addition, in the event that the licenses granted by Spark hereunder expand to include the Spark Manufacturing IP, the following provisions of this Section 3.1.6(b) shall apply solely to the extent that Novartis is exercising a sublicense to the applicable Patent Rights licensed to Spark pursuant to the applicable Existing Spark Agreement: (x) Novartis shall comply with, and shall require its Sublicensees to comply with, Sections 4.2, 4.4, 5.1-5.2, 7.1, 8.1, 10.1, 10.2, 10.3, 11.3-11.5, 12.5, 12.6 and 14.13 of the CHOP Agreement, (y) Novartis shall report to Spark the date of the First Commercial Sale in each country in the Novartis Territory occurring after such license expansion within [**] of such occurrence and (z) HHMI shall become an intended Third Party beneficiary of this Agreement for the purpose of enforcing HHMI's rights, including indemnification and insurance provisions, under the CHOP Agreement. Notwithstanding anything to the contrary in this Agreement, Novartis shall have no obligation for any milestone, royalty and other payment obligations payable under the Existing Spark Agreements.

3.1.7 Rights Retained by Spark. Novartis shall receive only those rights of Spark expressly granted by Spark under the provisions of this Agreement, and any right of Spark not expressly granted to Novartis under the provisions of this Agreement shall be retained by Spark, including the sole right to Manufacture Luxturna for the Spark Territory and the Novartis Territory (except as expressly provided in Section 3.1.1).

3.2 Grants by Novartis.

3.2.1 Development and Commercialization Licenses. Subject to the terms and conditions of this Agreement, Novartis hereby grants to Spark:

(a) a non-exclusive, royalty-free, fully paid-up right and license, with the right to grant sublicenses, under the Novartis IP and Novartis' interest in the Joint IP, to perform Spark's obligations under this Agreement;

(b) a non-exclusive, royalty-free, fully paid-up right and license, with the right to grant sublicenses, under the Novartis IP and Novartis' interest in the Joint IP to Develop and Commercialize Luxturna in the Field in the Spark Territory; and

(c) a non-exclusive, worldwide, royalty-free, fully paid-up right and license, with the right to grant sublicenses under any Novartis IP or Novartis' interest in any Joint IP developed as a result of Technical Development activities for which Spark pays [**] percent ([**]%) of the costs pursuant to Section 4.1.2(c) to Develop, Commercialize, Manufacture or otherwise exploit any product in any field.

3.2.2 Study Data License. Subject to the terms and conditions of this Agreement, Novartis hereby grants to Spark, an exclusive (even as to Novartis and its Affiliates), royalty-free, fully paid-up right and license, with the right to grant sublicenses, under Novartis' rights in study data Controlled by Novartis from any clinical trials of Luxturna conducted pursuant to this Agreement, solely to use such study data to Develop and Commercialize Luxturna in the Field for the Spark Territory (including the right to cross reference or include such study data in filings made with Regulatory Authorities for the Spark Territory). In addition, Spark shall have the right to use any information concerning any adverse events, and any product quality and product complaints involving adverse events, related to Luxturna, sufficient to enable Spark (or its applicable Affiliate or Sublicensee) to comply with its legal and regulatory obligations.

3.2.3 Rights Retained by Novartis. Spark shall receive only those rights of Novartis expressly granted by Novartis under the provisions of this Agreement, and any right of Novartis not expressly granted to Spark under the provisions of this Agreement shall be retained by Novartis.

3.2.4 Future In-License Agreements.

(a) [**].

(i) [**], the Parties shall [**].

(ii) [**] the Parties [**], a Party [**].

(b) Other Patent Rights.

(i) If [**] desires to enter any Third Party agreement for any Third Party Patent Right determined by [**] to be desirable (but not necessary) for the Development or Commercialization of Luxturna for the Novartis Territory, it shall provide written notice of such desire to the [**]. If the [**] agrees, in its reasonable discretion, that such Third Party Patent Rights are desirable for the Development or Commercialization of Luxturna for the Novartis Territory, then the [**] shall have the first right to enter into such a license. If the [**] determines to enter into such a license, then prior to doing so it shall provide the [**] with a reasonable opportunity to review and comment on the proposed terms of such license that are applicable to the [**] shall use reasonable efforts to negotiate the terms of such license accordingly. If neither the [**] nor any of its Affiliates enters into a Third Party agreement for such Third Party Patent Rights within [**] or,

if the [**] is using Commercially Reasonable Efforts to negotiate such Third Party Agreement, [**], or if the [**] provides written notice to the [**] that it does not intend to enter a license agreement for such Third Party Patent Rights, then the [**] may enter an agreement to obtain such a license.

(ii) If Spark enters into an agreement pursuant to Section 3.2.4(a) or 3.2.4(b)(i), and the agreement provides for a license under such Third Party Patent Rights in the Novartis Territory, then Spark shall inform Novartis and shall provide Novartis with a copy of such license. If Novartis notifies Spark in writing that it wishes to obtain a sublicense of such rights in the Novartis Territory, Spark shall grant such a sublicense to Novartis, and Novartis will be bound by the rights and obligations of such license as they apply to Novartis as a sublicensee, including all payment obligations that would be due under such agreement as a result of the sublicense thereof granted to Novartis and Novartis' exercise of such sublicensed rights, which amounts Novartis shall pay within [**] after receipt of invoice from Spark in respect thereof (or such shorter period as may be necessary to enable Spark to timely pay the applicable upstream licensor).

(iii) If Novartis enters into an agreement pursuant to Section 3.2.4(a) or 3.2.4(b)(i), then Novartis [**]. If the agreement provides for a license under such Third Party Patent Rights in the Spark Territory, then Novartis shall inform Spark and shall provide Spark with a copy of such license. If Spark notifies Novartis in writing that it wishes to obtain a sublicense of such rights in the Spark Territory, Novartis shall grant such a sublicense to Spark, and Spark will be bound by the rights and obligations of such license as they apply to Spark as a sublicensee, including all payment obligations that would be due under such agreement as a result of the sublicense thereof granted to Spark and Spark's exercise of such sublicensed rights.

(iv) Novartis shall have the right to deduct from royalty payments due under Section 6.3 [**] percent ([**]%) of the amounts paid (including upfront license fees, milestone payments and royalties) by Novartis in respect of Third Party Patent Rights licensed or sublicensed to Novartis for the Novartis Territory in accordance with Section 3.2.4(a) or this 3.2.4(b); [**].

3.3 Section 365(n) of the U.S. Bankruptcy Code. For purposes of Section 365(n) of the U.S. Bankruptcy Code (the “Code”) and any similar laws in any other country, all rights and licenses granted under or pursuant to any Section of this Agreement are rights to “intellectual property” (as defined in Section 101(35A) of the Code). The Parties agree that the licensee of such rights under this Agreement will retain and may fully exercise all of its protections, rights and elections under the Code and any similar laws in any other country. Each Party hereby acknowledges that (a) copies of research data, (b) laboratory samples, (c) product samples, (d) formulas, (e) laboratory notes and notebooks, (f) data and results related to clinical trials, (g) regulatory filings and approvals, (h) rights of reference in respect of regulatory filings and approvals, (i) pre-clinical research data and results, and (j) marketing, advertising and promotional materials, in each case, that relate to such intellectual property, constitute “embodiments” of such intellectual property pursuant to Section 365(n) of the Code, and that the licensee will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in its possession, will be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon its written request therefor,

unless the licensor elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, upon written request therefor by the licensee following the rejection of this Agreement by or on behalf of the licensor. The provisions of this Section 3.3 are without prejudice to any rights the non-subject Party may have arising under the Code, Laws of other jurisdictions governing insolvency and bankruptcy, or other applicable Law. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, including for purposes of the Code and any similar laws in any other country: (x) the right of access to any intellectual property (including all embodiments thereof) of the licensor, or any Third Party with whom the licensor contracts to perform an obligation of such licensor under this Agreement which is necessary for the Development or Commercialization of Luxturna; (y) the right to contract directly with any Third Party described in (x) to complete the contracted work, and (z) the right to cure any breach of or default under any such agreement with a Third Party and set off the costs thereof against amounts payable to such licensor under this Agreement.

ARTICLE 4 DEVELOPMENT, TECHNICAL DEVELOPMENT, AND REGULATORY ACTIVITIES

4.1 General.

4.1.1 Development Activities. Novartis shall use Diligent Efforts to Develop and seek Regulatory Approval for Luxturna in the Novartis Territory. Novartis shall conduct such Development in accordance with the Development Plan (including any timelines specified therein), and shall conduct all such Development activities in accordance with applicable Laws and, as applicable, Good Laboratory Practice and Good Clinical Practice. Subject to Section 3.1.7, Novartis shall be free to perform any Development activities for Luxturna for the Novartis Territory. Without limiting the foregoing, in the event that (a) [**], or (b) [**] (a “Terminated Country”), (i) [**]; (iii) such Terminated Country shall be excluded from the scope of the licenses granted to Novartis in Section 3.1.1 and 3.1.2, and thereafter the “Novartis Territory” shall be deemed to exclude such Terminated Country(ies) and the “Spark Territory” shall be deemed to include such Terminated Country(ies); and (iv) the consequences set forth in Section 10.7.3 shall apply with respect to such Terminated Country(ies).

4.1.2 Technical Development Activities.

(a) In each case to the extent set forth in the Development Plan (as discussed by the JSC):

(i) Spark shall undertake Technical Development activities related to obtaining or maintaining Regulatory Approvals;

(ii) Spark shall undertake Technical Development activities related to [**]; and

(iii) the Parties shall undertake Technical Development activities in respect of [**]. Acknowledging that Spark Controls the Spark Manufacturing IP (and that Novartis does not have access to or rights to exercise the Spark Manufacturing IP except as specifically

provided in Section 3.1.1), Spark shall provide reasonable assistance and support to Novartis with respect to Novartis' Technical Development activities.

(b) Each Party shall use commercially reasonable efforts to perform its obligations pursuant to this Section 4.1.2, and shall conduct all such Technical Development activities in accordance with applicable Laws.

(c) Novartis shall bear the costs of all Technical Development activities (except as otherwise expressly stated in Section 4.4.2), provided, however, that if Spark decides to use any developments or improvements resulting from such Technical Development within the Spark Territory, it shall [**]. For clarity, nothing in this Section 4.1.2(c) shall prejudice or otherwise override any cost sharing provisions of the Supply Agreement [**].

(d) For clarity, Spark shall not have an obligation to perform Technical Development included in any Development Plan or amendment to any Development Plan unless and until Spark has agreed to undertake such obligation.

4.2 Development Plan.

4.2.1 Both Parties may propose Development and Technical Development activities under the Development Plan. Novartis shall provide to Spark a preliminary Development Plan for [**] within [**] of the Effective Date, and shall update the Development Plan to reflect intended Development activities with respect to [**] within [**] of the Effective Date. In addition, subject to Section 4.4.2, if Novartis is required to conduct further Development of the Product for the EU following EU Regulatory Approval, including to satisfy Post-Approval Commitments to Regulatory Authorities, to seek label expansions or otherwise for product life cycle management purposes, Novartis shall provide to Spark a Development Plan for such activities. Either Party may propose a plan for Technical Development.

4.2.2 Updates to the Development Plan will be prepared by Novartis and discussed by the JSC on at least [**] basis. Subject to Section 4.1.2(d), the Parties shall use commercially reasonable efforts to perform activities allocated to such Party in the Development Plan.

4.2.3 The Parties expressly acknowledge and agree that there is no guarantee of a successful Development and that any Development program contains inherent risks. Novartis shall not be liable for failures to meet specified timeframes in the Development Plan due to technical impossibility or causes outside its reasonable control or caused by the other Party.

4.2.4 For the avoidance of doubt, nothing in this Section 4.2 grants the JSC an approval right or requires Novartis to Develop, seek Regulatory Approval and/or Commercialize Luxturna in a specific country(ies) or region(s).

4.3 Development Studies.

4.3.1 Spark Territory. Prior to the Effective Date, Spark has independently initiated ongoing clinical studies in the United States of Luxturna to support Spark's efforts to obtain EU Regulatory Approval and Regulatory Approval in the Spark Territory (collectively, the "Existing Luxturna Clinical Program"). Novartis acknowledges and agrees that Spark will lead, control and be responsible for the continued execution of such clinical studies and any other studies that Spark determines are necessary or desirable for Regulatory Approval or Commercialization in the Spark Territory. Without limiting Section 4.4.1(a), Spark shall consider in good faith Novartis' comments relating to the Existing Luxturna Clinical Program and such other studies to the extent the Existing Luxturna Clinical Program data and data from such other studies will be used by Novartis for the Development and Commercialization of Luxturna in the Novartis Territory under this Agreement.

4.3.2 Novartis Territory. Novartis will lead, control and be responsible for all studies, other than the Existing Luxturna Clinical Program, that Novartis determines are necessary or desirable for Development or Commercialization in the Novartis Territory. Any such studies will be included in the Development Plan, and Novartis may conduct such studies anywhere (in Novartis' discretion) in the Novartis Territory.

4.3.3 Study Data. As between the Parties, all study data shall be owned by the Party that is the licensor of such data pursuant to Section 3.1.2 or 3.2.2, as applicable, and the other Party shall receive no interest in such study data except as provided pursuant to Section 3.1.2, 3.2.2 or 10.7, as applicable. If a Party so requests, then such study data shall be provided by the licensing Party to the other Party and its Affiliates for the permitted regulatory, Development, Commercialization purposes at no additional cost.

4.3.4 Records. Each Party shall keep, and shall cause its applicable Affiliates and Sublicensees to keep, complete, true and accurate records of all study data Controlled by such Party from any clinical trials of Luxturna sponsored by such Party and its Affiliates and Sublicensees. Each Party and its applicable Affiliates and Sublicensees shall keep such books and records for such period as required under applicable Law. The other Party will have the right, at its own expense and upon its written request, to review such of the records of the sponsoring Party, Affiliates and Sublicensees in support of such other Party's rights and obligations hereunder. Each Party agrees to hold in confidence all information received and all information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any applicable Law.

4.4 Regulatory Activities.

4.4.1 Responsibilities.

(a) EU Regulatory Approval.

(i) General Obligation. Subject to Section 2.1.3, Spark shall use commercially reasonable efforts to obtain EU Regulatory Approval.

(ii) Conditional Regulatory Approvals.

(1) If EMA issues a conditional Regulatory Approval that permits Novartis to Commercialize Luxturna within the EU, then (a) Spark shall perform all necessary Technical Development activities in accordance with Section 4.1.2(a)(i) that are conditions of such Regulatory Approval, and (b) Novartis shall be responsible for performing all other Development activities required by EMA to satisfy the conditions in the conditional Regulatory Approval. As soon as reasonably practicable after issuance of the conditional Regulatory Approval, Spark shall assign or transfer such conditional Regulatory Approval, the orphan designation, and all other regulatory designations and/or exclusivities for Luxturna to Novartis.

(2) If EMA issues a conditional Regulatory Approval, or the European Commission issues a Regulatory Approval with conditions, in each case that does not permit Novartis to Commercialize Luxturna within the EU, then Spark shall be responsible for performing all Technical Development activities and Development activities required by EMA to obtain a Regulatory Approval that permits Novartis to Commercialize Luxturna within the EU (excluding conditions of the conditional Regulatory Approval that are not necessary to permit Novartis to Commercialize Luxturna within the EU once Spark performs the foregoing Technical Development activities and Development activities required by EMA for such Commercialization). As soon as reasonably practicable after EU Regulatory Approval, Spark shall assign or transfer such EU Regulatory Approval, the orphan designation, and all other regulatory designations and/or exclusivities for Luxturna to Novartis. For clarity, this Section 4.4.1(a)(ii)(2) shall not be construed to limit Spark's obligations pursuant to Section 4.1.2.

(iii) BREXIT. In the event that prior to Spark obtaining EU Regulatory Approval, a separate Regulatory Approval becomes necessary for the Commercialization of Luxturna in the United Kingdom, Spark shall use commercially reasonable efforts to seek Regulatory Approval and to comply with the provisions of this subsection (a) with respect to the United Kingdom *mutatis mutandis*, provided that if additional clinical Development activities are required, the JSC shall meet and confer to discuss the role of the Parties with respect to such activities in accordance with the provisions of Section 2.1.3(x).

(iv) Supremacy. To the extent any other provision of this Section 4.4.1 contradicts any provision of this Section 4.4.1(a), the provision of this Section 4.4.1(a) shall govern.

(b) Assistance. Spark, at [**] cost and expense, shall provide reasonable available additional information, in the form Spark has such information, including without limitation information relating to clinical studies conducted by Spark as reasonably requested by Novartis, to assist Novartis in its activities to obtain and maintain Regulatory Approval, including preparation of any filings with a Regulatory Authority relating to Luxturna for the Novartis Territory and its preparation for or of any other meeting or communication with any Regulatory Authority relating to Luxturna for the Novartis Territory. Subject to the provisions of 4.4.1(a), Novartis shall be the holder of Regulatory Approvals for Luxturna in the Field for the Novartis Territory.

(c) Participation. The Party not responsible for interfacing, corresponding and meeting with the applicable Regulatory Authorities in a country with respect to Luxturna for the Novartis Territory shall have the right, but not the obligation, to have a senior, experienced employee reasonably acceptable to the responsible Party participate as an observer in material or scheduled face-to-face meetings, video conferences and any teleconferences, involving participation of personnel beyond regulatory experts, with the Regulatory Authorities in [**], and shall be provided with advance access to the responsible Party's material documentation prepared for such meetings. Prior to submission of material correspondence to the applicable Regulatory Authority, the responsible Party shall, sufficiently in advance for the other Party to review and comment, provide the other Party any material correspondence with the applicable Regulatory Authority related to such meetings. The responsible Party shall also provide the other Party with copies of any material correspondence with the applicable Regulatory Authority relating to Development of, or the process of obtaining Regulatory Approval for, Luxturna in the Novartis Territory, and respond within a reasonable time frame to all reasonable inquiries by the other Party with respect thereto.

(d) Post-Approval Commitments; Maintenance. Subject to the specific provisions of Section 4.4.1(a), upon grant of Regulatory Approval (including any conditional Regulatory Approvals) for Luxturna for the Novartis Territory, Novartis shall perform all Post-Approval Commitments (other than activities for which Spark is responsible pursuant to Section 4.1.2) and comply with all requirements imposed by applicable Laws as the marketing authorization holder for Luxturna. Novartis shall be fully responsible for maintaining the Regulatory Approval for Luxturna for the Novartis Territory and Novartis, Spark and their respective Affiliates and Sublicensees shall not take any steps that might undermine such Regulatory Approval.

(e) Transfers. Except as required by a Regulatory Authority or applicable Laws or to a permitted assignee under Section 12.7, Novartis shall in no circumstances transfer any Regulatory Approval granted for Luxturna for the Novartis Territory to any Third Party without the prior consent of Spark.

4.4.2 Costs. The cost to obtain and maintain all necessary regulatory filings and Regulatory Approvals for Luxturna will be borne by [**], with the exception of the filing fees and all other costs related to obtaining the EU Regulatory Approval of Luxturna, including any activities required by Sections 4.4.1(a)(ii)(1)(a) and 4.4.1(a)(ii)(2) (which costs shall be borne by [**]) but excluding any activities required by Section 4.4.1(a)(ii)(1)(b) (which costs shall be borne by [**]).

4.5 Adverse Event and Product Complaint Reporting Procedures; Pharmacovigilance.

4.5.1 The Parties shall enter into a pharmacovigilance agreement (the "Pharmacovigilance Agreement") for Luxturna applying to the Novartis Territory and the Spark Territory within [**] after the Effective Date, but no later than when Novartis commences any clinical study of Luxturna. Such Pharmacovigilance Agreement shall contain the specific terms, conditions and obligations of the Parties with respect to the collection, reporting and monitoring of all adverse drug reactions, adverse events, medical inquiries, and other relevant drug or related device safety matters with respect to Luxturna during the Term. Each Party acknowledges that its

obligations under the Pharmacovigilance Agreement shall include the obligations imposed on each Party by the applicable Law. Each Party will (a) provide the other Party with all complaints, non-serious and serious adverse event information, and safety data from clinical studies, including related communications with and from Regulatory Authorities, hospitals, physicians or patients, in its control necessary or desirable for the other Party to comply with all applicable Laws with respect to Luxturna and (b) report and provide access to such information to the other Party in such a manner and time so as to enable the other Party to comply with all applicable Laws.

4.5.2 Each Party has established (or shall establish) and shall maintain, at its cost, a global adverse event database. At the time agreed under the Pharmacovigilance Agreement, Spark shall make a one-time transfer to Novartis of the legacy data for Luxturna in Spark's global adverse event database. This shall be provided in E2B format and/or CIOMS I format, understanding that certain elements will be redacted respecting appropriate data privacy laws. The Parties acknowledge that the transfer of data from the global adverse event database will require mutual cooperation between the Parties and the Parties will use reasonable efforts to complete this transfer as soon as possible. With effect from the Effective Date, Novartis shall have access to all data in Spark's global adverse event database for use in the Novartis Territory and Spark shall have access to all data in Novartis' global adverse event database for use in the Spark Territory. Novartis shall be responsible for submitting adverse events reports to the applicable Regulatory Authorities for the Novartis Territory, and Spark shall be responsible for submitting serious adverse events reports to the applicable Regulatory Authorities in the Spark Territory. In addition, each Party shall promptly notify the other if such Party becomes aware of any information or circumstance that is have a material adverse effect on the Development or Commercialization of Luxturna.

4.6 Decisions to Terminate or Suspend a Study Based on Safety Concerns. The Party sponsoring or controlling any clinical study of Luxturna may terminate or suspend such clinical study if (a) a Regulatory Authority or safety data review board for such clinical study has required such termination or suspension, or (b) such Party believes in good faith that such termination or suspension is warranted because of safety or tolerability risks to the study subjects. In either case, such Party shall promptly notify the other Party of such termination or suspension, and shall use all reasonable efforts to inform and consult with the other Party prior to taking such action.

ARTICLE 5 COMMERCIALIZATION

5.1 Diligence. Novartis shall use Diligent Efforts to Commercialize Luxturna in accordance with the approved label therefor in the Field in the Novartis Territory. Without limiting the foregoing, in the event (a) Novartis determines not to use Diligent Efforts, or (b) following written notice from Spark that Novartis has ceased to use Diligent Efforts and Novartis has failed to resume Diligent Efforts within [**] of the date of such written notice, to Commercialize or continue Commercialization of Luxturna in a Terminated Country, (i) Novartis may elect to forego or suspend Commercialization activities with respect to such Terminated Country upon notice to Spark, (ii) such election shall not be deemed a breach of Novartis' obligations under this Agreement (including without limitation Section 5.1); (iii) such Terminated Country shall be excluded from the scope of the licenses granted to Novartis in Section 3.1.1 and 3.1.2, and thereafter the "Novartis

“Territory” shall be deemed to exclude such Terminated Country(ies) and the “Spark Territory” shall be deemed to include such Terminated Country(ies) and (iv) the consequences set forth in Section 10.7.3 shall apply with respect to such Terminated Country(ies).

5.2 Product Trademarks. Novartis, in consultation with the JSC, shall determine the Product Trademarks in the Novartis Territory. In connection therewith, Novartis may determine whether to use the LUXTURNA trademark for the Novartis Territory but shall not attempt, and shall have no authority to influence Spark’s branding strategy in the Spark Territory.

5.3 Advertising and Promotional Materials. Novartis shall develop and approve relevant written sales, promotion and advertising materials relating to Luxturna (“Promotional Materials”) for use in the Novartis Territory, which shall be consistent with the plans discussed at the JSC and with Novartis’ standard operating procedures, and compliant with applicable Laws and the provisions of the applicable Regulatory Approvals. Copies of all Promotional Materials used in the Novartis Territory will be archived by Novartis in accordance with Novartis’ standard operating procedures in accordance with applicable local Law.

5.4 Pricing and Reimbursement. Novartis and its Affiliates shall control and take the lead in all pricing and reimbursement approval proceedings relating to Luxturna in the Novartis Territory in accordance with the JSC-reviewed high-level general pricing and reimbursement strategy for the Novartis Territory. Novartis and its Affiliates shall be responsible for negotiating and shall have final decision-making authority in respect to the pricing and reimbursement for Luxturna in the Novartis Territory. Spark shall provide Novartis with reasonable access to data in Spark’s control, in the form Spark possesses such data, as is reasonably necessary or desirable to support Novartis to carry out health technology assessments (which may include, for example, [**]), provided that, Spark shall not be required to generate any further analyses or validation of any data, or otherwise to incur any costs or expense related to pricing and reimbursement after the Effective Date.

5.5 Other Responsibilities. Novartis shall be solely responsible for the following functions in the Novartis Territory:

5.5.1 managing all returns of Luxturna. If Luxturna sold in the Novartis Territory is returned to Spark, it shall promptly be shipped to a facility designated by Novartis; and

5.5.2 managing all aspects of Luxturna order processing, invoicing and collection, distribution, inventory and receivables.

5.6 Manufacture and Supply. Subject to the terms of the Supply Agreement, Spark shall retain the responsibility to Manufacture, and Novartis shall purchase from Spark, clinical and commercial supplies of Products (as defined in the Supply Agreement), and Spark shall supply Novartis’s clinical and commercial requirements of Products for the Novartis Territory. All Manufacturing and supply by Spark of Products for Development and Commercialization by Novartis shall be covered by the Supply Agreement and a quality agreement executed by the Parties as set forth in the Supply Agreement (the “Quality Agreement”).

ARTICLE 6
FINANCIAL PROVISIONS

6.1 Upfront Payments. Novartis shall pay Spark a non-refundable, non-creditable, one-time payment of one hundred five million dollars (\$105,000,000) within five (5) Business Days following the Effective Date.

6.2 Milestones. Spark shall notify Novartis in writing of the achievement of milestone event I below and, in accordance with the timelines set forth in Section 6.4, Novartis shall notify Spark in writing of the achievement of each milestone event II and III below. Spark shall issue an invoice to Novartis for each corresponding milestone payment as set forth below. For clarity, each referenced milestone event may be attained only once, and in no event shall any milestone payment be earned or paid more than once. Novartis shall make the corresponding non-refundable, non-creditable, one-time payments to Spark in accordance with Section 6.4.3:

Milestone Event	Payment
I. EU Regulatory Approval*	\$25,000,000
II. Achievement of aggregate Net Sales of Luxturna in [**] of \$[**]	[**]
III. Achievement of aggregate Net Sales of Luxturna in [**] of \$[**]	[**]

* With respect to the milestone payment in respect of EU Regulatory Approval, the milestone event shall not be triggered and Novartis shall have no obligation to pay such milestone payment (i) upon issuance of a conditional Regulatory Approval unless such conditional Regulatory Approval permits Novartis to Commercialize Luxturna within the EU, provided that in such event such milestone payment shall become payable once all conditions in such conditional Regulatory Approval that are required to be satisfied to permit Novartis to Commercialize Luxturna within the EU have been satisfied, or (ii) upon issuance of Regulatory Approval in the United Kingdom during a period of time when the United Kingdom is no longer a member state of the European Union.

6.3 Royalties. Novartis shall pay to Spark, on a Royalty Region-by-Royalty Region basis, a royalty of (a) [**] percent ([**]%) in respect of Net Sales of Luxturna in such Royalty Region during the Base Royalty Term and (b) [**] percent ([**]%) in respect of Net Sales of Luxturna in such Royalty Region during the Continued Royalty Term. For clarity, Novartis shall have no obligations to pay any royalty within a Royalty Region following the expiration of the Continued Royalty Term in such Royalty Region.

6.4 Reports; Invoices; Payments.

6.4.1 Within [**] after the end of each Calendar Quarter during the Royalty Term, Novartis shall submit to Spark a report providing (i) the Net Sales of Luxturna during such Calendar Quarter, (ii) a detailed calculation of the applicable royalties under Section 6.3, and (iii)

notification of any Net Sales milestone event set forth in Section 6.2 achieved during such Calendar Quarter;

6.4.2 Spark shall issue an invoice to Novartis for payments due pursuant to Section 6.3; and

6.4.3 Except as set forth in Sections 3.2.4 and 6.1, Novartis shall pay to Spark all undisputed amounts within [**] from receipt of an invoice therefor.

6.5 Records; Audits. Novartis shall keep, and shall cause its applicable Affiliates and Sublicensees to keep, complete, true and accurate records in accordance with its Accounting Standards of the items underlying Net Sales and amounts payable to Third Parties pursuant to any licenses or sublicenses granted pursuant to Section 3.2.4. Novartis and its applicable Affiliates and Sublicensees shall keep such books and records for at least [**] following the end of the Calendar Year to which they pertain. Spark will have the right [**], at its own expense, to have an independent, internationally-recognized, certified public accounting firm (the “Auditor”), selected by Spark and reasonably acceptable to Novartis, upon the written request of Spark, not more than [**] and not more frequently than [**] with respect to records covering any specific period of time, review such of the records of Novartis, its Affiliates and Sublicensees in the location(s) where such records are customarily maintained upon reasonable notice and during regular business hours, for the sole purpose of verifying the basis and accuracy of payments made under this Agreement by Novartis within the prior [**] period. Before beginning its audit, the Auditor shall execute an undertaking reasonably acceptable to Novartis by which the Auditor agrees to keep confidential all information reviewed during the audit. The Auditor shall have the right to disclose to the Parties only its conclusions regarding any payments owed under this Agreement. In addition, Spark shall only be entitled to audit the books and records of Novartis from the [**] in which the audit request is made. Spark agrees to hold in confidence all information received and all information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any applicable Law. The Auditor shall provide its audit report and basis for any determination to Novartis at the time such report is provided to Spark before it is considered final. If the review of such records reveals that the Novartis has failed to accurately report information pursuant to this Agreement, then Novartis shall promptly pay to Spark any resulting amounts due under this Agreement together with interest calculated in the manner provided in Section 6.9. If Novartis has underpaid by an amount greater than [**] percent ([**]%) of the amounts due for the period audited, Novartis shall also pay the reasonable costs of such review.

6.6 Tax Matters. Each Party shall be solely responsible for all net income taxes due with respect to payments received by such Party under this Agreement and for all of its other tax obligations. Novartis shall make all payments to Spark hereunder from accounts located within the United States or Switzerland and, except as otherwise required by then-applicable Law, shall not deduct or withhold any tax from any such payments. If then-applicable Law requires Novartis to deduct or withhold tax from any payment due to Spark hereunder, Novartis shall timely withhold and deduct the amount of such tax and pay it over to the relevant Governmental Authority, and shall promptly transmit to Spark an official tax certificate or other evidence of such payment sufficient to enable Spark to claim payment of such taxes. Novartis shall cooperate with Spark and shall use

reasonable efforts to lawfully avoid or reduce any deduction and withholding of tax in respect of any payments made to Spark hereunder or to secure a refund of any taxes so deducted and withheld. Novartis shall cooperate with Spark and shall use reasonable efforts to lawfully avoid or reduce indirect taxes arising in connection with this Agreement and the transactions contemplated hereby.

6.7 Currency Exchange. All payments to be made by Novartis to Spark shall be made in U.S. Dollars, to a Spark bank account able to receive U.S. Dollars. Net Sales amounts used to calculate royalties and milestones shall be converted to U.S. Dollars in accordance with Novartis' then-current standard exchange rate methodology as applied in its external reporting for the conversion of foreign currency sales into U.S. Dollars.

6.8 Blocked Payments. If, by reason of applicable Laws in any country, it becomes impossible or illegal for Novartis or its Affiliate or Sublicensee to transfer, or have transferred on its behalf, royalties or other payments to Spark, Novartis shall promptly notify Spark of the conditions preventing such transfer and such royalties or other payments shall be deposited in local currency in the relevant country to the credit of Spark in a recognized banking institution designated by Spark or, if none is designated by Spark within a period of [**], in a recognized banking institution selected by Novartis or its Affiliate or Sublicensee, as the case may be, and identified in a notice given to Spark pursuant to Section 12.3.

6.9 Late Payments. The paying Party shall pay interest to the receiving Party on the aggregate amount of any payment that is not paid on or before the date such payment is due under this Agreement at a rate per annum equal to the lesser of the prime or equivalent rate per annum quoted by *The Wall Street Journal* on the first Business Day after such payment is due, plus [**] percent ([**]%), or the highest rate permitted by applicable Law, calculated on the number of days such payment is paid after the date such payment is due, and compounded monthly.

6.10 Resolution of Disputes. If there is a dispute, claim or controversy relating to any financial obligation by one Party to the other Party pursuant to this Agreement, such Party shall provide such other Party with written notice setting forth in reasonable detail the nature and factual basis for such good-faith dispute and each Party agrees that it shall seek to resolve such dispute within [**] after the date such written notice is received. If no such resolution is reached by the Parties, the dispute shall be resolved through the procedures set forth in ARTICLE 11.

6.11 No Guarantee. Spark and Novartis acknowledge and agree that nothing in this Agreement shall be construed as representing an estimate or projection of anticipated sales of Luxturna in the Novartis Territory, and that the milestone events and Net Sales levels set forth in this Agreement or that have otherwise been discussed by the Parties are merely intended to define the milestone payments and royalty obligations to Spark in the event such milestone events or Net Sales level are achieved. Without prejudice to the express provisions of Sections 4.1 and 5.1, neither Party provides any representation, warranty or guarantee that (a) Development of Luxturna in the Novartis Territory will be successful, (b) Regulatory Approval for Luxturna in any specific country within the Novartis Territory will be sought or obtained, or (c) any other particular results will be achieved with respect to the Commercialization of Luxturna in the Novartis Territory hereunder or any specific country therein.

ARTICLE 7
INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION
AND RELATED MATTERS

7.1 Ownership of Intellectual Property.

7.1.1 **Existing IP.** Nothing in this Agreement shall affect Spark's ownership of the Spark IP existing as the Effective Date or Novartis' ownership of the Novartis IP existing as of the Effective Date, which in each case shall remain owned by the Party having such rights.

7.1.2 **Arising IP.** Each Party shall promptly notify the other Party of any new Intellectual Property created by such Party during the Term in the performance of this Agreement. Any such Intellectual Property shall be owned as follows:

(a) any such Intellectual Property that is solely conceived, reduced to practice, authored, created or developed ("Created") by or on behalf of one Party or its Affiliates (and not by or on behalf of the other Party or its Affiliates) shall be owned by the Creating Party and shall be included with the Spark IP or Novartis IP, as applicable, and included in the licenses granted to the other Party pursuant to ARTICLE 3; and

(b) any other such Intellectual Property that is Created jointly by or on behalf of both of the Parties or their Affiliates shall be jointly owned by the Parties on the basis of each Party having an undivided interest in the whole ("Joint IP"). Subject to the terms and conditions of this Agreement, each Party shall have the right to exploit Joint IP as it may determine, without any duty to account to the other Party or obtain the other Party's consent for any such exploitation, and shall provide such reasonable assistance to the other Party as may be required for it to enjoy the benefit of this Section 7.1.2(b).

(c) Questions of inventorship or authorship for purposes of determining whether new Intellectual Property created during the Term in the performance of this Agreement is Novartis IP, Spark IP, or Joint IP shall be resolved in accordance with United States patent or copyright Laws, as applicable.

7.2 Handling of Patent Rights.

7.2.1 **By Novartis.** Novartis shall have the sole right to Handle Patent Rights included in the Novartis IP worldwide ("Novartis Patent Rights").

7.2.2 **By Spark.** Spark shall have the sole right to Handle Patent Rights included in the Spark IP worldwide ("Spark Patent Rights").

7.2.3 **Joint Patent Rights.** The Parties will jointly control the Handling of Patent Rights included in the Joint IP ("Joint Patent Rights"). Spark shall have primary responsibility for Handling Joint Patent Rights in the Spark Territory and Novartis shall have primary responsibility for Handling Joint Patent Rights in the Novartis Territory. If a Party elects not to Handle any Joint Patent Right for which it has primary responsibility (or, after commencement of such Handling,

desires to cease Handling any Joint Patent Right), then such Party shall notify the other Party of such election and such other Party shall be entitled to Handle such Joint Patent Right in the applicable jurisdiction.

7.2.4 Costs and Expenses. The Party Handling any Patent Right under this Section 7.2 shall bear one hundred percent (100%) of the costs thereof.

7.2.5 Cooperation. Each Party agrees to cooperate with the other with respect to Handling Patent Rights pursuant to this Section 7.2. With respect to Joint Patent Rights, or any other Patent Right Covering Luxturna in the Field in the Novartis Territory, the Party responsible for Handling such Patent Rights shall provide the other Party with advance copies (which may be in draft form) of all material filings as well as copies of all material correspondence from the relevant patent office, in each case relating to such Patent Rights, and shall consider in good faith all comments from such other Party relating to such filings and correspondence.

7.3 Third Party Infringement.

7.3.1 Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (a) infringement of any of the Spark Patent Rights, Novartis Patent Rights or Joint Patent Rights, in each case that Cover Luxturna in the Field in the Novartis Territory or (b) other unauthorized use or violation of any of the Spark IP, Novartis IP or Joint IP, in each case relating to Luxturna in the Field in the Novartis Territory, of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such known or suspected infringement or unauthorized use or violation.

7.3.2 Enforcement Rights. Subject to the provisions of any Third Party license agreement under which Spark's rights in Spark IP or either Party's rights in the Joint IP are granted:

(a) Novartis shall have the first right, but not the obligation, to institute, prosecute and control any action or proceeding that it believes is reasonably required to protect or otherwise enforce any of the Spark IP or Joint IP against Third Parties Developing, Manufacturing or Commercializing products that are competitive with Luxturna in the Field for the Novartis Territory through counsel of its own choice. Prior to instituting any such action or proceeding, Novartis will give Spark at least [**] notice of its intention to institute any such action or proceeding. Novartis shall consider in good faith any comments from Spark prior to instituting any such action or proceeding. If Novartis is not permitted (e.g., for local legal reasons) to bring such action and requests Spark to bring such action on Novartis' behalf, then Spark shall bring such action at Novartis' sole cost and expense. Notwithstanding the foregoing, Spark may elect to contribute [**] percent ([**]%) of the costs and expenses of such action or proceeding by providing written notice to Novartis within [**] of the notice specified in Section 7.3.1. Should Spark elect to contribute [**] percent ([**]%) of the costs and expenses of such action or proceeding, the Parties agree that there will be joint consensus decision-making relating to enforcement strategy for Luxturna in the Field for the Novartis Territory, provided that the Party controlling the action shall have final decision-making authority relating to such action so long as such Party does not settle any such action without

the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed.

(b) If Novartis fails to initiate a suit or take other appropriate action pursuant to Section 7.3.2(a) within [**] of the notice specified in Section 7.3.1 (or within [**] in the case of any action brought under a non-U.S. version of the Hatch-Waxman Act), then Spark may, in its discretion, initiate a suit or take other appropriate action against Third Parties Developing, Manufacturing or Commercializing products that are competitive with Luxturna in the Field in the Novartis Territory.

(c) Neither Party shall settle or compromise any action or proceeding under this Section 7.3.2 without the consent of the other Party, which consent shall not be unreasonably withheld.

7.3.3 Novartis Sole Right to Enforce. Subject to the provisions of any Third Party license agreement under which Novartis' rights in Novartis IP are granted, Novartis shall have the sole right, but not the obligation, to initiate a suit or take other appropriate action that it believes is reasonably required to protect (i.e., prevent or abate actual or threatened infringement, unauthorized use, or violation of) or otherwise enforce any of the Novartis IP worldwide.

7.3.4 Spark Sole Right to Enforce. Subject to the provisions of any Third Party license agreement under which Spark's rights in Spark IP or either Party's rights in the Joint IP are granted, Spark shall have the sole right, but not the obligation, to initiate a suit or take other appropriate action that it believes is reasonably required to protect (i.e., prevent or abate actual or threatened infringement, unauthorized use, or violation of) or otherwise enforce (a) the Joint IP in the Spark Territory against Third Parties Developing, Manufacturing or Commercializing products that are competitive Luxturna in the Field, and (b) subject to Section 7.3.2, the Spark IP worldwide.

7.3.5 Conduct of Certain Actions; Costs. The Party initiating suit shall have the sole and exclusive right to select counsel for any suit initiated by it pursuant to Section 7.3.2, Section 7.3.3 or Section 7.3.4, but with regards to Section 7.3.2 Novartis will consider in good faith any comments on the choice of counsel received from Spark. If required under applicable Law in order for the initiating Party to initiate or maintain such suit, the other Party shall join as a party to the suit. Such other Party shall offer reasonable assistance to the initiating Party in connection therewith at no charge to the initiating Party except for reimbursement of reasonable out-of-pocket expenses incurred in rendering such assistance. The initiating Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings initiated by it pursuant to Section 7.3.2, Section 7.3.3 and Section 7.3.4, including the fees and expenses of the counsel selected by it, unless Spark elects to contribute [**] percent ([**]%) of the costs in accordance with Section 7.3.2. The other Party shall have the right to participate and be represented in any such suit by its own counsel at its own expense.

7.3.6 Recoveries. With respect to any suit or action referred to in Section 7.3.2, any recovery obtained as a result of any such proceeding, by settlement or otherwise, shall be applied in the following order of priority:

- (a) first, the Parties shall be reimbursed for all costs incurred in connection with such proceeding paid by the Parties and not otherwise recovered; and
- (b) second, any remainder shall be [**].

7.3.7 Patent Invalidity Claim. If a Third Party at any time asserts a counterclaim to a patent infringement claim initiated by a Party that any Spark Patent Right or Joint Patent Right that Covers Luxturna in the Field is invalid or otherwise unenforceable (an “Invalidity Claim”), control of the response to such claim in the Field in the Novartis Territory shall, as between the Parties, be determined in the same manner as enforcement rights with respect to such Patent Right are determined pursuant to Section 7.3.2, with the time periods set forth in Section 7.3.2 shortened where necessary to provide Spark sufficient time to respond without a loss of rights, and the non-controlling Party shall cooperate with the controlling Party in the preparation and formulation of such response, and in taking other steps reasonably necessary to respond, to such Invalidity Claim. Neither Party shall settle or compromise any Invalidity Claim without the consent of the other Party, which consent shall not be unreasonably withheld. If the Invalidity Claim does not arise in connection with a suit or action referred to in Section 7.3.2(a), Control of and the costs and expenses of responding to the Invalidity Claim shall be borne by the Party responsible for Handling the applicable Patent Right in accordance with Section 7.2.

7.4 Claimed Infringement. If a Party becomes aware of any claim that the Development or Commercialization of Luxturna infringes or otherwise violates the intellectual property rights of any Third Party, such Party shall promptly notify the other Party. In any such instance, the Parties shall cooperate and shall mutually agree upon an appropriate course of action and any settlement of such claim. Each Party shall have an equal right to participate in any settlement discussions that are held with such Third Parties. If there is a dispute between the Parties as to whether or not a Third Party Patent Right Covers Luxturna, the Parties agree to select an independent patent counsel reasonably acceptable to both Parties (the “Independent Patent Counsel”) to make such determination. The Parties agree that if the Independent Patent Counsel determines that the subject Third Party Patent Right Covers Luxturna, they will accept such determination for purposes of Section 3.2.4, if applicable. If the Independent Patent Counsel determines that the subject Third Party Patent Right does not Cover Luxturna or is invalid, either Party may still obtain a license, but shall be solely responsible for any payment obligation to the Third Party. Each Party shall provide to the other Party copies of any notices it receives from any Third Party regarding any patent nullity actions, any declaratory judgment actions and any alleged infringement or other violation of Third Party intellectual property rights relating to the Development or Commercialization of Luxturna. Such notices shall be provided promptly, but in no event after more than [**] following receipt thereof. The Parties shall equally share the costs and expenses of the Independent Patent Counsel.

7.5 Patent Term Extensions. The Parties shall cooperate, if necessary and appropriate, with each other in gaining patent term extension (including those extensions available under the Supplementary Certificate of Protection of Member States of the EU and other similar measures in any other country) wherever applicable to Patent Rights in the Novartis Territory Controlled by either Party that Cover Luxturna in the Field. The Parties shall, if necessary and appropriate, use commercially reasonable efforts in good faith to agree upon a joint strategy relating to patent term

extensions, but, in the absence of mutual agreement with respect to any extension issue in the Novartis Territory, the patent or the claims of the patent shall be selected on the basis of the scope, enforceability and remaining term of the patent in the relevant country or region. All filings and costs for such extensions shall be made by the Party responsible for Handling the applicable Patent Right in accordance with Section 7.2.

7.6 License Recordals. The Parties shall cooperate, if necessary and appropriate, with each other in recording any license agreements wherever applicable to Patent Rights in the Novartis Territory that Cover Luxturna in the Field at Novartis' sole cost and expense.

7.7 Patent Marking. Each Party agrees to comply with the patent marking statutes in each country in which Luxturna is sold by such Party, its Affiliates or its Sublicensees.

7.8 Trademarks.

7.8.1 Each Party and its Affiliates shall retain all right, title and interest in and to its and their respective corporate names and logos.

7.8.2 Unless otherwise agreed in writing by the Parties, and subject to any Third Party rights in the relevant Trademarks, Spark shall own the trademark for the name and logo of *LUXTURNA* worldwide and Novartis shall own all other Product Trademarks in the Novartis Territory.

7.8.3 The Party owning a Trademark pursuant to this Section 7.8 shall be exclusively entitled to register and be the owner of the domain names corresponding to or containing such Trademark in any generic Top Level Domains (gTLDs), including the new and to be introduced gTLDs. The Party owning a Trademark shall also own all goodwill associated therewith throughout the world.

7.8.4 The Parties agree that each Party, its Affiliates and Sublicensees shall comply strictly with the other Party's trademark style and usage standards that such other Party communicates to such Party from time to time in connection with the use by such Party, its Affiliates and Sublicensees of Trademarks Controlled by such other Party. The Parties agree that in the event of a Supply Transition Event, if Novartis elects to use Trademarks Controlled by Spark in connection with its branding strategy in the Novartis Territory, the Parties shall agree in good faith to reasonable and customary applicable trademark quality control standards.

7.8.5 Neither Party shall use any Product Trademark to identify any product other than Luxturna.

7.8.6 Novartis shall be solely responsible for Trademark matters in the Novartis Territory at Novartis' cost, including decision-making, filing, litigation, customs registrations and enforcement, and Spark shall be solely responsible for implementing such strategy and Trademark matters, including Product Trademark matters in the Spark Territory at Spark's cost, including decision-making, filing, litigation, customs registrations and enforcement. Novartis shall have the first right to enforce the Product Trademarks in the Novartis Territory, at Novartis' cost

and with the reasonable information to and assistance of Spark, and Spark shall have the first right to enforce the Product Trademarks in the Spark Territory, at Spark's cost and with the reasonable information to and assistance of Novartis.

7.8.7 If either Party becomes aware of any infringement of any Product Trademark by a Third Party, such Party shall promptly notify the other Party. The Parties shall cooperate and inform each other of relevant activities in their respective territory and consider in good faith the other Party's feedback if there is the potential for an impact to the other Party's territory.

7.8.8 Except as otherwise stated in this Agreement, Novartis shall not, and shall ensure that its Affiliates and Sublicensees do not, without Spark's prior written approval, use or seek to register any Trademark or domain name consisting of, or containing "Luxturna" or any other Product Trademark of Spark.

ARTICLE 8 CONFIDENTIALITY AND PUBLICITY

8.1 Confidential Information. Subject to the other provisions of this ARTICLE 8, each Party agrees to keep in confidence and not to disclose to any Third Party, or use for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, any Confidential Information of the other Party. As used herein, "Confidential Information" means confidential strategy, development plans, research information, manufacturing and technical information, technology, devices, products, clinical trial designs, clinical and pre-clinical data or other business information, objectives or technical information in any form or medium of a Party or its Affiliates disclosed by or on behalf of a Party in connection with this Agreement, whether prior to, on or following the Effective Date and whether disclosed orally, electronically, by observation or in writing. The terms of this Agreement and the Supply Agreement shall be considered Confidential Information hereunder. The restrictions on the disclosure and use of Confidential Information set forth in the first sentence of this Section 8.1 shall not apply to any Confidential Information that:

8.1.1 was known by the receiving Party prior to disclosure by the disclosing Party hereunder (as evidenced by the receiving Party's written records or other competent evidence);

8.1.2 is or becomes generally known or part of the public domain through no fault of the receiving Party;

8.1.3 is disclosed to the receiving Party by a Third Party having a legal right to make such disclosure without violating any confidentiality or non-use obligation that such Third Party has to the disclosing Party; or

8.1.4 is independently developed by personnel of the receiving Party who did not have access to the other Party's Confidential Information (as evidenced by the receiving Party's written records or other competent evidence).

In addition, if either Party is required to disclose Confidential Information of the other Party by applicable Law or legal process, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange, including Nasdaq, such Party shall comply with Section 8.5.4.

8.2 Employee, Consultant and Advisor Obligations. Each Party agrees that it and its Affiliates shall provide or permit access to Confidential Information received from the other Party and such Party's Affiliates and representatives only to the receiving Party's employees, consultants, advisors, licensors and permitted subcontractors, licensees and distributors, and to the employees, consultants, advisors and permitted subcontractors, licensees and distributors of the receiving Party's Affiliates, who in such Party's reasonable judgment have a need to know such Confidential Information to assist the receiving Party with the activities contemplated by this Agreement and who are subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially equivalent to the obligations of confidentiality and non-use of the receiving Party pursuant to Section 8.1.

8.3 Permitted Disclosures. Either Party may disclose Confidential Information (a) to *bona fide* potential investors, licensees, licensors, collaborators, lenders and acquirors/acquirees, and to such Party's consultants and advisors, the existence and terms of this Agreement to the extent necessary in connection with a proposed equity or debt financing of such Party, an actual or proposed license, collaboration or similar arrangement, or a proposed acquisition or business combination, (b) to *bona fide* potential Sublicensees or and distributors, so long as such recipients are bound in writing to maintain the confidentiality of such information in accordance with the terms of this Agreement, and (c) as reasonably necessary in connection with the prosecution and maintenance of Patent Rights as contemplated by this Agreement, in connection with regulatory filings made with Regulatory Authorities with respect to Luxturna, or in connection with the prosecuting or defending of any legal proceeding, as contemplated by this Agreement.

8.4 Responsibility for Compliance. Spark or Novartis, as applicable, shall remain responsible for any failure by any Person to whom such Party discloses the other Party's Confidential Information pursuant to Section 8.2 or Section 8.3 to treat such information as required under Section 8.1 (as if such Person were a Party directly bound to the requirements of Section 8.1).

8.5 Publicity.

8.5.1 The Parties shall issue press releases as set forth on Exhibit 8.5.1 hereto following the Effective Date.

8.5.2 Neither Party shall, without the prior written consent of the other Party, not to be unreasonably withheld or delayed, issue any other press release or make any public announcement (whether verbally or in writing) to any Third Party that (a) references the other Party (other than pre-agreed language for ownership of trademarks); (b) references joint activities under this Agreement; or (c) relates to this Agreement or the other Party. A Party's consent shall not be required to the extent such press release or public announcement that (i) subject to Section 8.5.4, is required by securities law disclosure requirements or otherwise required by applicable Laws, or legal process, in which event the Party issuing such press release or making such public

announcement will, to the extent possible, provide the other Party with advance notice and a draft thereof and reasonably consider any timely comment with respect thereto provided by such other Party or (ii) is of any subject matter included in any prior press release or public announcement.

8.5.3 Subject to the last sentence of Section 8.5.2, any Party proposing to make a press release or public announcement requiring the other Party's consent shall provide the proposed text to the other Party for its review prior to the date of disclosure. The reviewing Party shall respond to the other Party's proposal no later than [**] after the proposing Party's delivery of the proposed text, and may condition its consent on the publishing Party's agreement to implement the reviewing Party's reasonable revisions to the proposed text.

8.5.4 A Party may disclose this Agreement and its terms, and material developments or material information generated under this Agreement, in securities filings with the U.S. Securities and Exchange Commission (or equivalent foreign agency) to the extent required by applicable Law after complying with the procedure set forth in this Section 8.5.4.

(a) In such event, the Party seeking such disclosure will prepare a draft confidential treatment request and proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party agrees to promptly (and in any event, no more than [**] after receipt of such confidential treatment request and proposed redactions (or such lesser period of time as required by applicable Law)) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines prescribed by applicable Law. The Party seeking such disclosure shall exercise reasonable efforts to obtain confidential treatment of this Agreement from the U.S. Securities and Exchange Commission (or equivalent foreign agency) as represented by the redacted version reviewed by the other Party.

(b) Further, each Party acknowledges that the other Party may be legally or by stock exchange rules required to make public disclosures (including in filings with Government Authorities or stock exchanges) of the terms of this Agreement or certain material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by law or by stock exchange rules, provided that the Party seeking such disclosure first provides the other Party a copy of the proposed disclosure, except where prohibited by applicable Law, and provided further that (except to the extent that the Party seeking disclosure is required to disclose such information to comply with applicable Law and rules) if the other Party demonstrates to the reasonable satisfaction of the Party seeking disclosure, within [**] of such Party's providing the copy (or such lesser period of time as required by applicable Law), that the public disclosure of previously undisclosed information will materially adversely affect the Development or Commercialization of Luxturna (including with respect to such Party's Intellectual Property protection strategy), the Party seeking disclosure will remove from the disclosure such specific previously undisclosed information as the other Party shall reasonably request to be removed.

8.6 Publications.

8.6.1 Subject to this Section 8.6, either Party may publish or present the results of Development carried out by such Party on Luxturna following review by the other Party

for patentability and protection of such other Party's Confidential Information and potential impact on its plans for Development and Commercialization of Luxturna, provided that, Novartis' review and publication rights under this Section 8.6.1 shall commence upon EU Regulatory Approval.

8.6.2 Each Party shall provide the other Party with a copy of each proposed publication pursuant to Section 8.6.1 at least [**] in advance of submission for publications in peer-reviewed publications and at least [**] in advance of submission for posters, abstracts and oral presentations or scientific publications. If a proposing Party does not receive feedback from the other Party during the applicable review period, then it is deemed that there is a non-objection by the receiving Party to the content of such publication.

8.6.3 The Parties will cooperate to remove a Party's Confidential Information following such Party's request and reasonably cooperate on timing for late-breaking or otherwise urgent submission requirements and to minimize any impact on the reviewing Party's plans for Development and Commercialization of Luxturna. A reviewing Party, acting in good faith, may delay publication of a publication proposed pursuant to Section 8.6.2 above for up to [**] to secure related Intellectual Property rights in the subject matter of the publication.

8.7 No Liability for Public Disclosures by Other Party. Nothing in this Agreement shall be construed to impose upon either Party any liability or other obligation (either to the other Party or to any other Person) with respect to any press release, publication or other form of public disclosure or statement of the other Party.

ARTICLE 9 REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS; INDEMNIFICATION

9.1 Authority. Spark and Novartis each represents and warrants to the other Party that, as of the Effective Date, it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation and it has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement that it has the right to grant to the other the licenses granted pursuant to this Agreement, and that it has taken all corporate action required by applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement.

9.2 Consents. Spark and Novartis each represents and warrants to the other Party that, as of the Effective Date, except for any Regulatory Approval, pricing or reimbursement approval or similar approval necessary for the Development or Commercialization of Luxturna, all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained by the Effective Date.

9.3 No Conflict. Spark and Novartis each represents and warrants to the other Party that, as of the Effective Date, the execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder and the licenses granted or to be granted by such

Party pursuant to this Agreement (a) do not conflict with or violate any requirement of any Law existing as of the Effective Date applicable to such Party, (b) do not conflict with or result in a breach of any provision of its organizational documents, and (c) do not materially conflict with, violate, breach or constitute a default under any contractual obligation of such Party or any of its Affiliates existing as of the Effective Date.

9.4 Enforceability. Spark and Novartis each represents and warrants to the other Party that, as of the Effective Date, this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms.

9.5 No Debarment. (a) Spark represents, warrants and covenants to Novartis that as of the Effective Date, neither Spark nor any of its Affiliates, nor, to its knowledge, any other Person involved in the Development of Luxturna prior to the Effective Date, has been debarred or is subject to debarment pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act or comparable Laws in the Novartis Territory, as applicable, and (b) Spark and Novartis each represents, warrants and covenants to the other Party that neither such Party nor any of its Affiliates will knowingly use in any capacity, in connection with the Development of Luxturna, any Person who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, or who is the subject of a conviction described in such section, or comparable Laws in the Novartis Territory, as applicable. Each Party agrees to inform the other Party in writing immediately if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or comparable Laws in the Novartis Territory, as applicable, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of such Party's knowledge, is threatened, relating to the debarment or conviction of such Party or any Person used in any capacity by such Party or any of its Affiliates in connection with the Development of Luxturna.

9.6 Employment. The purpose of this Agreement is simply the grant to Novartis of an exclusive right and license to Develop, have Developed, Commercialize and have Commercialized Luxturna in the Field for the Novartis Territory as set out in Section 3.1 hereof. For the avoidance of any doubt, Novartis will not be acquiring any business or any business assets from [**]:

9.6.1 Each Party shall notify the other in writing within [**] from becoming aware of the same;

9.6.2 Novartis, [**] and Spark [**] Novartis [**] Novartis [**] Novartis [**] Novartis [**] Spark [**] Novartis [**] Novartis [**] Novartis [**] Novartis [**] Spark [**].

9.7 Other Products. If, within [**] following the Effective Date, Novartis or any of its Affiliates Commercializes any Gene Therapeutic, other than Luxturna, in any country within the Novartis Territory, for treatment, prevention, cure or control of RPE65-mediated retinitis pigmentosa or Leber's Congenital Amaurosis in humans, Spark, in its discretion, and upon notice to Novartis, may elect to [**] *mutatis mutandis*.

9.8 Additional Representations, Warranties and Covenants of Spark. Spark represents, warrants and covenants to Novartis that, as of the Effective Date:

9.8.1 To Spark's knowledge, Spark has the right to use and disclose and to enable Novartis to use and disclose (in each case under appropriate conditions of confidentiality) all Know-How and Confidential Information included in the Spark IP in the Field in the Novartis Territory.

9.8.2 To Spark's knowledge, the Development, Manufacture, use and Commercialization of Luxturna does not infringe the Patent Rights or misappropriate the Know-How of any Third Party. To Spark's knowledge it has not received any written notice of an alleged, threatened or actual claim of infringement or misappropriation.

9.8.3 Spark has not initiated or been involved in any proceedings or Claims in which it alleges that any Third Party is or was infringing or misappropriating any Spark IP, nor have any such proceedings been threatened by Spark.

9.8.4 To Spark's knowledge, the Spark IP comprises all of the intellectual property rights used by Spark, its Affiliates, consultants and contractors in the Development of Luxturna prior to the Effective Date.

9.8.5 Spark has not granted any license to any Third Party under the Spark IP that is inconsistent with the licenses granted to Novartis hereunder, and, except as identified in Section 3.1.6, there are no agreements or arrangements to which Spark or any of its Affiliates is a party relating to Luxturna or the Spark IP that would limit the rights granted to Novartis under this Agreement or that restrict or will result in a restriction on Novartis' ability to Develop, Manufacture (to the extent permitted pursuant to this Agreement), use or Commercialize Luxturna in the Novartis Territory as permitted under this Agreement.

9.8.6 All of Spark and its Affiliates' employees and officers employed prior to the Effective Date or following the Effective Date, and all consultants who have participated or continue to participate in the Development of Luxturna, have executed agreements or have existing obligations under applicable Laws requiring assignment to Spark of all inventions necessary for the Development or Commercialization of Luxturna which were made during the course of and as the result of their association with Spark (or any Spark Affiliate), excluding any such inventions that have been licensed to Spark pursuant to an Existing Spark Agreement, and all such employees, officers and consultants have executed agreements or have existing obligations under applicable Laws obligating such Persons to maintain as confidential Spark and its Affiliates' Confidential Information as well as confidential information of other Persons (including Novartis and its Affiliates) which such Person has or may receive.

9.8.7 Spark will conduct all of its activities under this Agreement consistent with Law and prevailing industry practices.

9.9 Additional Representations, Warranties and Covenants of Novartis. Novartis represents, warrants and covenants to Spark that, as of the Effective Date:

9.9.1 Novartis has not granted any license to any Third Party that is inconsistent with the licenses granted or to be granted to Spark hereunder.

9.9.2 All of its employees, officers, and consultants have executed agreements or have existing obligations under applicable Laws requiring assignment to Novartis of all inventions made during the course of and as the result of their association with Novartis and obligating the individual to maintain as confidential Novartis' Confidential Information as well as confidential information of other Persons (including Spark and its Affiliates) which such individual may receive, to the extent required to support Novartis' obligations under this Agreement.

9.9.3 Novartis will conduct all of its activities under this Agreement consistent with Law and prevailing industry practices.

9.10 No Implied Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO THE PRODUCTS. THE PARTIES AGREE THAT MILESTONE EVENTS AND NET SALES LEVELS SET OUT IN THIS AGREEMENT OR THAT HAVE OTHERWISE BEEN DISCUSSED BY THE PARTIES AS OF THE EFFECTIVE DATE ARE MERELY INTENDED TO DEFINE THE MILESTONE PAYMENTS AND ROYALTY OBLIGATIONS IF SUCH MILESTONE EVENTS OR NET SALES LEVELS ARE ACHIEVED. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP OR COMMERCIALIZE ANY PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR SALES LEVEL OF SUCH PRODUCT WILL BE ACHIEVED AT ALL OR WITHIN ANY COUNTRY OR JURISDICTION WITHIN SUCH PARTY'S RESPECTIVE TERRITORY.

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9.11 Indemnification.

9.11.1 By Spark. Spark shall indemnify, defend and hold harmless Novartis, its Affiliates and their respective directors, officers, employees and agents (collectively, the “Novartis Indemnified Parties”), from, against and in respect of any and all Claims, to the extent arising out of resulting from:

(a) any uncured breach of any representation, warranty or covenant made by Spark in this Agreement;

(b) the Development or Commercialization by Spark, its Affiliates and Sublicensees of Luxturna in the Spark Territory;

(c) the gross negligence, intentional misconduct or violation of Law by or of Spark or any of the other Spark Indemnified Parties; or

(d) any acts or omissions by or of Spark or any Spark Affiliate in relation to any of their respective employees prior to the Effective Date for which Novartis or any Novartis Affiliate is or becomes liable by operation of applicable Law;

provided that, in the case of each of clauses (a)–(d) above, Spark shall not be obliged to so indemnify, defend and hold harmless the Novartis Indemnified Parties for any Claims to the extent Novartis has an obligation to indemnify Spark Indemnified Parties under Section 9.11.2 or to the extent such Claims arise out of or result from the gross negligence, willful misconduct or violation of Law of or by Novartis or any of the other Novartis Indemnified Parties other than any refusal by Novartis or any Novartis Affiliate to employ any employee of Spark or any Spark Affiliate, until the date it is ordered to do so by a competent Government Authority, who was prior to the Effective Date assigned to working on Luxturna and/or any dismissal by Novartis or any Novartis Affiliate of any such employee who claims that their contract of employment has transferred to Novartis by operation of Law or any failure by Novartis or any Novartis Affiliate pursuant to applicable Law to furnish Spark or any Spark Affiliate with required information in respect of such employees.

9.11.2 By Novartis. Novartis shall indemnify, defend and hold harmless Spark, its Affiliates and their respective directors, officers, employees and agents (collectively, the “Spark Indemnified Parties”), from, against and in respect of any and all Claims to the extent arising out of or resulting from:

(a) any uncured breach of any representation, warranty or covenant made by Novartis in this Agreement;

(b) the Development or Commercialization by Novartis, its Affiliates and Sublicensees of Luxturna in the Novartis Territory;

(c) the gross negligence, intentional misconduct or violation of Law by or of Novartis or any of the other Novartis Indemnified Parties; or

(d) any acts or omissions by or of Novartis or any Novartis Affiliate arising after the Effective Date in relation to any individuals employed by Spark prior to the Effective Date and subsequently hired or engaged by Novartis or any Novartis Affiliate other than a refusal by Novartis or any Novartis Affiliate to employ a former employee of Spark or any Spark Affiliate, until the date it is ordered to do so by a competent Government Authority, or the termination of employment of any such former employee of Spark or any Spark Affiliate by Novartis or any Novartis Affiliate in circumstances where Section 9.6 applies;

provided that, in the case of each of clauses (a)–(d) above, Novartis shall not be obliged to so indemnify, defend and hold harmless the Spark Indemnified Parties for any Claims to the extent Spark has an obligation to indemnify Novartis Indemnified Parties under Section 9.11.1 or to the extent such Claims arise out of or result from the gross negligence, willful misconduct or violation of Law of or by Spark or any of the other Spark Indemnified Parties.

In the event that the licenses granted by Spark hereunder expand to include the Spark Manufacturing IP, to the extent that Novartis is exercising a sublicense to Patent Rights licensed to Spark pursuant to the CHOP Agreement, Novartis shall indemnify, defend and hold harmless HHMI, its trustees, officers, employees and agents as set forth in Section 11.7 of the CHOP Agreement.

9.11.3 Claims for Indemnification.

(a) A Person entitled to indemnification under this Section 9.11 (an “Indemnified Party”) shall give prompt written notification to the Party from whom indemnification is sought (the “Indemnifying Party”) of any Claim or fact in respect of which the Indemnified Party may base a claim for indemnification hereunder (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Claim as provided in this Section 9.11 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice). Such notice (the “Indemnification Claim Notice”) shall contain a description of the Claim and the nature and amount of the Claim (to the extent that the nature and amount of such Claim is known at such time). Upon the request of the Indemnifying Party, the Indemnified Party shall furnish promptly to the Indemnifying Party copies of all correspondence, communications and official documents (including court documents) received or sent in respect of such Claim.

(b) Within [**] after delivery of such notification, the Indemnifying Party shall assume control of the defense of such action, suit, proceeding or claim with counsel reasonably satisfactory to the Indemnified Party. The assumption of the defense of a Claim by the Indemnifying Party shall not be construed as acknowledgement that the Indemnifying Party is liable to indemnify any indemnitee in respect of the Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party’s claim for indemnification. If it is ultimately decided that the Indemnifying Party is not obligated to indemnify or hold an indemnitee harmless from and against the Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses (including reasonable attorneys’ fees and costs of suit) incurred by the Indemnifying Party in its defense of the Claim. If the Indemnifying Party does not give written notice to the Indemnified Party, within [**] after receipt of the Indemnification Claim Notice,

of the Indemnifying Party's election to assume the defense and handling of such Claim, the provisions of clause (f) below shall govern.

(c) The Indemnified Party may participate in, but not control, any such Claim at its own expense; provided that if the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such Claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith. The Indemnified Party shall also cooperate with the Indemnifying Party in the defense of such Claim, including by furnishing such records, information and testimony, providing witnesses and attending such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith, providing access during normal business hours to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making the Indemnified Party, the indemnitees and its and their employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information provided, all at the Indemnifying Party's expense.

(d) The Indemnifying Party shall keep the Indemnified Party advised of the status of such Claim and the defense thereof and shall consider recommendations made by the Indemnified Party with respect thereto.

(e) The Indemnified Party shall not agree to any settlement of such Claim without the prior written consent of the Indemnifying Party. The Indemnifying Party shall have the right to settle such Claim on any terms the Indemnifying Party chooses; provided that it shall not, without the prior written consent of the Indemnified Party, agree to a settlement of any Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder or which admits any wrongdoing or responsibility for the Claim on behalf of the Indemnified Party.

(f) If the Indemnifying Party does not give written notice to the Indemnified Party as set forth in Section 9.11.3(b) or fails to conduct the defense and handling of any Claim in good faith after having assumed such, the Indemnified Party may, at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate. In such event, the Indemnified Party shall keep the Indemnifying Party timely apprised of the status of such Claim and shall not settle such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld. If the Indemnified Party defends or handles such Claim, the Indemnifying Party shall cooperate with the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and shall be entitled to participate in the defense and handling of such Claim with its own counsel and at its own expense.

9.12 Direct Claims for Breach. If a Party believes it has been damaged directly (i.e., not arising from a Claim of a Third Party), such Party shall provide a Notice of Dispute to the other pursuant to Section 12.3 of this Agreement. All such disputes shall be governed by ARTICLE 11

of this Agreement. For clarity, this Section 9.12 is not intended to limit any other right or remedy of a Party with respect to this Agreement.

9.13 Integration of this Agreement and Supply Agreement. Spark and Novartis each acknowledge that the Supply Agreement and this License Agreement were entered into as part of one integrated transaction. As such, in the case of a claim for damages or indemnification, neither Spark nor Novartis shall assert that the performance and/or payment under one agreement was separate and apart from payment and/or performance under the other agreement.

9.14 Measure of Damages. Neither Party shall have liability to the other under this Agreement, whether pursuant to Section 9.11, ARTICLE 11 or otherwise, in contract, tort or otherwise, for [**]; provided that the foregoing limitation shall not apply to any such damages paid or payable to Third Parties in connection with an indemnifiable Claim pursuant to Section 9.11 or in the case of gross negligence or fraud.

9.15 No Exclusion. Neither Party excludes any liability for death or personal injury caused by its negligence or that of its employees, agents or subcontractors to the extent such exclusion is prohibited by applicable Law.

ARTICLE 10 TERM AND TERMINATION

10.1 Term. Unless terminated earlier in accordance with this ARTICLE 10, this Agreement shall remain in force for the period commencing on the Effective Date and ending on the expiration of the last to expire Royalty Term (the “Term”).

10.2 Termination for Material Breach. Upon any material breach of this Agreement by a Party (the “Breaching Party”), the other Party (the “Non-Breaching Party”) may give written notice to the Breaching Party specifying the claimed particulars of such breach. The Breaching Party shall have a period of [**] after such notice if such material breach is a breach of a payment obligation or [**] after such notice in the case of any other material breach in which to cure such breach; provided that, if such breach other than a payment breach is capable of being cured and cannot be cured within such [**] period, and the Breaching Party notifies the Non-Breaching Party within such period that it has initiated actions to cure such breach and thereafter diligently pursues such actions, the Breaching Party shall have such additional period as is reasonable in the circumstances, but in no event longer than [**] after the end of the original cure period, to cure such breach. Any termination by any Party under this Section 10.2 and the effects of termination provided in this ARTICLE 10 shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party. If the Breaching Party fails to cure the breach within the time period set forth above, the Non-Breaching Party shall have the right thereafter to terminate this Agreement effective immediately by giving written notice to the Breaching Party to such effect; provided that the Non-Breaching Party may, by notice to the Breaching Party, designate a later date for such termination in order to facilitate an orderly transition of activities relating to Luxturna or elect not to terminate this Agreement.

10.3 Termination for Insolvency. Each Party shall have the right to terminate this Agreement upon written notice to the other Party if an Insolvency Event occurs with respect to such other Party. In any event when a Party first becomes aware of the likely occurrence of any Insolvency Event in regard to that Party, it shall promptly so notify the other Party in sufficient time to give the other Party sufficient notice to protect its interests under this Agreement.

10.4 Termination by Novartis for Convenience. Novartis shall have the right to terminate this Agreement upon one (1) year's prior written notice to Spark. Following such notice of termination, Spark may elect to accelerate the effective date of such termination to any time earlier than the end of such one-year notice period upon written notice to Novartis specifying such earlier termination date; provided that such earlier date is consistent with the orderly wind down set forth in Section 10.7.2(i).

10.5 Termination by Novartis for Breach of Supply Agreement. In the event Novartis terminates the Supply Agreement in full pursuant to Section 14.2 thereof due to an uncured material breach by Spark, Novartis may, upon thirty (30) days' prior written notice to Spark, terminate this Agreement, provided that, Novartis may not terminate this Agreement if, following a Supply Transition Event, Novartis assumes the right to Manufacture Luxturna pursuant to Article 9 of the Supply Agreement as a consequence of such Supply Transition Event.

10.6 Termination by Novartis for Change in Control of Spark. Novartis may, upon sixty (60) days' prior written notice to Spark, to be given by Novartis within thirty (30) days following the earliest public announcement of such event, unilaterally terminate this Agreement following a Spark Change in Control.

10.7 Effects of Termination.

10.7.1 Spark Material Breach, Insolvency, Breach of Supply Agreement. In the event Novartis has the right to terminate this Agreement pursuant to Section 10.2 (Material Breach), 10.3 (Insolvency) or 10.5 (Breach of Supply Agreement), Novartis may elect, in its sole discretion, to terminate this Agreement in accordance with the specific notice and timing requirements set forth in Section 10.2, 10.3 or 10.5, as applicable:

- (a) In the event Novartis exercises any such right to terminate:
 - (i) Novartis may pay for and take receipt of Product in respect of orders already placed pursuant to the Supply Agreement;
 - (ii) Novartis may continue to exercise the license granted pursuant to Section 3.1.1 to Commercialize such Product until supply is exhausted (including supply obtained pursuant to Section 10.7.1(a)(i)), and [**];
 - (iii) Novartis shall have no obligation to pay the [**];
 - (iv) Novartis shall wind down, or if requested by Spark and at Spark's cost, transition to Spark or its designee, any clinical study of Luxturna as to which Novartis

is the regulatory sponsor that is ongoing as of the effective date of termination to the extent such clinical study was being carried out by Novartis or funded by Novartis immediately prior to termination of this Agreement;

(v) the licenses granted to Novartis in Section 3.1 shall terminate upon exhaustion of the Product referenced in Section 10.7.1(a)(i) (except as set forth in Section 10.7.4) and the licenses granted to Spark in Section 3.2 shall expand to cover the Novartis Territory upon the effective date of termination and survive;

(vi) Novartis shall promptly transfer on an as-is, where-is basis to Spark or Spark's designee possession and ownership of all governmental or regulatory correspondence, conversation logs, filings and approvals (including all Regulatory Approvals and pricing and reimbursement approvals) relating to the Development, Manufacture or Commercialization of Luxturna, to the extent permitted under applicable Law, and Novartis shall reasonably cooperate, at no additional out-of-pocket cost to Novartis, with requests by Spark for assistance necessary to facilitate Spark's assumption of regulatory responsibilities for Luxturna in the applicable countries in which direct transfer is not permitted;

(vii) Novartis shall promptly provide Spark with a summary of all Third Party agreements relating to the Development or Commercialization of Luxturna to which Novartis is a party and shall transfer to Spark any such Third Party agreements solely relating to the Development or Commercialization of Luxturna that Spark requests be assigned, to the extent such transfer is permitted thereunder; with respect to each agreement relating to the Development or Commercialization of Luxturna that is not transferred to Spark, at Spark's request, Novartis shall reasonably facilitate a direct introduction between Spark and the Third Party counterparty to such agreement;

(viii) the Related Agreements shall terminate, subject to any surviving obligations set forth therein;

(ix) Novartis shall execute all documents and take all such further actions as may be reasonably requested by Spark in order to give effect to the foregoing clauses in this Section 10.7.1;

(x) the Parties shall agree upon an orderly wind down of Development and Commercialization activities hereunder (including those activities being performed by their Affiliates, Sublicensees or Third Party contractors and any ongoing supply obligations) and each Party shall make all payments due and owing to one another and to Third Parties, provided that unless otherwise agreed or required under applicable Laws, all such transitional activities and obligations shall cease with effect from the [**] of the date of termination of this Agreement; and

(xi) Novartis' performance of transition activities pursuant to Sections 10.7.1(a)(iv) through 10.7.1(a)(x) and the expansion of licenses pursuant to Section 10.7.1(a)(v) (collectively, the "Post-Termination Obligations") is conditioned on the Parties, within [**] of the effective date of termination, negotiating in good faith commercially reasonable terms

therefor, taking into further account the overall circumstances of the particular termination, Novartis' ability to achieve a reasonable economic return and the residual value of the Novartis Territory rights to Luxturna at the time of termination.

(b) In the event Novartis has any such right to terminate this Agreement, but declines to exercise such right:

(i) Novartis shall provide written notice to Spark that it intends to exercise its rights under this Section 10.7.1(b) (within [**] after such termination would otherwise become effective);

(ii) Novartis may exercise the provisions of Article 9 of the Supply Agreement (which rights include the rights to receive and assume responsibility for supply or have such responsibility transitioned to a Third Party contractor);

(iii) Novartis may continue to order and take receipt of Product in accordance with the Supply Agreement and shall continue to pay royalties in accordance with Section 6.3 with respect to such Product (subject, if applicable, to the specific modifications set forth in Section 10.7.1(b)(iv)); and

(iv) If, following an applicable Supply Transition Event that is a basis for such termination, Novartis assumes control of Manufacturing of Luxturna pursuant to Article 9 of the Supply Agreement, then commencing with Novartis's assumption of Manufacturing, the royalty rate during the balance of the Base Royalty Term, if any, shall be reduced to [**] percent ([**]%) of the royalty rate that would otherwise apply pursuant to Section 6.3 and the royalty rate during the Continued Royalty Term shall be reduced to [**]%, and Novartis shall be entitled to offset against all royalties due and payable to Spark the actual, documented costs incurred by Novartis in transferring Manufacturing from Spark to Novartis (or its designee) pursuant to Section 9 of the Supply Agreement.

10.7.2 Termination in Full by Spark for Novartis Material Breach or Insolvency; Termination by Novartis for Convenience or Change of Control. In the event of any termination of this Agreement by Spark in full pursuant to Section 10.2 (Material Breach) or Section 10.3 (Insolvency), or by Novartis pursuant to Section 10.4 (Convenience) or Section 10.6 (Change of Control), the following provisions of this Section 10.7.2 shall apply:

(a) Novartis shall pay for and take receipt of orders already placed, completed and/or in process pursuant to the Supply Agreement;

(b) With respect to the Fixed Facility Fee:

(i) in the event of termination by Spark pursuant to Section 10.2 (Material Breach) or Section 10.3 (Insolvency), Novartis shall be obligated to pay the Fixed Facility Fee in respect of [**]. Novartis shall pay the Fixed Facility Fee for each such Calendar Year on or before December 31 of the applicable Calendar Year; and

(ii) in the event of termination by Novartis pursuant to Section 10.4 (Convenience), Novartis shall be obligated to pay the Fixed Facility Fee in respect of [**]; provided, however, that if Spark enters into an arrangement with a Third Party to Develop or Commercialize Luxturna in all or a portion of the Novartis Territory, Novartis shall only be obligated to pay the Fixed Facility Fee in respect of [**]. Novartis shall pay the Fixed Facility Fee for each such Calendar Year on or before December 31 of the applicable Calendar Year; and

(iii) in the event of termination by Novartis pursuant to Section 10.6 (Change of Control), Novartis shall only pay the Fixed Facility Fee in respect of [**]. Novartis shall pay the Fixed Facility Fee on or before December 31 of such Calendar Year.

(c) Novartis shall wind down, or if requested by Spark and at Spark's cost, transition to Spark or its designee, any clinical study of Luxturna as to which Novartis is the regulatory sponsor that is ongoing as of the effective date of termination to the extent such clinical study was being carried out by Novartis or funded by Novartis immediately prior to termination of this Agreement;

(d) the licenses granted to Novartis in Section 3.1 shall terminate (except as set forth in Section 10.7.4) and the licenses granted to Spark in Section 3.2 shall expand to cover the Novartis Territory and survive;

(e) Novartis shall promptly transfer on an as-is, where-is basis to Spark or Spark's designee possession and ownership of all governmental or regulatory correspondence, conversation logs, filings and approvals (including all Regulatory Approvals and pricing and reimbursement approvals) relating to the Development, Manufacture or Commercialization of Luxturna, to the extent permitted under applicable Law, and Novartis shall reasonably cooperate, at no additional out-of-pocket cost to Novartis, with requests by Spark for assistance necessary to facilitate Spark's assumption of regulatory responsibilities for Luxturna in the applicable countries in which direct transfer is not permitted;

(f) Novartis shall promptly provide Spark with a summary of all Third Party agreements relating to the Development or Commercialization of Luxturna to which Novartis is a party and shall transfer to Spark any such Third Party agreements solely relating to the Development or Commercialization of Luxturna that Spark requests be assigned, to the extent such transfer is permitted thereunder; with respect to each agreement relating to the Development or Commercialization of Luxturna that is not transferred to Spark, at Spark's request, Novartis shall reasonably facilitate a direct introduction between Spark and the Third Party counterparty to such agreement;

(g) the Related Agreements shall terminate, subject to any surviving obligations set forth therein;

(h) Novartis shall execute all documents and take all such further actions as may be reasonably requested by Spark in order to give effect to the foregoing clauses in this Section 10.7.2; and

(i) the Parties shall agree upon an orderly wind down of Development and Commercialization activities hereunder (including those activities being performed by their Affiliates, Sublicensees or Third Party contractors and any ongoing supply obligations) and each Party shall make all payments due and owing to one another and to Third Parties, provided that unless otherwise agreed or required under applicable Laws, all such transitional activities and obligations shall cease with effect from the [**] of the date of termination of this Agreement.

10.7.3 Partial Termination. In the event of partial termination of this Agreement with respect to a Terminated Country pursuant to Section 4.1 or Section 5.1, the following provisions of this Section 10.7.3 shall apply:

(a) Novartis shall wind down, or if requested by Spark and at Spark's cost, transition to Spark or its designee, any clinical study of Luxturna as to which Novartis is the regulatory sponsor that is ongoing as of the effective date of such partial termination to the extent such clinical study was being carried out by Novartis or funded by Novartis for the Terminated Country immediately prior to such partial termination;

(b) the licenses granted to Novartis in Section 3.1 shall terminate with respect to such Terminated Country (except as set forth in Section 10.7.4) and the licenses granted to Spark in Section 3.2 shall expand to cover such Terminated Country;

(c) Novartis shall promptly transfer on an as-is, where-is basis to Spark or Spark's designee possession and ownership of all governmental or regulatory correspondence, conversation logs, filings and approvals (including all Regulatory Approvals and pricing and reimbursement approvals) relating to the Development, Manufacture or Commercialization of Luxturna in such Terminated Country, to the extent permitted under applicable Law, and Novartis shall reasonably cooperate, at no additional out-of-pocket cost to Novartis, with requests by Spark for assistance necessary to facilitate Spark's assumption of regulatory responsibilities for Luxturna in such Terminated Country if direct transfer is not permitted; provided, however, that if the Regulatory Approval covers both a Terminated Country and other non-terminating jurisdictions within the Novartis Territory, Novartis shall retain the Regulatory Approval but shall take such steps as are reasonably practicable under applicable Laws to enable Spark to market Luxturna in the Terminated Country as if it were the holder of a Regulatory Approval in such Terminated Country alone;

(d) Novartis shall promptly provide Spark with a summary of all Third Party agreements relating to the Development or Commercialization of Luxturna to which Novartis is a party and shall transfer to Spark any such Third Party agreements solely relating to the Development or Commercialization of Luxturna for such Terminated Country that Spark requests be assigned, to the extent such transfer is permitted thereunder; with respect to each agreement relating to the Development or Commercialization of Luxturna for such Terminated Country that is not transferred to Spark, at Spark's request, Novartis shall reasonably facilitate a direct introduction between Spark and the Third Party counterparty to such agreement;

(e) Novartis shall execute all documents and take all such further actions as may be reasonably requested by Spark in order to give effect to the foregoing clauses in this Section 10.7.3; and

(f) the Parties shall agree upon an orderly wind down of Development and Commercialization activities with respect to such Terminated Country (including those activities being performed by their Affiliates, Sublicensees or Third Party contractors and any ongoing supply obligations) and each Party shall make all payments due and owing to one another and to Third Parties, provided that unless otherwise agreed or required under applicable Laws, all such transitional activities and obligations shall cease with effect from the [**] of the date of such partial termination of this Agreement.

10.7.4 Survival of Novartis Licenses. The licenses granted to Novartis under this Agreement shall survive (i) to the extent necessary for Novartis to perform its post-termination obligations under this ARTICLE 10, and (ii) as provided in Section 3.1.3.

10.7.5 Post-Expiration Supply. Upon expiration of the last to expire Royalty Term, the Parties shall meet and discuss the post-expiration provision of Product supply and Spark agrees to consider, in good faith, any request of Novartis to enter into a new supply arrangement. In the event the Parties cannot agree on a post-expiration supply arrangement, Spark shall transition Manufacture to Novartis, its Affiliate or a Third Party contract manufacturer pursuant to Section 9.2(e) of the Supply Agreement.

10.8 Return of Confidential Information. Within [**] following the expiration or termination of this Agreement, except to the extent and for so long as a Party retains license rights under this Agreement, each Party shall deliver to the other Party, or at the delivering Party's option destroy, any and all Confidential Information of the other Party in its possession, except for one copy which may be retained in its confidential files for archive purposes and subject to any copies remaining on its standard computer back-up devices (which copies the Party agrees not to access after termination).

10.9 Survival. In the event of any expiration or termination of this Agreement, (a) all financial obligations under ARTICLE 6 (i) that have accrued as of the effective date of such expiration or termination, whether or not they have become due, shall remain in effect and (ii) shall continue to apply with respect to Net Sales of Luxturna supplied by Spark pursuant to the Supply Agreement after the effective date of such expiration or termination and (b) the provisions set forth in Sections 3.1.3, 3.2.1(b) (with respect to the Spark Territory and, to the extent provided in Section 10.7, with respect to the Novartis Territory), 3.2.1(c), 3.2.2 (with respect to the Spark Territory and, to the extent provided in Section 10.7, with respect to the Novartis Territory), 6.5, 6.6, 6.7, 6.8, 6.9, 6.10, 7.1, 7.8.1, 7.8.2, ARTICLE 8 (except for Sections 8.5 and 8.6), Sections 9.6.2, 9.10, 9.11, 9.12, 9.13, 9.14, 9.15, 10.7, 10.8, 10.9, ARTICLE 11 and ARTICLE 12 (and defined terms necessary to interpret the foregoing), shall survive.

ARTICLE 11

DISPUTE RESOLUTION

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11.1 In General. If any dispute or disagreement arises between Novartis and Spark in respect of this Agreement or any Related Agreement, they shall follow the following procedures in an attempt to resolve the dispute or disagreement:

11.1.1 The Party claiming that such a dispute exists shall give notice in writing to the other Party of the nature of the dispute (a “Notice of Dispute”).

11.1.2 Within [**] of receipt of a Notice of Dispute, the Alliance Managers shall meet and use reasonable efforts to resolve the dispute. If the Alliance Managers are unable to resolve the dispute within [**] of such initial meeting, they shall refer the matter to the JSC, which shall meet and use reasonable efforts to resolve the dispute. If the JSC has been disbanded or is unable to resolve the dispute within [**] of such referral, the Executive Officers (or a designate of the Executive Officer) of each Party shall meet in person or by teleconference and exchange written summaries reflecting, in reasonable detail, the nature and extent of the dispute, and at this meeting, they shall use their reasonable efforts to resolve the dispute.

11.1.3 If within [**] the dispute has not been resolved by the Executive Officers, or if, for any reason, the meeting described in Section 11.1.2 has not been held within [**] of initial receipt of the Notice of Dispute, then, subject to Section 11.2, the Parties agree that either Party may initiate litigation to resolve the dispute.

11.2 Equitable Relief. Nothing in this Agreement shall limit the right of either Party to seek to obtain in any court of competent jurisdiction any equitable or interim relief or provisional remedy, including injunctive relief.

11.3 Survival. The provisions of this ARTICLE 11 shall survive for [**] from the date of termination or expiration of this Agreement.

ARTICLE 12 MISCELLANEOUS

12.1 Choice of Law. This Agreement shall be governed by and interpreted under the Laws of the State of Delaware, United States, excluding: (a) any provision thereof that would apply the Law of any other jurisdiction; (b) the United Nations Conventions on Contracts for the International Sale of Goods; (c) the 1974 Convention on the Limitation Period in the International Sale of Goods (the “1974 Convention”); and (d) the Protocol amending the 1974 Convention, done at Vienna April 11, 1980.

12.2 Jurisdiction and Venue. Each Party irrevocably submits to the exclusive jurisdiction of the United States District Court for the District of Delaware for the purposes of any suit, action or other proceeding arising out of this Agreement. Each Party agrees to commence any such action, suit or proceeding in the United States District Court for the District of Delaware or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the Superior Court of the State of Delaware, Wilmington. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any such action, suit or proceeding arising out of this Agreement in the United States District Court for the District of Delaware (or the Superior Court

of the State of Delaware, Wilmington, as applicable), and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. For the avoidance of doubt, both Parties hereby irrevocably waive any right they may have to a trial by jury arising from any dispute under this Agreement.

12.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address specified in this Section 12.3 and shall be: (a) delivered personally; (b) transmitted by facsimile; or (c) sent via a reputable international overnight delivery service. Any such notice, instruction or communication shall be deemed to have been delivered (i) upon receipt if delivered by hand or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission), provided that an original document is sent via an internationally recognized overnight delivery service (receipt requested), or (ii) one (1) Business Day after it is sent via a reputable international overnight delivery service.

If to Spark:

Spark Therapeutics, Inc.
3737 Market Street, Suite 1300
Philadelphia, PA 19104
USA
Attention: General Counsel
Facsimile: [**]

With copy to:

WilmerHale LLP
60 State Street
Boston, MA 02109
USA
Attention: Steven D. Barrett, Esq.
Facsimile No.: (617) 526-5000

If to Novartis:

Novartis Pharma AG
Lichtstrasse 35
CH 4002 Basel
Switzerland
Attn: Head of Pharma BD&L
Fax: [**]

Novartis Pharma AG
Lichtstrasse 35
CH-4002 Basel
Switzerland
Attn: General Counsel
Fax [**]

With a copy to:

Arnold & Porter Kaye Scholer LLP
250 West 55th Street
New York, NY 10019-9710
Attention: Derek M. Stoldt, Esq.
Facsimile No.: [**]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith.

12.4 **Severability.** If, under applicable Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision of this Agreement (such invalid or unenforceable provision, a “Severed Clause”), this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use reasonable, good faith efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of the Severed Clause and this Agreement.

12.5 **Integration.** This Agreement constitutes the entire agreement between the Parties hereto with respect to the subject matter of this Agreement and supersedes all previous agreements, whether written or oral including, without limitation, that certain Mutual Non-Disclosure Agreement by and between Novartis and Spark, dated September 27, 2017 (the “CDA”), which obligations between Novartis and Spark are hereby terminated as of the Effective Date, provided that the rights and obligations of the Parties in Section 8 of the CDA shall survive as set forth therein. The Parties acknowledge and agree that, as of the Effective Date, all Confidential Information (as defined in the CDA) disclosed by a Party pursuant to the CDA shall be considered Confidential Information of such Party and subject to the terms set forth in this Agreement. This Agreement may be amended only in writing signed by properly authorized representatives of each of Spark and Novartis. In the event of any conflict between a substantive provision of this Agreement and any Exhibit hereto or any Related Agreement, the substantive provision of this Agreement shall prevail.

12.6 **Independent Contractors; No Agency.** Neither Party shall have any responsibility for the hiring, firing or compensation of the other Party’s employees or for any employee benefits. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party’s written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party’s legal relationship under this Agreement to the other Party shall be that of independent contractor. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Spark and Novartis, or to constitute one as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes.

12.7 **Assignment; Successors.** Neither Party will assign, transfer or novate this Agreement without the prior written consent of the other Party, except assignment or transfer will be permitted by notice in writing, and without the prior written consent of the other Party, to: (a) any of the assigning Party’s Affiliates; or (b) a purchaser of a substantial part of a Party’s assets or business relating to the subject matter of this Agreement. This Agreement shall be binding upon, and shall inure to the benefit of, all successors and permitted assigns. Any permitted assignee will assume all obligations of its assignor under this Agreement. Any assignment, transfer or novation made in violation of this Section 12.7 shall be wholly void and invalid, the assignee, transferee or successor shall acquire no rights whatsoever, and the non-assigning Party shall not recognize, nor shall it be required to recognize, the assignment, transfer or novation.

12.8 Performance by Other Persons. Subject to Section 3.1.5, each Party may exercise its rights and perform its obligations under this Agreement itself or through any of its Affiliates or permitted Sublicensees, and may subcontract its Development and Commercialization activities hereunder as it deems appropriate without the other Party's consent (including to distributors or wholesalers in the ordinary course of business). Each Party shall be responsible for the performance and compliance with this Agreement of its Affiliates, permitted Sublicensees, authorized agents and subcontractors.

12.9 Force Majeure. No Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and no Party shall be deemed in breach of its obligations, if such failure or delay is due to any natural disaster, explosion, fire, flood, act of nature (including tornadoes, thunderstorms, earthquakes, typhoons, hurricanes, and tsunamis), war, hostilities between nations, civil commotions, terrorism, riots, embargo, losses or shortages of power, [**], sabotage, or any other cause reasonably beyond the control of such Party. The Party affected by such force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its good faith estimate of the likely extent and duration of the interference with its activities), and will use commercially reasonable efforts in good faith to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. If the performance of any such obligation under this Agreement is delayed owing to such a force majeure for any continuous period of more than [**], the Parties will consult with respect to an equitable solution, including the possibility of the mutual termination of this Agreement.

12.10 No Third Party Beneficiaries. Except for Indemnified Parties as set forth in Section 9.11, this Agreement shall not be construed as conferring any rights or remedies upon any Person other than the Parties and their respective successors and permitted assigns.

12.11 Execution in Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided electronically by PDF or facsimile transmission shall be deemed to be original signatures.

12.12 English Language. This Agreement is written and executed in the English language. Any translation into any other language shall not be an official version of this Agreement and in the event of any conflict in interpretation between the English version and such translation, the English version shall prevail.

12.13 Expenses. Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.

12.14 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

[Signature page follows]

IN WITNESS WHEREOF, Spark and Novartis have caused this Agreement to be duly executed by their authorized representatives, in duplicate as of the Effective Date.

NOVARTIS PHARMA AG

By: /s/ Marc Ceulemans

Name: Marc Ceulemans
Title: Head Strategic Venture Capital Fund & Pharma Equities

By: /s/ Bartosz Dzikowski

Name: Bartosz Dzikowski
Title: Authorized Signatory

IN WITNESS WHEREOF, Spark and Novartis have caused this Agreement to be duly executed by their authorized representatives, in duplicate as of the Effective Date.

SPARK THERAPEUTICS, INC.

By: /s/ Jeffrey D. Marrazzo

Name: Jeffrey D. Marrazzo
Title: CEO

Exhibit 1.1.21**Existing Spark Agreements**

License Agreement, by and between Spark (formerly AAvenue Therapeutics, LLC) and The Children's Hospital of Philadelphia, dated October 14, 2013, as amended by that certain (i) License Agreement Amendment, dated December 26, 2013, (ii) License Agreement Amendment No. 2, dated May 16, 2014, (iii) License Agreement Amendment No. 3, dated December 5, 2014, and (iv) License Agreement amendment No. 4, dated October 8, 2015, and as supplemented by that certain License Agreement by and between Spark and The Children's Hospital of Philadelphia dated on or about November 20, 2015 (collectively, the "CHOP Agreement").

Amended and Restated Patent License Agreement, by and between Spark and The Trustees of the University of Pennsylvania, dated December 31, 2015 (the "UPenn Agreement").

Patent License Agreement, by and between Spark Therapeutics, Inc. and The National Institutes of Health, dated December 26, 2014 (the "NIH Agreement").

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Exhibit 3.1.6**Relevant Sections of NIH Agreement**
(as required by Section 4.3 thereof)

5.1 Prior to the First Commercial Sale, at NIH's reasonable request and to the extent reasonably available and already existing on-hand at Licensee's facilities, the Licensee agrees to provide the NIH with reasonable quantities of Licensed Products or materials made through the Licensed Processes solely for NIH's internal non-commercial research use only. The NIH may not transfer any Licensed Products obtained pursuant to this paragraph to any third party without the prior written consent of Licensee.

5.2 The Licensee agrees that products used or sold in the United States embodying Licensed Products or produced through use of Licensed Processes shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the NIH.

* * *

8.1 The Licensee agrees to keep accurate and correct records of Licensed Products, if any, made, used, sold, or imported and Licensed Processes practiced under this Agreement appropriate to determine the amount of royalties due the NIH. These records shall be retained for at least [**] following a given reporting period and shall be available during normal business hours for inspection, at the expense of the NIH, by an accountant or other designated auditor selected by the NIH for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to the NIH information relating to the accuracy of reports and royalty payments made under this Agreement. If an inspection shows an underreporting or underpayment in excess of [**] percent ([**]%) for any twelve (12) month period, then the Licensee shall reimburse the NIH for the cost of the inspection at the time the Licensee pays the unreported royalties, including any additional royalties as required by Paragraph 9.7. All royalty payments required under this Paragraph shall be due within [**] of the date the NIH provides the Licensee notice of the payment due.

* * *

10.1 The Licensee shall use its reasonable commercial efforts to bring the Licensed Products and Licensed Processes to Practical Application. "Reasonable commercial efforts" for the purposes of this provision shall include reasonable efforts to adhere to the Commercial Development Plan in Appendix E and toward the performance of the Benchmarks in Appendix D. The efforts of any sublicensee shall be considered the efforts of the Licensee.

10.2 Upon the First Commercial Sale, until the expiration or termination of this Agreement, the Licensee shall use its reasonable commercial efforts to make Licensed Products and Licensed Processes reasonably accessible to the United States public.

* * *

12.5 The Licensee shall indemnify and hold the NIH, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by or on behalf of the Licensee, its directors, employees, or third parties of any Licensed Patent Rights; or

(b) the design, manufacture, distribution, or use of any Licensed Products, Licensed Processes or materials by the Licensee, or other products or processes developed in connection with or arising out of the Licensed Patent Rights.

* * *

13.7 The NIH reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this Agreement if it is determined that the action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the Licensee.

13.8 Within [**] of receipt of written notice of the NIH's unilateral decision to modify or terminate this Agreement, the Licensee may, consistent with the provisions of 37 C.F.R.) i404.1 1, appeal the decision by written submission to the designated the NIH official. The decision of the designated the NIH official shall be the final agency decision. The Licensee may thereafter exercise any and all administrative or judicial remedies (or both) that may be available.

13.9 Within [**] of expiration or termination of this Agreement under this Article 13, a final report shall be submitted by the Licensee. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to the NIH shall become immediately due and payable upon termination or expiration. Unless otherwise specifically provided for under this Agreement, upon termination or expiration of this Agreement, the Licensee shall return all Licensed Products or other materials included within the Licensed Patent Rights to the NIH or provide the NIH with written certification of the destruction thereof. The Licensee may not be granted additional NIH licenses if the final reporting requirement is not fulfilled.

Exhibit 8.5.1**Press Releases**

(Commence on following page)

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis exclusively licenses first ophthalmology gene therapy in all markets outside the US, a milestone for patients with rare inherited vision loss

- *Novartis enters into a licensing and supply agreement to develop, register and commercialize investigational gene therapy voretigene neparvovec outside the US; Spark Therapeutics retains US rights for LUXTURNA™ (voretigene neparvovec-rzyl)*
- *Voretigene neparvovec is an investigational one-time gene therapy to restore functional vision for patients with biallelic mutations of the RPE65 gene*
- *This investigational therapy provides patients with a working copy of the RPE65 gene to treat otherwise progressive vision loss that typically leads to blindness*

Basel, January 24, 2018 – Novartis today announced a licensing agreement with Spark Therapeutics covering development, registration and commercialization rights to voretigene neparvovec in markets outside the US. Voretigene neparvovec, known as LUXTURNA™ (voretigene neparvovec-rzyl) in the US, received FDA approval on December 19, 2017 as a one-time gene therapy to restore functional vision in children and adult patients with biallelic mutations of the RPE65 (retinal pigment epithelial 65 kDa protein) gene¹. The market authorization application (MAA) with the European Medicines Agency (EMA) was filed on July 31, 2017. Currently there is no existing therapy for this disease outside the US.

"No otherwise healthy child should have to go blind due to this devastating disease. Gene therapy is a promising new avenue to potentially address this unmet need," said Shreeram Aradhya, Global Head of Medical Affairs and Chief Medical Officer, Novartis Pharmaceuticals. "This collaboration builds on our commitment to ophthalmology. We look forward to leveraging our global presence to ensure that patients outside the US have access to this potentially life-changing treatment."

Novartis will make an upfront payment as well as pay milestones and royalties to Spark Therapeutics reflective of the late stage of the opportunity. Spark Therapeutics retains exclusive rights for LUXTURNA™ in the US and will retain responsibility for obtaining EMA approval. Commercialization rights will be transferred to Novartis upon successful completion of registration and issuance of market authorization. Novartis has exclusive rights to pursue development, registration and commercialization in all other countries outside the US. Spark Therapeutics will be responsible for the supply of voretigene neparvovec worldwide under a separate manufacturing and supply agreement with Novartis.

Mutations in the RPE65 gene lead to reduced or absent levels of RPE65 isomerohydrolase activity, blocking the visual cycle and resulting in progressive vision loss and ultimately,

blindness¹. Only a few thousand people worldwide are affected by this ultra-orphan condition^{1,2}. Pending approval, Novartis will work with physicians to establish new approaches to facilitating diagnosis and treatment at specialized treatment centers.

About Novartis in ophthalmology

Novartis is a leading ophthalmology company, with therapies that treat both front and back of the eye disorders, including retina diseases, glaucoma, dry eye and other external eye diseases. In 2016, approximately 200 million patients worldwide were treated with Novartis ophthalmic products.

About LUXTURNA™

LUXTURNA™ is an adeno-associated virus (AAV) vector-based gene therapy indicated in the United States for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician. Mutations in the RPE65 (retinal pigment epithelial 65 kDa protein) gene lead to reduced or absent levels of RPE65 isomerohydroxylase activity, blocking the visual cycle and resulting in impairment of vision. Injection of LUXTURNA™ into the subretinal space results in transduction of some retinal pigment epithelial cells with a cDNA encoding normal human RPE65 protein, thus providing the potential to restore the visual cycle.

The safety data reflect exposure to LUXTURNA™ in two clinical trials consisting of 41 subjects (81 eyes) with confirmed biallelic RPE65 mutation-associated retinal dystrophy. 40 of the 41 subjects received sequential subretinal injections to each eye. The efficacy in pediatric and adult patients with biallelic RPE65 mutation-associated retinal dystrophy was evaluated in an open-label, two-center, randomized trial. The average age of the 31 randomized subjects was 15 years (range 4 to 44 years), including 64% pediatric subjects (n=20, age from 4 to 17 years) and 36% adults (n=11). The efficacy of LUXTURNA was established on the basis of multi-luminance mobility testing (MLMT) score change from Baseline to Year 1.

Indication and Important Safety Information

LUXTURNA (voretigene neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.

Patients must have viable retinal cells as determined by the treating physicians.

Warnings and Precautions

- **Endophthalmitis** may occur following any intraocular surgical procedure or injection. Use proper aseptic injection technique when administering LUXTURNA, and monitor for and advise patients to report any signs or symptoms of infection or inflammation to permit early treatment of any infection.
- **Permanent decline in visual acuity** may occur following subretinal injection of LUXTURNA. Monitor patients for visual disturbances.
- **Retinal abnormalities** may occur during or following the subretinal injection of LUXTURNA, including macular holes, foveal thinning, loss of foveal function, foveal dehiscence, and retinal hemorrhage. Monitor and manage these retinal abnormalities appropriately. Do not administer LUXTURNA in the immediate vicinity of the fovea. Retinal abnormalities may occur during or following vitrectomy, including retinal tears, epiretinal membrane, or retinal detachment. Monitor patients during and following the injection to permit early treatment of these retinal abnormalities. Advise patients to report any signs or symptoms of retinal tears and/or detachment without delay.
- **Increased intraocular pressure** may occur after subretinal injection of LUXTURNA. Monitor and manage intraocular pressure appropriately.
- **Expansion of intraocular air bubbles** Instruct patients to avoid air travel, travel to high elevations or scuba diving until the air bubble formed following administration of LUXTURNA has completely dissipated from the eye. It may take one week or more following injection for the air bubble to

dissipate. A change in altitude while the air bubble is still present can result in irreversible vision loss. Verify the dissipation of the air bubble through ophthalmic examination.

- **Cataract** Subretinal injection of LUXTURNA, especially vitrectomy surgery, is associated with an increased incidence of cataract development and/or progression.

Adverse Reactions

- In clinical studies, ocular adverse reactions occurred in 66% of study participants (57% of injected eyes), and may have been related to LUXTURNA, the subretinal injection procedure, the concomitant use of corticosteroids, or a combination of these procedures and products.
- The most common adverse reactions (incidence ≥ 5% of study participants) were conjunctival hyperemia (22%), cataract (20%), increased intraocular pressure (15%), retinal tear (10%), dellen (thinning of the corneal stroma) (7%), macular hole (7%), subretinal deposits (7%), eye inflammation (5%), eye irritation (5%), eye pain (5%), and maculopathy (wrinkling on the surface of the macula) (5%).

Immunogenicity

Immune reactions and extra-ocular exposure to LUXTURNA in clinical studies were mild. No clinically significant cytotoxic T-cell response to either AAV2 or RPE65 has been observed. Study participants received systemic corticosteroids before and after subretinal injection of LUXTURNA to each eye, which may have decreased the potential immune reaction to either AAV2 or RPE65.

Pediatric Use

Treatment with LUXTURNA is not recommended for patients younger than 12 months of age, because the retinal cells are still undergoing cell proliferation, and LUXTURNA would potentially be diluted or lost during the cell proliferation. The safety and efficacy of LUXTURNA have been established in pediatric patients. There were no significant differences in safety between the different age subgroups.

Please see the full US Prescribing Information for LUXTURNA here.

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "promising," "potentially," "builds on," "commitment," "potential," "will," "look forward," "investigational," "currently," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for voretigene neparvovec and the other investigational and approved products described in this press release, or regarding potential future revenues from such products, or regarding the licensing agreement and the manufacturing and supply agreement with Spark Therapeutics. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that voretigene neparvovec or the other investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. Neither can there be any guarantee that Spark Therapeutics will successfully manufacture and supply voretigene neparvovec, or in sufficient quantities, or in a timely fashion, under the manufacturing and supply agreement. Nor can there be any guarantee that Novartis will successfully establish new specialized treatment centers. Neither can there be any guarantee that we will achieve any or all of the intended goals and objectives of either or both of the licensing and manufacturing and supply agreements, or that such agreements will be commercially successful. In particular, our expectations regarding the licensing agreement, the manufacturing and supply agreement, voretigene neparvovec and the other investigational and approved products described in this press release could be affected by, among other things, regulatory actions or delays or government regulation generally; the ability of Spark Therapeutics to successfully manufacture and supply voretigene neparvovec;

the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; safety, quality or manufacturing issues; potential or actual data security and data privacy issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 121,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit <http://www.novartis.com>.

References

1. US Food and Drug Administration. FDA approves novel gene therapy to treat patients with a rare form of inherited vision loss. December 19, 2017. Last accessed: January 22, 2018.
2. Novartis. Data on File. 2018.

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Spark Therapeutics Enters into a Licensing and Supply Agreement for Investigational Voretigene Neparvovec Outside the U.S.

Novartis Pharmaceuticals will commercialize investigational voretigene neparvovec when and if approved in Europe and all other markets outside the U.S.; Spark Therapeutics retains U.S. commercial rights for LUXURNA™ (voretigene neparvovec-rzyl)

Agreement leverages Novartis' extensive ex-US ophthalmology capabilities and infrastructure to the benefit of patients outside of U.S.

Spark Therapeutics to receive \$105 million as an upfront fee and is eligible to receive up to \$65 million in milestone payments, as well as receive a royalty on net sales outside the U.S.

PHILADELPHIA, Jan. 24, 2018 (GLOBE NEWS) -- Spark Therapeutics (NASDAQ:ONCE), a fully integrated gene therapy company dedicated to challenging the inevitability of genetic disease, today announced it has entered into a licensing agreement with Novartis Pharmaceuticals to develop and commercialize investigational voretigene neparvovec outside the U.S., while Spark Therapeutics will continue to exclusively commercialize LUXURNA™ (voretigene neparvovec-rzyl) in the U.S. Under the agreement, Spark Therapeutics will retain regulatory responsibility for obtaining European Medicines Agency approval for investigational voretigene neparvovec. Spark Therapeutics also entered into a separate agreement to manufacture and supply investigational voretigene neparvovec to Novartis. No other programs in Spark Therapeutics' pipeline are part of this agreement.

Under the terms of the licensing agreement, Novartis will pay Spark Therapeutics \$105 million in cash as an upfront fee. Spark Therapeutics is eligible to receive up to an additional \$65 million in cash milestone payments based on near-term European Regulatory Agency (EMA) regulatory approval and initial sales outside the U.S. in certain markets. Spark Therapeutics is also entitled to receive royalty payments on net sales of investigational voretigene neparvovec outside the U.S.

"By leveraging Novartis' large, existing commercial and medical infrastructure in ophthalmology, as well as its commitment to commercializing genetic-based medicines, we help ensure that more patients with confirmed biallelic *RPE65* mutation-associated retinal dystrophy who live outside the U.S., and importantly outside of Europe, have access to investigational voretigene neparvovec," said Dan Faga, chief business officer, Spark Therapeutics. "We intend to use the proceeds from this transaction to continue to develop our robust pipeline of investigational gene therapies to create a path to a world where no life is limited by genetic disease."

Indication and Important Safety Information for LUXURNA

LUXURNA™ (voretigene neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic *RPE65* mutation-associated retinal dystrophy.

Patients must have viable retinal cells as determined by the treating physicians.

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