

EX-10.50 5 dex1050.htm COLLABORATION AGREEMENT

Exhibit 10.50

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

COLLABORATION AGREEMENT

BY AND BETWEEN

AMGEN INC.

AND

GLAXO GROUP LIMITED

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COLLABORATION AGREEMENT

This Collaboration Agreement (this “*Agreement*”) is entered into as of the 27th day of July, 2009 (the “*Effective Date*”) by and between Amgen Inc., a Delaware corporation with a place of business at 1 Amgen Center Drive, Thousand Oaks, CA 91320 (“*Amgen*”) and Glaxo Group Limited, registered in England as company number 305979, doing business as “GlaxoSmithKline” and having its principal office at Glaxo Wellcome House, Berkley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom (“*GSK*”). Amgen and GSK are sometimes referred to herein individually as a “*Party*” and collectively as the “*Parties*”.

RECITALS

WHEREAS, Amgen is a biotechnology company that researches, develops, manufactures and commercializes novel therapeutics to treat grievous illness;

WHEREAS, Amgen has developed the proprietary product Ivory (as defined below) for the treatment of certain diseases and conditions;

WHEREAS, Amgen and GSK desire to collaborate with respect to the commercialization of Ivory as set forth in more detail herein;

WHEREAS, Amgen and GSK desire to share certain expenses and revenues with respect to Ivory as set forth in more detail herein; and

WHEREAS, Amgen and GSK are entering into a separate agreement of even date herewith whereby GSK will conduct certain activities with respect to Ivory as specified therein in the Expansion Territory (as defined therein).

NOW, THEREFORE, in consideration of the premises and the mutual promises set forth herein, and intending to be legally bound, the Parties agree as follows:

1. DEFINITIONS

- 1.1. “*Affiliate*” means, with respect to a Party, any Person which controls, is controlled by or is under common control with such Party. For purposes of this Section 1.1, “control” means: (i) in the case of corporate entities, direct or indirect ownership of fifty percent (50%) or more of the stock or shares entitled to vote for the election of directors; and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity or income interest therein (or, in each of (i) and (ii), if applicable, such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction).
- 1.2. “*Agreement*” has the meaning set forth in the Preamble.
- 1.3. “*Alliance Manager*” has the meaning set forth in Section 2.15 (Alliance Managers).
- 1.4. “*Allocable Overhead*” means overhead costs (including Employment Costs and Third Party costs) related to the manufacture or support of the manufacturing of a product (including quality, process development and process improvements). Allocable Overhead costs are Indirect Costs and include all costs for supervisory services, occupancy and similar functions and activities customarily treated as overhead, including costs attributable to: (i) depreciation of or rent/lease expenses for property, facilities and capital equipment; (ii) company and facilities management (e.g.,

supervisors, human resources and purchasing); (iii) facilities services, security, surveillance, environmental protection, utilities, maintenance and repair (e.g., engineering and production planning); (iv) logistical costs; (v) finance and accounting support, data processing, legal affairs, training and information systems services; (vi) insurance (e.g., fire, product liability and business interruption insurance); (vii) indirect materials, supplies and consumables; (viii) general services (e.g., telephones, fax, postal services, copying and office services and equipment, cleaning, health services, and energy maintenance); (ix) process development (optimization/characterization), process validation, quality assurance and quality control costs; (x) internal/external efforts required to complete and submit any regulatory or governmental approval relating to the manufacture of Ivory or a facility manufacturing Ivory; (xi) product and inventory losses; and (xii) cycle count adjustments. Allocable Overhead may be allocated based upon percent of effort, resource utilization or other reasonable measure. [*].

- 1.5. “Amgen” has the meaning set forth in the Preamble.
- 1.6. “Amgen Costs” has the meaning set forth in Section 6.1.2 (Amgen Costs).
- 1.7. “Amgen Housemarks” means the corporate logo of Amgen, the trademark “Amgen” and any other related trademark, trade name or service mark (whether registered or unregistered) containing the word “Amgen” and all intellectual property rights residing in the foregoing.
- 1.8. “Amgen’s Patent Attorneys” means Amgen’s in-house patent attorney, [*], primarily responsible for patent matters with respect to Ivory in the Collaboration Scope.
- 1.9. “Amgen Sales Force Costs” means the allocable share of Amgen’s (or its Affiliates’) sales force costs for sales representatives responsible for Detailing Ivory in the Collaboration Scope in accordance with this Agreement, calculated in accordance with Section 6.1.10 (Calculation of Sales Force Costs).
- 1.10. [*].
- 1.11. “Applicable Laws” means, individually and collectively, any federal, state, local, national and supra-national laws, treaties, statutes, ordinances, rules and regulations, including any rules, regulations, guidance, guidelines or requirements having the binding effect of law of national securities exchanges, automated quotation systems or securities listing organizations, Governmental Authorities, courts, tribunals, agencies other than Governmental Authorities, legislative bodies and commissions that are in effect from time to time during the Term and applicable to a particular activity hereunder.
- 1.12. “Assisting Party” has the meaning set forth in Section 13.5 (Defense of Third Party Claims).
- 1.13. “Audited Party” has the meaning set forth in Section 7.4 (Audits).
- 1.14. “Auditing Party” has the meaning set forth in Section 7.4 (Audits).
- 1.15. “Brand Book” means the Product Trademark usage and style guide for Ivory established and updated from time-to-time by the JBT.

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- 1.16. “*Brand Plan*” means the brand plan for Ivory established by the JBT.
- 1.17. “*Bundle*” means Ivory sold together with another pharmaceutical compound for a single price.
- 1.18. “*Change of Control*” means: (i) the acquisition, directly or indirectly, by any person, entity or “group” (within meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”)) by means of a transaction or series of related transactions, of (a) beneficial ownership of fifty percent (50%) or more of the outstanding Voting Securities of a Party (or the surviving entity, as applicable, whether by merger, consolidation, reorganization, tender offer or other similar means), or (b) all, or substantially all, of the assets of a Party and its Affiliates; or (ii) any consolidation or merger of a Party with or into any Third Party, or any other corporate reorganization involving a Third Party, in which those persons or entities that are stockholders of the Party immediately prior to such consolidation, merger or reorganization (or prior to any series of related transactions leading up to such event) own fifty percent (50%) or less of the surviving entity’s voting power immediately after such consolidation, merger or reorganization.
- 1.19. “*Change of Control Notice*” has the meaning set forth in Section 15.2 (Change of Control of Amgen).
- 1.20. “*COGS*” means the Standard Cost for Ivory adjusted to reflect the sum of actual Direct Costs and Indirect Costs for the Inventory Layer from which such Ivory was taken less, to the extent not previously deducted, net non-refundable taxes or duties and distribution and warehousing costs. COGS will be calculated consistently with other products and in accordance with GAAP.
- 1.21. “*Collaboration* [”]” has the meaning set forth in Section 14.11.3.
- 1.22. “*Collaboration Budget*” has the meaning set forth in Section 2.10 (Joint Steering Committee).
- 1.23. “*Collaboration Field*” means the use of Ivory in any Collaboration SKU (including 60mg Collaboration SKU presentations) for the treatment, palliation or prevention of one (1) or more of the following diseases and conditions in humans: (i) post-menopausal osteoporosis; (ii) glucocorticoid induced osteoporosis; and (iii) male osteoporosis. The Collaboration Field does not include the Excluded Field.
- 1.24. “*Collaboration Losses*” has the meaning set forth in Section 6.5 (Collaboration Losses).
- 1.25. “*Collaboration Review Committee*” or “*CRC*” means the committee established to resolve issues in accordance with Article 2 (Scope and Governance).
- 1.26. “*Collaboration Profit (Loss)*” has the meaning set forth in Section 6.1.8 (Calculation of Profit (or Loss)).
- 1.27. “*Collaboration Scope*” means the Collaboration Field in the Collaboration Territory.
- 1.28. “*Collaboration SKUs*” means those SKUs pursued by Amgen and labeled for use for the treatment, palliation or prevention of one (1) or more of the following diseases and conditions in the Collaboration Territory in humans: (i) post-menopausal osteoporosis; (ii) glucocorticoid induced osteoporosis; and (iii) male osteoporosis.

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- 1.29. “*Collaboration Territory*” means those countries set forth on the Collaboration Territory Schedule and any country added pursuant to Section 2.16 (Territorial Expansion).
- 1.30. “*Collaboration Territory R&D Costs*” means those costs incurred by or on behalf of either Party or its Affiliates in connection with research and development of Ivory in accordance with the Development Plan in the Collaboration Field for the primary benefit of the Collaboration Territory (including the costs of Phase IV Trials undertaken in the Collaboration Field for the benefit of the Collaboration Territory); provided, that, notwithstanding anything to the contrary in this Agreement, Collaboration Territory R&D Costs will exclude the costs of all of Amgen’s internal FTEs that are involved in the conduct of research and development, which will be deemed Qualified Amgen R&D Costs.
- 1.31. “*Commercially Reasonable Efforts*” means, with respect to activities of a Party related to Ivory under this Agreement, the efforts and resources typically used by that Party (or, if a Party does not engage in that activity for other products or compounds, by biotechnology and/or pharmaceutical companies that are similar in size and financial resources to such Party) in the conduct of such activities with respect to products of comparable market potential, taking into account all relevant factors including, as applicable, stage of development, efficacy and safety relative to competitive products in the marketplace, actual or anticipated Governmental Authority approved labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), cost and likelihood of obtaining Regulatory Approval, and actual or projected profitability. For purposes of clarity, Commercially Reasonable Efforts will be determined on a country-by-country basis within the Collaboration Territory, and it is anticipated that the level of effort may be different for different countries and may change over time, reflecting changes in the status of Ivory and the country(ies) involved.
- 1.32. “*Contract Interest Rate*” means the [*] effective for the date that payment was due, as published by The Wall Street Journal, Eastern U.S. Edition, on the date such payment was due (or, if unavailable on such date, the first date thereafter on which such rate is available), or, if lower, the maximum rate permitted by Applicable Law.
- 1.33. “*Copyright*” means all right, title, and interest in and to all copyrightable works and any copyright registration or corresponding legal right.
- 1.34. “*Country Plans*” has the meaning set forth in Section 3.2 (Country Plans).
- 1.35. “*Country Team*” means one of the teams overseeing commercialization of Ivory in the Collaboration Field in a given country (or countries) within the Collaboration Territory in accordance with Article 2 (Scope and Governance).
- 1.36. “*Designated GSK Activities*” means those activities for which GSK is responsible pursuant to Section 3.1 (Allocation of Operational Responsibilities) or 3.3 (Designated GSK Activities).
- 1.37. “*Defending Party*” has the meaning set forth in Section 13.5 (Defense of Third Party Claims).
- 1.38. “*Detail*” means an interactive face-to-face visit by a sales representative with a medical professional having prescribing authority or who is able to influence prescribing

decisions, within the target audience during which approved uses, safety, effectiveness, contraindications, side effects, warnings and/or other relevant characteristics of a pharmaceutical product are discussed in an effort to increase prescribing preferences of a pharmaceutical product for its approved uses. Detail includes First Position Details, Second Position Details and Other Details. Activities conducted by medical support staff (such as medical science liaisons) will not constitute Details. E-details, activities conducted at conventions or similar gatherings and activities performed by market development specialists, managed care account directors and other personnel not performing face-to-face sales calls or not specifically trained with respect to a pharmaceutical product will not constitute Details. “Detailing” means the act of performing Details and to “Detail” mean to perform Details.

- 1.39. “Detail Report” has the meaning set forth in Section 3.11.1 (Reporting).
- 1.40. “Development Budget” means the budget applicable to the Development Plan. The Development Budget applicable to the Initial Development Plan (the “Initial Development Budget”) is attached hereto as the Development Budget Schedule.
- 1.41. “Development Plan” means the plan established by the JDC covering: (i) the research and development (including Phase IV Trials) of Ivory in the Collaboration Field for (a) the primary benefit of one (1) or more countries or regions in the Collaboration Territory, or (b) if not for the primary benefit of one (1) or more countries or regions in the Collaboration Territory, then otherwise useful to the Collaboration Scope; (ii) the preparation and submission of Regulatory Filings; and (iii) the obtaining, maintenance or expansion of Regulatory Approvals of Ivory in the Collaboration Scope. The initial Development Plan (the “Initial Development Plan”) covering calendar years 2009 through 2012 is attached hereto as the Development Plan Schedule, and will be reviewed and updated by the JDC on an annual basis or more frequently as agreed by the Parties. For the avoidance of doubt, information contained in the Initial Development Plan covering January 1, 2009 through the Effective Date is provided for informational purposes only, and is not intended to create any obligations on GSK with respect to such development during such period, including the obligation to pay or share any costs associated with such development for such period.
- 1.42. “Direct Costs” means all costs incurred by or on behalf of Amgen and/or its Affiliates for resources and rights directly associated with the manufacture of Ivory, including raw materials and finishing supplies used to manufacture Ivory, payments to subcontractors with respect to the manufacture of Ivory, payments (including royalties) to Third Parties for rights used in the manufacture of Ivory, and Employment Costs for personnel directly involved in any aspect of manufacturing Ivory such as equipment operators, line mechanics, set up mechanics and material handlers to supply the line.
- 1.43. [*]
- 1.44. [*]
- 1.45. [*]
- 1.46. [*]
- 1.47. “Effective Date” has the meaning set forth in the Preamble.
- 1.48. “EMA” means the European Medicines Agency, and any successor agency thereto.

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- 1.49. *“Employment Costs”* means all actual costs incurred by or on behalf of a Party and/or its Affiliates with respect to any employee.
- 1.50. *“Excluded Field”* means the use of Ivory for any purpose outside the Collaboration Field, including veterinary or diagnostic purposes, and including the use of Ivory for the treatment, palliation or prevention of the following diseases and conditions in humans: (i) bone metastases; (ii) bone loss induced by cancer therapy or hormone ablation therapy; and (iii) cancer-related bone damage.
- 1.51. *“Excluded Territory”* means the United States of America, Canada, Japan, Bahrain, Jordan, Kuwait, Oman, Qatar, Egypt, Morocco, Tunisia, Algeria, Libya, Saudi Arabia, Turkey, the United Arab Emirates and any other country not included within the Expansion Territory (as defined in the Expansion Agreement) and, with respect to each of the foregoing, the territories and possessions thereof.
- 1.52. *“Expansion Agreement”* means the agreement entered into between the Parties of even date herewith, pursuant to which Amgen grants GSK certain rights with respect to Ivory in the Expansion Territory (as defined in the Expansion Agreement).
- 1.53. *“First Position Detail”* means a Detail in which the applicable pharmaceutical product is Detailed before any other product and the predominant portion of time is devoted to the Detailing of such pharmaceutical product.
- 1.54. *“For Cause Audit”* has the meaning set forth in Section 3.14.4 (Manufacturing).
- 1.55. *“FTE”* means, with respect to a person (other than an employee that Details Ivory), the equivalent of the work of one (1) employee full time for one (1) year (consisting of at least a total of 45.5 weeks or 1,820 hours per year (excluding vacations and holidays)). Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (e.g., time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. For an employee that Details Ivory, FTEs will be calculated as set forth in Section 6.1.10 (Calculation of Sales Force Costs).
- 1.56. *“FTE Rate”* means, with respect to a particular type of employee and geography, for the period commencing on the Effective Date until such time as the JSC agrees otherwise, the fully-burdened amount set forth on the FTE Rate Schedule per full-time employee per year (as of the Effective Date), which rate will be increased by [*] of the then-current FTE Rate on January 1 of 2010 and each subsequent calendar year. For the avoidance of doubt, the JSC may agree to continue to use the rates set forth in the FTE Rate Schedule or to use different rates, which may be higher or lower than those set forth in the FTE Rate Schedule. The FTE Rate Schedule will be updated in writing to reflect any such agreement of the JSC.
- 1.57. *“GAAP”* means the then current generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity or other entity generally recognized as having the right to establish such principles in the United States, in each case consistently applied.
- 1.58. *“GDP”* means the applicable provisions governing distribution of medicinal products for human use, including European Commission Directive (2003/94/EC) (principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use), European

Commission Guidelines (94/C 63/03) (the Guidelines on Good Distribution Practice of Medicinal Products for Human Use), European Commission Directive (2001/83/EC)(relating to medicinal products for human use) and any applicable local guidelines in respect of good distribution practice for pharmaceutical products, in each case, as amended.

- 1.59. “*GMP*” means practices with respect to the manufacture of Ivory as required by the following: (i) if Ivory will be supplied to any jurisdiction adopting the International Conference on Harmonisation Guidelines other than the European Union (which is addressed below), ICHQ7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, (ii) if the site of manufacture of Ivory is within the European Union or will be supplied to a country within the European Union, the principles and guidelines of Good Manufacturing Practices for medicinal products as defined within European Commission Directive 2003/94/EC and associated European Union Guidelines to Good Manufacturing Practice, (iii) if the site of manufacture is in the United States of America, provisions of 21 C.F.R. parts 210 and 211, or (iv) if Ivory will be supplied to any other country not falling within (i)-(iii) above, then the requirements shall be no more onerous than the requirements set out in (i)-(iii) above. “*ICHQ7*” means the ICH Harmonised Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7, as amended from time to time.
- 1.60. “*Governmental Authority*” means any government or supranational administrative agency, commission or other governmental or supranational authority, body or instrumentality, or any federal, state, local, domestic or foreign governmental or supranational regulatory body.
- 1.61. “*GSK*” has the meaning set forth in the Preamble.
- 1.62. “*GSK Costs*” has the meaning set forth in Section 6.1.1 (GSK Costs).
- 1.63. “*GSK Housemarks*” means the corporate logo of GSK, the trademarks “GSK”, “GlaxoSmithKline” and any other related trademark, trade name or service mark (whether registered or unregistered) containing the word “GlaxoSmithKline” and intellectual property rights residing in the foregoing.
- 1.64. “*GSK Inventions*” means any Invention made solely by GSK or its Affiliates (and not jointly with Amgen or any of its Affiliates) during the Term in the course of performing the activities contemplated hereunder that relates substantially to the composition of matter, formulation or use of Ivory.
- 1.65. “*GSK Sales Force Costs*” means the allocable share of GSK’s (and/or its Affiliates’) costs for sales representatives responsible for Detailing Ivory in the Collaboration Scope in accordance with this Agreement, calculated in accordance with Section 6.1.10 (Calculation of Sales Force Costs).
- 1.66. “*IFRS*” means the then current International Financial Reporting Standards, consistently applied.
- 1.67. “*Indirect Costs*” means Allocable Overhead and Employment Costs attributed to the manufacture and supply of Ivory, and not included in the definition of Direct Costs.

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- 1.68. *"Infringement Claim"* has the meaning set forth in Section 9.7 (Defense and Settlement of Third Party Claims of Infringement).
- 1.69. *"Invention"* means any idea, concept, discovery, invention, improvement or trade secret.
- 1.70. *"Inventorship Margin"* means: (i) [*] with respect to calendar year Ivory Net Revenues in an amount less than or equal to [*]; (ii) [*] with respect to calendar year Ivory Net Revenues in an amount over [*] up to and including [*]; and (iii) [*] with respect to calendar year Ivory Net Revenues greater than [*].
- 1.71. *"Inventory Layer"* means all amounts of Ivory manufactured at a specific site during a given calendar year.
- 1.72. *"ISS"* means a clinical study or research study initiated and conducted by an individual not employed by or on the behalf of a Party.
- 1.73. *"Ivory"* means Amgen's proprietary antibody, denosumab.
- 1.74. *"Ivory Intellectual Property"* means any Invention, Know-How, Patents, Product Trademark, trademark application, electronic media registrations (including domain names, usernames, websites, blogs and the like), or Copyright owned or controlled by Amgen or its Affiliates that is related to Ivory in the Collaboration Scope.
- 1.75. *"Ivory Net Revenues"* means: (i) the aggregate of the gross invoiced sales prices for Ivory that is sold or transferred for value by Amgen or its Affiliates to Third Parties in the Collaboration Territory and used in the Collaboration Scope, minus the following amounts incurred or paid (each as recognized by GAAP and each to the extent not already deducted when calculating COGS) by Amgen or its Affiliates with respect to such sales or transfers for value (regardless of the period in which such amounts are incurred or paid):
- 1.75.1. trade, cash, prompt payment and/or quantity discounts;
 - 1.75.2. payments to government agencies, returns, refunds, allowances, rebates and chargebacks;
 - 1.75.3. retroactive price reductions applicable to sales of Ivory;
 - 1.75.4. fees paid to distributors, wholesalers, selling agents (excluding any sales representatives of a Party or any of its Affiliates), group purchasing organizations and managed care entities;
 - 1.75.5. the standard inventory cost (actual acquisition or manufacture cost) of devices used for dispensing or administering Ivory which are shipped with the Ivory and included in the gross invoiced sales prices;
 - 1.75.6. credits or allowances for product replacement, whether cash or trade;
 - 1.75.7. any tax, tariff, duty or governmental charge levied on the sales, transfer, transportation or delivery of Ivory (including any tax such as a value added or similar tax or government charge), other than franchise or income tax of any kind whatsoever;
 - 1.75.8. [*];

- 1.75.9. [*]; and
- 1.75.10. any import or export duties or their equivalent borne by the relevant seller;
plus (ii) any Recoveries made pursuant to Section 9.8 (Enforcement).
- 1.76. “*Ivory Patent and Trademarks*” has the meaning set forth in Section 9.6 (Prosecution and Maintenance).
- 1.77. “*Joint Brand Team*” or “*JBT*” means the joint brand team established pursuant to Article 2 (Scope and Governance).
- 1.78. “*Joint Claim*” has the meaning set forth in Section 13.5 (Defense of Third Party Claims).
- 1.79. “*Joint Development Committee*” or “*JDC*” means the development committee established pursuant to Article 2 (Scope and Governance).
- 1.80. “*Joint Invention*” has the meaning set forth in Section 9.1 (Invention Ownership).
- 1.81. “*Joint Steering Committee*” or “*JSC*” means the steering committee established pursuant to Article 2 (Scope and Governance).
- 1.82. [*].
- 1.83. “*Know-How*” means all tangible and intangible techniques, information, technology, practices, trade secrets, Inventions (whether patentable or not), methods, processes, knowledge, know-how, conclusions, skill, experience, test data and results (including pharmacological, toxicological, manufacturing, and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms, including works of authorship and Copyrights. Know-How does not include Patents.
- 1.84. “*Other Detail*” means any Detail other than a First Position Detail or a Second Position Detail.
- 1.85. “*Party*” or “*Parties*” has the meaning set forth in the Preamble.
- 1.86. “*Patent Coordinator*” means those employees of each of the Parties appointed pursuant to Section 2.14 (Patent Coordinators) to serve as each such Party’s primary liaison with the other Party on matters relating to intellectual property as described in this Agreement.
- 1.87. “*Patents*” means the issued patents and pending patent applications (including certificates of invention, applications for certificates of invention and priority rights) in any country or region, including all provisional applications, refilings, substitutions, continuations, continuations-in-part, divisions, renewals, all letters patent granted thereon, and all reissues, re-examinations and patent term extensions thereof, and all international or foreign counterparts of any of the foregoing (including supplemental protection certificates, patents of addition and the like).
- 1.88. “*Person*” means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, “group” as defined in Section 13(d)(3) of the Exchange Act, sole proprietorship, unincorporated organization, Governmental Authority or any other form of entity not specifically listed herein.

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- 1.89. “*Phase IV Trial*” means any clinical study initiated in the Collaboration Territory following the first Regulatory Approval for Ivory in the Collaboration Scope for the indication being studied. Phase IV Trials may include epidemiological studies, modeling and pharmacoeconomic studies, ISS and post-marketing surveillance studies.
- 1.90. “*Product Trademarks*” means the trademark “Prolia™,” any other related trademark, trade name or service mark (whether registered or unregistered) containing the word “Prolia™,” and any other trademark, trade name or service mark (whether registered or unregistered) selected by the JBT for use on, with, or to refer to Ivory (other than Amgen Housemarks and GSK Housemarks, as applicable) in the Collaboration Territory during the Term, and all intellectual property rights residing in the foregoing.
- 1.91. “*Promotional Materials*” has the meaning set forth in Section 3.10 (Promotional Materials).
- 1.92. “*Prosecution and Maintenance*” means the preparation, filing, and prosecution of patent applications and maintenance of patents, as well as re-examinations and reissues with respect to such patents, together with the conduct of interferences and the defense of oppositions with respect to such patent application or patent; and “*Prosecute and Maintain*” has the correlative meaning.
- 1.93. “*Qualified Amgen R&D Costs*” means those costs incurred by or on behalf of Amgen or its Affiliates in connection with research and development of Ivory useful to the Collaboration Scope, but excluding: (i) Collaboration Territory R&D Costs; and (ii) any costs applicable to the research and development of Ivory for the sole benefit of one (1) or more countries or regions in the Excluded Territory or Expansion Territory and not useful in the Collaboration Scope. “Qualified Amgen R&D Costs” will include the costs of all of Amgen’s internal FTEs that are involved in the conduct of development of Ivory in the Collaboration Field, regardless of whether directed to the Collaboration Territory or countries outside the Collaboration Territory (including the Expansion Territory and/or the Excluded Territory). Such FTE costs will not be included in Collaboration Territory R&D Costs.
- 1.94. “*Recoveries*” means all monies received by Amgen from a Third Party in connection with the final, non-appealable judgment (or judgment with respect to which the time period for appeal has expired), award or settlement of any enforcement with respect to any Ivory Intellectual Property, to the extent such judgment, award or settlement pertains to activities within the Collaboration Scope.
- 1.95. “*Regulatory Approval*” means a product-specific approval from a Governmental Authority necessary for the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of Ivory.
- 1.96. “*Regulatory Filing*” means any filing with any Governmental Authority with respect to the research, development manufacture, distribution, pricing, reimbursement, marketing or sale of Ivory.
- 1.97. “*Remediation Plan*” has the meaning set forth in Section 14.2.2.

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- 1.98. [*]
- 1.99. [*]
- 1.100. “*Routine Audit*” has the meaning set forth in Section 3.14.4 (Manufacturing).
- 1.101. “*Rules*” has the meaning set forth in Section 16.2 (Arbitration).
- 1.102. “*Sales Forecast*” means the sales forecast set forth in the Sales Forecast Schedule.
- 1.103. “*Samples*” has the meaning set forth in Section 3.13 (Samples).
- 1.104. “*Second Position Detail*” means a Detail in which the applicable pharmaceutical product is Detailed in the second position (i.e., no more than one (1) other product is presented to or discussed with the healthcare professional before Ivory) and the second most predominant portion of time is devoted to the Detailing of such pharmaceutical product.
- 1.105. “*Segregate*” means, with respect to two (2) programs: (i) [*] (whether employees, consultants, Third Party contractors or otherwise and whether or not located within the [*] (for the purposes of this Section 1.105, “*Personnel*”)) [*]; (ii) to ensure that [*] and vice versa; (iii) to ensure that [*] and vice versa; and (iv) from time-to-time, upon the reasonable request of the other Party, to provide information requested relating to the foregoing items (i) through (iii), and to reasonably cooperate to enable the other Party to verify that such restrictions are in place and sufficient to achieve the foregoing. For clarity, [*] as set forth herein.
- 1.106. “*Special Meeting*” has the meaning set forth in Section 14.2.2.
- 1.107. “*Standard Costs*” means, with respect to a Collaboration SKU, standard cost for the Inventory Layer from which such Collaboration SKU was taken, as reflected in Amgen’s accounting records at the time such Collaboration SKU is sold. Such Standard Cost, calculated annually for the period commencing January 1 and ending December 31 of the same year, is the sum of estimated Direct and Indirect Costs for Ivory produced as of such date of sale.
- 1.108. [*]
- 1.109. [*]
- 1.110. “*Taxes*” means any tax, excise or duty, other than taxes upon income.
- 1.111. “*Term*” means the period commencing on the Effective Date and ending upon [*], unless and until sooner terminated pursuant to any provision of this Agreement.
- 1.112. “*Third Party*” means any Person that is not a Party, or an Affiliate of a Party.
- 1.113. “*Third Party Claim*” means any claim, action, lawsuit, or other proceeding brought by any Third Party. [*]
- 1.114. “*VAT*” means the tax imposed by Council Directive 2006/112/EC of the European Community and any national legislation implementing that directive together with legislation supplemental thereto and in particular, in relation to the United Kingdom, the tax imposed by the Value Added Tax Act of 1994 or other tax of a similar nature imposed in other countries in the Collaboration Territory instead of or in addition to value added tax.

1.115. “*Voting Securities*” means securities entitled to be voted generally or in the election of directors of a Person.

2. SCOPE AND GOVERNANCE

- 2.1. Purpose of the Collaboration. The purpose of the collaboration is for the Parties to collaborate in the commercialization of Ivory in the Collaboration Scope and for the Parties to share in certain costs and revenues related to Ivory, all as described in more detail herein.
- 2.2. Co-Exclusive Appointment. Subject to the terms and conditions of this Agreement, Amgen hereby retains GSK on a co-exclusive basis with Amgen to Detail Ivory in the Collaboration Scope and to conduct the Designated GSK Activities.
- 2.3. Governance. With respect to the Collaboration Scope, the collaboration will be governed by: (i) the CRC, which will be responsible for the resolution of issues within the collaboration that cannot be resolved by the JSC; (ii) the JSC, which will be responsible for oversight of the collaboration; (iii) the JBT, which will be responsible for developing the Brand Plan for Ivory within the Collaboration Scope; (iv) a Country Team for each country within the Collaboration Territory (provided that one (1) Country Team may oversee more than one (1) country (e.g., Benelux countries)); (v) the JDC, which will be responsible for establishing the Development Plan and discussing the activities to be conducted thereunder; and (vi) the Patent Coordinators responsible for intellectual property issues as set forth herein. All such committees and teams (the terms committee and team being used interchangeably herein) will be formed promptly following the Effective Date. Each such committee and team will oversee the activities undertaken by the Parties in the Collaboration Scope within the scope of authority of such committee or team, including monitoring progress against plans and outlining how Parties will collaborate in the conduct of such activities. It is expected that the committees and teams will develop plans and strategies assigned to it in a collaborative manner and will serve as a forum for discussion of and input into such plans and strategies.
- 2.4. Decision Making Standards. The decisions made and actions taken by the CRC, JSC, JBT, JDC, Country Teams and Patent Coordinators will be made with the interests of both Parties (including the Parties’ interests in the collaboration) (as presented to such committee or team) duly considered in good faith. Subject to the terms of this Agreement and Applicable Law, the decisions of such teams and committees will be made in accordance with the discretion and business judgment of the members thereof.
- 2.5. Membership. Each of the JSC, JBT and JDC will be comprised of three (3) members appointed by Amgen, and three (3) members appointed by GSK (or such other number of members as agreed in writing by the Parties). The JSC, JBT and JDC will each be led by two (2) co-chairs, one (1) appointed by each of the Parties. Each Country Team will be comprised of four (4) members appointed by Amgen, and four (4) members appointed by GSK (or other number of members as agreed in writing by the Parties). The CRC will be comprised of one (1) member appointed by each of the Parties, and such members initially will be the President of Pharmaceuticals, Europe (or his or her designee) for GSK and Executive Vice-President, Global Commercial Operations (or

his or her designee) for Amgen. Each Party will ensure that the committee members appointed by it have the appropriate level of seniority and decision-making authority commensurate with the responsibilities of the committee to which they are appointed.

- 2.6. Replacement of Members. Each Party will have the right to replace its committee members by written notice to the other Party. In the event any committee member becomes unwilling or unable to fulfill his or her duties hereunder, the Party that appointed such member will promptly appoint a replacement by written notice to the other Party.
- 2.7. Establishment of Subcommittees. Each committee will have the right to establish subcommittees or working teams with respect to issues within its area of responsibility as it sees fit (e.g., pricing, manufacturing or operations). Each Country Team will have the right to establish a local operations team to facilitate the performance of its responsibilities.
- 2.8. No Authority to Amend or Modify. Notwithstanding anything herein to the contrary, no committee will have any authority to amend, modify or waive compliance with this Agreement.
- 2.9. Collaboration Review Committee. The CRC will be responsible for resolving any issues within the collaboration that cannot be resolved by the JSC.
- 2.9.1. *Meetings*. The CRC will meet as requested by the JSC to resolve unresolved issues, via teleconference or videoconference or as otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend CRC meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. All CRC meetings must have all members in attendance.
- 2.9.2. *Decision Making*. The CRC will make decisions by consensus with each Party having one vote. In the event of a deadlock the decision will be made by the member appointed to the CRC by Amgen.
- 2.10. Joint Steering Committee. The JSC will be responsible for overseeing the collaboration, including the commercialization of Ivory in the Collaboration Scope generally. The JSC will be a forum for: (i) discussing commercialization strategy; (ii) approving the Brand Plan established by the JBT; (iii) reviewing the allocation of operational responsibility between the Parties set forth in the Country Plans; (iv) allocating operational responsibility between the Parties for activities that are applicable to the Collaboration Scope as a whole (i.e. that are not country-specific); (v) developing and updating a rolling three (3) year Sales Forecast and supply forecast; (vi) developing and updating the expense budget (expressed in U.S. Dollars, unless otherwise agreed by the Parties) for commercialization activities to be undertaken pursuant to the collaboration based upon the Brand Plan and Country Plans (the “*Collaboration Budget*”); (vii) reviewing and approving the draft pricing and access plan proposed by the JBT; (viii) reviewing the Standard Costs of Ivory on an annual basis and additionally if and when the Standard Costs exceed, or are expected to exceed, the expected Standard Costs by [*] or more; (ix) discussing sourcing matters related to the manufacture of

Ivory, including: (a) to what extent Third Parties will be used to manufacture Ivory for the Collaboration Scope and any material changes to the arrangement with such Third Party manufacturer(s) in advance of implementation of such changes; and (b) methodology of allocating Inventory Layers to the Collaboration Scope; (x) discussing adequacy of supply of Ivory for the Collaboration Scope in connection with then-current forecasts and any occurrence that may require a For Cause Audit as provided in Section 3.14.4 (Manufacturing), (xi) agreeing to an amended FTE Rate Schedule, and (xii) discussing regulatory matters. The JSC will conduct its activities in consultation and/or cooperation with the JDC with respect to those matters that such committees determine appropriate, including regulatory matters and the usefulness of development to the commercial potential of Ivory in the Collaboration Scope.

2.10.1. *Meetings.* The JSC will meet quarterly, via teleconference or videoconference or otherwise (with at least two (2) meetings per calendar year being in person), or as otherwise agreed by the Parties. Any in-person meetings will be held on an alternating basis between GSK's and Amgen's European headquarters, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend JSC meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of the JSC as reasonably required to resolve particular matters requested by such Party by at least ten (10) business days prior written notice to the co-chair appointed by the other Party. All JSC meetings must have at least one (1) member appointed by each Party in attendance.

2.10.2. *Reporting.* Each Party will keep the JSC fully and promptly informed of progress and results of activities in the Collaboration Scope for which it is responsible or that it is permitted to conduct hereunder through its members on the JSC and as otherwise provided herein. Each Party will fully inform the JSC with respect to its activities in the Collaboration Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof. Notwithstanding the foregoing, Amgen will have no obligation to provide proprietary manufacturing information to GSK through any committee or otherwise.

2.10.3. *Decision Making.* The JSC will make decisions by consensus with each Party having one vote. In the event of a deadlock on an issue, the decision will be made by the members of the JSC appointed by Amgen, provided that the members appointed by either Party will have the right to require that such issue be escalated to the CRC for determination. Notwithstanding the foregoing, in the event of a decision on any matter that requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on Ivory or a Party, the members of the JSC appointed by Amgen will have the right to make an interim decision pending CRC determination.

2.11. Joint Brand Team. The JBT will be responsible for developing specified plans and overseeing specified commercial activities relating to Ivory in the Collaboration Scope generally. The JBT will be a forum for discussing, developing, and agreeing upon the

Brand Plan for submission to the JSC for approval. The JBT's responsibilities will include: (i) cross-functional, collaborative development and updating of the Brand Plan including strategies and tactics at the regional level; (ii) consolidation of expense and Sales Forecasts from the country level; (iii) developing and updating a draft pricing and access plan for JSC approval; (iv) tactical alignment of commercialization activities with expense budget allocations; and (v) core message element development, updating and communication to the Country Teams. The JBT will conduct its activities in consultation and/or cooperation with the Country Teams with respect to those matters that such teams determine appropriate.

2.11.1. *Meetings.* The JBT will meet monthly, via teleconference or videoconference or otherwise (with at least four (4) meetings per calendar year being in person), or as otherwise agreed by the Parties. Any in-person meetings will be held on an alternating basis between GSK's and Amgen's European headquarters, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend JBT meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of the JBT as reasonably required to resolve particular matters requested by such Party by at least ten (10) business days prior written notice to the co-chair appointed by the other Party. All JBT meetings must have at least one (1) member appointed by each Party in attendance.

2.11.2. *Reporting.* Each Party will keep the JBT fully and promptly informed of progress and results of activities in the Collaboration Scope for which it is responsible or that it is permitted to conduct hereunder through its members on the JBT and as otherwise provided herein. Each Party will fully inform the JBT with respect to its activities in the Collaboration Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof.

2.11.3. *Decision Making.* The JBT will make decisions by consensus with each Party having one vote. In the event of a deadlock, the decision will be made by the members of the JBT appointed by Amgen, provided that the members appointed by either Party will have the right to require that such issue be escalated to the JSC for determination. In the event of a decision on a matter that requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on Ivory or a Party, the members of the JBT appointed by Amgen will have the right to make an interim decision pending JSC determination.

2.12. Joint Development Committee. The JDC will be responsible for updating the Development Plan and the Development Budget, reviewing clinical protocols for studies to be conducted under the Development Plan, and overseeing the conduct and progress of the activities set forth in the Development Plan including regulatory matters. In addition to the foregoing, the JDC will discuss development to be undertaken by Amgen outside the Collaboration Scope to the extent either Party reasonably believes such development is reasonably likely to have a material adverse effect on Ivory within the Collaboration Scope (and Amgen will provide summary information of Ivory development to be undertaken by Amgen outside the Collaboration Scope in order to

enable GSK to make such determination). The JDC will conduct its activities in consultation and/or cooperation with the JSC with respect to those matters as such committees determine appropriate, including regulatory matters and the usefulness of development to the commercial potential of Ivory in the Collaboration Scope.

- 2.12.1. *Meetings.* The JDC will meet quarterly, via teleconference or videoconference or otherwise (with at least one (1) meeting per calendar year being in person), or as otherwise agreed by the Parties. Any in-person meetings will be held on an alternating basis between GSK's and Amgen's European or global headquarters, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend JDC meetings, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of the JDC as reasonably required to discuss particular matters requested by such Party by at least ten (10) business days prior written notice to the co-chair appointed by the other Party. All JDC meetings must have a member appointed by each Party in attendance.
 - 2.12.2. *Reporting.* Each Party will keep the JDC fully and promptly informed of progress and results of activities in the Collaboration Scope for which it is responsible or that it is permitted to conduct hereunder through its members on the JDC and as otherwise provided herein. Each Party will fully inform the JDC with respect to its activities in the Collaboration Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof.
 - 2.12.3. *Decision Making.* The JDC will make decisions by consensus with each Party having one vote. In the event of a deadlock, the decision will be made by the members of the JDC appointed by Amgen, provided that the members appointed by either Party will have the right to escalate to the CRC for determination decisions that: (i) involve a safety issue; (ii) are likely to have a material impact on the Development Budget; or (iii) involve development that is likely to have a material adverse effect on commercialization of Ivory in the Collaboration Scope, in each case, in the reasonable opinion of the escalating Party. In the event of a decision on a matter that requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on Ivory or a Party, the members of the JDC appointed by Amgen will have the right to make an interim decision pending CRC determination.
- 2.13. Country Teams. Country Teams will be responsible for localizing and implementing marketing strategy and brand planning, allocation of sales representatives, coordination of primary and specialty care sales representatives, determination of Detail frequency and weighting, determination of customer targets, planning sales implementation meetings, review of local sales performance metrics and market research, review of local forecasts for revenue and expenses and review of local access and reimbursement matters, in each case for the relevant country or countries. All such matters will be in accordance with the Brand Plan. The Country Teams will conduct their activities in consultation and/or cooperation with the JBT with respect to those matters that such teams determine appropriate.

- 2.13.1. *Meetings.* Each Country Team will meet six (6) times per year, or as otherwise agreed by the Parties. Meetings will be held on an alternating basis between GSK's and Amgen's headquarters for the relevant country, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend Country Team meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of a Country Team as reasonably required to resolve particular matters requested by such Party by at least ten (10) business days prior written notice to the designated member appointed by the other Party. All Country Team meetings must have at least one (1) member appointed by each Party in attendance. At the request of the JBT, each Country Team will attend international brand strategy and/or communications summits.
- 2.13.2. *Reporting.* Each Party will keep each Country Team fully and promptly informed of progress and results of activities in the relevant region for which it is responsible or that it is permitted to conduct hereunder through its members on the relevant Country Team and as otherwise provided herein. Each Party will fully inform each Country Team with respect to its activities in the Collaboration Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof.
- 2.13.3. *Decision Making.* Each Country Team will make decisions by consensus. In the event of a deadlock, the decision will be made by the members of the relevant Country Team appointed by Amgen, provided that the members appointed by either Party will have the right to require that such issue be escalated to the JSC for determination. In the event of a decision that requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on Ivory or a Party, the members of the Country Team appointed by Amgen will have the right to make an interim decision pending JSC determination.
- 2.14. Patent Coordinators. The Parties will each appoint a Patent Coordinator promptly after the Effective Date of the Agreement. The Patent Coordinators will serve as the primary contacts and forum for discussion between the Parties with respect to intellectual property matters involving Ivory worldwide in the Collaboration Field, and will cooperate with respect to the activities set forth in Article 9 (Intellectual Property). A [*] in each case within the Collaboration Scope or outside the Collaboration Scope to the extent such matter [*]. The Patent Coordinators will meet as often as agreed by them (and at least semi-annually if requested), via teleconference or videoconference or as otherwise agreed, to discuss matters arising out of the activities set forth in Article 9 (Intellectual Property). To the extent reasonably requested by either Patent Coordinator, the Patent Coordinators will solicit the involvement of more senior members of their respective legal departments (up to the most senior intellectual property attorney, where appropriate) with respect to critical issues, and may escalate issues to the JSC for input. Each of the Patent Coordinators will consider comments and suggestions made by the other in good faith. Notwithstanding anything in this Agreement to the contrary, neither Patent Coordinator will have the obligation to disclose information to the extent

prohibited by obligation of confidentiality or protective order, that would result in loss of attorney-client or other relevant legal privilege, that constitutes proprietary manufacturing information or where the other Party has an actual or potential conflict of interest with respect to such information (e.g., where sharing such information would be reasonably likely to provide the recipient with a commercial advantage with respect to a product competitive to Ivory that is being developed or commercialized by such Party).

- 2.15. Alliance Managers. Promptly after the Effective Date, each Party will appoint a person who will oversee interactions between the Parties between meetings of the committees and teams established hereunder (each, an “*Alliance Manager*”). Unless otherwise agreed by the Parties, the Alliance Managers will attend all meetings of the JSC and will have the right to attend all meetings of the JDC and JBT, as non-voting participants at such meetings. Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.
- 2.16. Territorial Expansion. Any country that accedes to the European Union (other than a country in the Excluded Territory) after the Effective Date will become part of the Collaboration Territory and incorporated in the collaboration. The Parties will cooperate to ensure a smooth and orderly transition of such country into the collaboration and avoid any action reasonably likely to have a material adverse effect on Ivory. If GSK is the holder of any Regulatory Filings in such country, GSK will transfer to Amgen ownership of, or if such transfer is not possible or until such transfer occurs, provide Amgen a right of reference and right of access to, any Regulatory Filings related to Ivory in the applicable country as requested by Amgen. Amgen will have the right to instruct GSK to abandon any Regulatory Filing in the Collaboration Territory for Ivory, and GSK will promptly do so if so instructed. If a country accedes to the European Union and is incorporated into the collaboration pursuant to this Section 2.16 (Territorial Expansion), Ivory Net Revenues from sales of Ivory in such country will not be included within Ivory Net Revenues for the purpose of calculating the Inventorship Margin, but will be included in Ivory Net Revenues for all other purposes hereunder.
- 2.17. Internal Governance. The Parties acknowledge that the committee and decision-making structure set forth herein is without prejudice to, and does not supplant, the Parties’ internal decision-making structures.

3. COLLABORATION ACTIVITIES – ALLOCATION AND REPORTING

- 3.1. Allocation of Operational Responsibility. The JSC will be responsible for allocating non-country-specific commercial activities within the Collaboration Scope to Amgen and/or GSK and for determining whether operational responsibility for any such activity should be transferred from GSK to Amgen or vice versa. The Country Teams will be responsible for allocating country-specific commercial activities within the Collaboration Scope to Amgen and/or GSK in the applicable country or region overseen by such Country Team, and for determining whether operational responsibility for any such activity should be transferred from GSK to Amgen or vice versa. The Country Teams will keep the JSC informed of the initial allocation of country-specific activities and transfers thereof between the Parties. Unless and until

determined otherwise by the JSC or the relevant Country Team in accordance with the foregoing, the Parties' initial commercial responsibilities will be as set forth in the Country Plans referenced in Section 3.2 (Country Plans), and in Sections 3.3 (Designated GSK Activities) and 3.4 (Designated Amgen Activities).

- 3.2. Country Plans. Allocations of commercial operational responsibility for countries and regions within the Collaboration Scope will be set forth in country plans developed by the relevant Country Team (as such plans may be updated or modified from time-to-time by the relevant Country Team and approved by the JSC), the "*Country Plans*"). Country Plans will be developed by the relevant Country Team promptly upon request by the JBT, taking into account the planned launch timing for the relevant country.
- 3.3. Designated GSK Activities. GSK will be responsible for [*].
- 3.4. Designated Amgen Activities. Amgen will have operational responsibility to perform [*].
- 3.5. Collaboration in Commercialization Activities. The allocation of operational responsibility for commercialization activities hereunder as well as the conduct of such activities by the Parties will be subject to comprehensive discussion by the JSC, JBT and Country Teams, as applicable, where each Party will consider the input of the other with respect to the conduct of such activities. The commercial activities will be allocated on a country-specific and non-country specific basis by such committees and/or teams taking into consideration all relevant factors, including the capabilities of each Party to deliver the highest quality product in the most cost-effective manner, without duplication of efforts between the Parties. Each of the JBT and Country Teams, as applicable, will endeavor to meet the goals of the Brand Plan and Country Plans within the parameters of the Collaboration Budget established by the JSC.
- 3.6. Amgen Participation Increase and Transition.
- 3.6.1. *Participation Increase*. Commencing [*], Amgen will have the right, but not the obligation, to contribute up to [*] of the minimum number of full-time primary care sales representatives for Detailing Ivory in one (1) or more countries in the Collaboration Territory. Amgen will provide written notice to GSK via the JSC at least [*] prior to the date on which Amgen desires to increase its participation, such notice to set forth the level of Amgen's participation and the country or countries of the Collaboration Territory in which Amgen will participate. The Country Teams will be responsible for amending the Country Plans to provide for such reallocation of resources, which will be subject to review by the JSC.
- 3.6.2. *Potential Quid*. No later than [*] from the Effective Date, GSK will discuss with Amgen the potential for Amgen's sales force to promote one (1) or more of GSK's products on terms mutually acceptable to the Parties. If the Parties fail to agree on an arrangement for Amgen to promote such product(s), then GSK will consider in good faith engaging in discussions with Amgen, from time-to-time, if additional product quid opportunities become available. For the avoidance of doubt, nothing herein obligates Amgen to promote, or obligates GSK to engage Amgen to promote one (1) or more of GSK's products, and any such agreement must be in a writing duly executed by each of the Parties.

- 3.7. All Sales by Amgen. This Agreement does not authorize GSK, its Affiliates or their respective agents or employees to sell Ivory. Amgen will have the sole right, in Amgen's discretion, to price Ivory (including with respect to trade, quantity or other discounts), determine the launch conditions and terms of sale for Ivory, take orders for and returns of Ivory, issue credits for Ivory, sell Ivory and book sales thereof and GSK will have no rights with respect to Ivory outside the Collaboration Scope. GSK will promptly forward to Amgen all orders for, and requests to order, Ivory. Amgen will have the right to refuse or cancel any order for Ivory without liability to GSK. GSK will not interfere with any agreement of Amgen or any of its Affiliates related to Ivory, including pricing and contracting for the sale of Ivory.
- 3.8. Training. The Parties will jointly (except where impracticable) train the sales representatives hereunder with respect to the promotion of Ivory in the Collaboration Scope (and update such training from time to time as appropriate); (including compliance training as determined by the JBT). The JBT will be responsible for developing the Ivory training programs and materials for the sales forces of Amgen and GSK with respect to Ivory in the Collaboration Scope. Training of the Parties' sales forces will be conducted using only training materials and programs developed by the JBT. Amgen will own all right, title and interest in the training materials developed hereunder (except with respect to any GSK Housemarks contained therein).
- 3.9. Information Concerning Ivory.
- 3.9.1. *Public Statements.* GSK will ensure that no claims or representations in respect of Ivory or the characteristics thereof are made by or on behalf of it or its Affiliates (by sales force members or otherwise) that have not been approved by Amgen and neither Party will make any claim or representation that does not represent an accurate summary or explanation of the labeling of Ivory.
- 3.9.2. *Ownership.* GSK will not represent to any Third Party that it has any proprietary or property right or interest in Ivory (or the Product Trademarks or any Patents claiming or covering Ivory or its manufacture, use or sale), except for the rights expressly granted to GSK hereunder. Furthermore, GSK acknowledges that it does not have any right, title or interest in Ivory or the Product Trademarks.
- 3.10. Promotional Materials. All written sales, promotion and advertising materials relating to Ivory (collectively "*Promotional Materials*") (including translations) will be produced by Amgen in accordance with the Brand Plan developed by the JBT and reviewed and approved by the JSC. Any Promotional Materials will include, if permitted by Applicable Law, the Amgen Housemarks and the GSK Housemarks (provided, however, that Amgen will be entitled a reasonable transition period after any required legal approval is obtained to design, order, receive and implement Promotional Materials revised to include the GSK Housemarks). Materials that include the GSK Housemarks will use such GSK Housemarks in accordance with any reasonable usage guidelines provided by GSK, and any usage not conforming with such guidelines will require GSK's prior approval as to the use of such GSK Housemarks. GSK will

respond to any such requests for approval within ten (10) business days. In the absence of such response within such period, the request will be deemed approved. Unless otherwise determined by the JSC, Amgen will be responsible for the printing and delivery to GSK of Promotional Materials for use in GSK's Detailing obligations hereunder, and costs therefor will be included as Amgen Costs for purposes of Collaboration Profit (Loss). Other than GSK's use and distribution of Promotional Materials that are approved by the JSC and used and distributed in connection with GSK's Detailing of Ivory within the Collaboration Scope, GSK will not produce or modify (other than as concepts for consideration by Amgen), or distribute or otherwise use any promotional or communications material relating to Ivory. If so instructed by Amgen, GSK will immediately cease to use any Promotional Materials and will collect and destroy any such materials from its sales representatives (and record and document such collection and destruction (and provide a copy of such documentation to Amgen upon request)). Amgen will own all right, title and interest in and to any and all Promotional Materials including applicable Copyrights and trademarks (except with respect to any GSK Housemarks included in any Promotional Materials), and GSK will execute all documents and take all actions as are reasonably requested by Amgen to vest title to such Promotional Materials, Copyrights and trademarks in Amgen.

3.11. Detailing Reports and Audit Rights.

3.11.1. *Reporting.* Each Party will provide the other Party with a report (each a "*Detail Report*"), in such form and manner as determined by the JSC, within twenty (20) calendar days after the end of each calendar month included in the Term, setting forth the following information regarding the efforts of the reporting Party's sales force in Detailing Ivory during the preceding month: (i) the total number of Details made by such sales force, including a breakdown of First Position Details, Second Position Details and Other Details by target and frequency of Detail by customer priority; and (ii) such other information as may be specified by the JSC or JBT.

3.11.2. *Audits.* Each Party will keep complete and accurate records of its Detailing of Ivory in sufficient detail to permit the other Party to audit its performance of Details hereunder. During normal business hours and with not less than ten (10) days' advance written notice, a Party will permit the other Party or its authorized representatives to: (i) have access to the records of Detailing activities maintained by such Party for purposes of verifying the accuracy of reports described in Section 3.12.1 (Reporting); and (ii) audit such records; provided, that such audits may not be performed by a Party more than once per calendar year. Any and all audits undertaken pursuant to this Section 3.11.2 (Audits) will be performed at the sole and exclusive expense of the auditing Party and will not be included in Amgen Costs or GSK Costs, as the case may be, for purposes of calculating Collaboration Profit (Loss). If an audit reveals an overstatement of Details of greater than five percent (5%) of the correct amount for the audited period, then the audited Party will pay the reasonable out-of-pocket cost of such inspection.

3.12. Medical Inquiries and Product Inquiries. GSK will comply with the directions and policies which Amgen may formulate concerning responses to be made to medical

questions or inquiries from members of the medical and paramedical professions and consumers regarding Ivory (including, if so directed, by referring such questions or inquiries to Amgen) and will, if so requested by Amgen, provide Amgen with details of inquiries received and responses given (including reporting regulatory and safety information as provided in Section 10.1.5 (Regulatory and Safety Information)). For questions which GSK and its professional sales representatives have not received prepared answers or which are not answered by then existing Ivory information provided by Amgen (including with respect to technical information such as identification, ingredients or stability/storage), GSK will refer such questions to Amgen. For medical inquiries related to Ivory, including those related to information outside of labeling or which GSK and its professional sales representatives are unable or not authorized under accepted national and international pharmaceutical industry codes of practices to answer, GSK will redirect such inquiries to Amgen. Unless otherwise determined by the JSC, all responses to such medical inquiries from patients, medical professionals, or other third Parties will be provided solely by Amgen. GSK will provide reasonable assistance to Amgen, at Amgen's request and expense, in an effort to fully respond to such communications.

- 3.13. Samples. The JBT will determine and specify in the Brand Plan whether and in what manner and quantities of samples of Ivory ("*Samples*") will be provided to customers. If the JBT determines that Samples will be provided through the sales force, Amgen will provide GSK with such Samples which GSK will use solely in Detailing Ivory in accordance with the Brand Plan. The Parties will maintain such records with respect to Samples as are required by Applicable Law and applicable national and international pharmaceutical industry codes of practices and will allow representatives of the other Party to inspect such records on reasonable request. Amgen will be solely responsible for the filing of any necessary or required reports to Governmental Authorities with respect to Samples, and GSK will reasonably cooperate with Amgen with respect thereto. If Samples are to be provided through sales representatives, Amgen will ship the Samples to one central warehouse of GSK, as designated by GSK, and the risk of loss and responsibility for handling and warehousing of Samples will pass to GSK upon delivery to a carrier designated by GSK. GSK will be responsible for distributing Samples to its sales representatives in a timely manner. If Amgen determines that another method of Sample distribution is more appropriate, then the Parties will reasonably cooperate to facilitate such distribution. Each Party will be responsible for securing the return of and reconciling existing Sample inventories from its own discontinued field sales representatives and other personnel. Within thirty (30) days after the expiration or termination of this Agreement, or as otherwise requested by Amgen, GSK will return, or otherwise dispose of in accordance with instructions from Amgen, all remaining Samples provided by Amgen and will provide Amgen with a certified statement that all remaining Samples have been returned or otherwise properly disposed of and that GSK is no longer in possession or control of any such Samples.
- 3.14. Non-Commercial Activities. Unless otherwise determined by the JDC, Amgen will have the sole right to perform, itself or through its Affiliates or designees, all non-commercialization activities with respect to Ivory in the Collaboration Scope. In addition, Amgen will have the sole right to perform activities with respect to Ivory outside the Collaboration Scope and GSK will not promote or conduct any activities

with respect to Ivory outside the Collaboration Scope except as may be expressly agreed pursuant to a written agreement between the Parties. Activities to be conducted by Amgen with respect to Ivory in the Collaboration Scope include:

- 3.14.1. *Research and Development.* Global research and development activities in accordance with the Development Plan, including Phase IV Trials, generation of health economics information, and approval of requests to perform ISS;
- 3.14.2. *Regulatory.* Seeking, obtaining and holding all Regulatory Approvals and holding and controlling all Regulatory Filings for Ivory in each of the Collaboration Territory countries, as well as responsibility for all regulatory interactions and communications in the Collaboration Territory;
- 3.14.3. *Safety.* Maintaining the global safety database and core data sheet for Ivory, assessing and reporting adverse events, and handling any product complaints and/or recalls; and
- 3.14.4. *Manufacturing.* All manufacturing of Ivory for all indications and uses in accordance with applicable product specifications and GMP, including labeling, fill/finish, packaging, selection of presentations and manufacturing-related regulatory activities (including regulatory inspections). GSK will have the right to audit Amgen's manufacturing facilities and any Third Party manufacturing facilities used for the manufacture of Ivory in the Collaboration Scope on a periodic basis, not to exceed once every eighteen (18) months for routine audits ("*Routine Audits*") or as defined below with respect to for-cause audits ("*For Cause Audits*") (provided such request is made within sixty (60) days of GSK being informed of or becoming aware of an event that would permit a For Cause Audit in GSK's reasonable opinion). GSK will bear the cost of all Routine Audits and For Cause Audits of Amgen manufacturing facilities conducted by GSK and such costs will not be subject to cost-sharing between the Parties under this Agreement. The costs of any Routine Audits and For Cause Audits of any Third Party manufacturing facility requested by GSK will be included in GSK Costs and will be subject to the cost-sharing principles under this Agreement, unless otherwise provided below. GSK will notify Amgen in writing if GSK desires to conduct any manufacturing audit, and the Parties will mutually agree upon reasonable audit agendas in advance and reasonably cooperate in the conduct of such audit. If GSK notifies Amgen that GSK desires to conduct either a For Cause Audit or Routine Audit of a Third Party manufacturer, Amgen will notify GSK if Amgen's contract with such Third Party manufacturer permits GSK to conduct such audit, in which case Amgen will allow GSK to conduct such audit (with Amgen's participation, if it chooses). If Amgen's contract with such Third Party manufacturer does not permit GSK to conduct audits, then Amgen will conduct such audit and share the results with GSK to the extent permitted under Amgen's contract with such Third Party manufacturer. Notwithstanding the foregoing, the Parties will cooperate to coordinate and achieve reasonable efficiencies with respect to audits of Third Party manufacturers as follows: (i) if GSK requests a Routine Audit of a Third Party manufacturer, and Amgen has conducted a Routine Audit of such manufacturer in the previous [*], then Amgen will share with GSK the

results of any Routine Audit of such Third Party (to the extent permitted under Amgen's contract with such Third Party manufacturer), (ii) if after sharing the results described under (i), GSK would like to proceed with a Routine Audit of such Third Party, then, to the extent permitted under Amgen's contract with such Third Party manufacturer, GSK may conduct such Routine Audit (or, to the extent permitted under Amgen's contract with such Third Party manufacturer, Amgen will conduct such Routine Audit if GSK is not permitted to do so under the applicable Third Party manufacturing contract) and the costs of such Routine Audit will be borne by GSK and will not be subject to cost-sharing under this Agreement. Any audit of a Third Party manufacturer will be subject to the terms and conditions of Amgen's contract(s) with such manufacturer and GSK will cooperate and coordinate with Amgen to comply with all reasonable terms and conditions communicated by Amgen in connection with the performance of such audit. Any audit of an Amgen manufacturing facility will comply with Amgen's reasonable policies and procedures. GSK's Routine Audits will be limited in scope to what is reasonably necessary to confirm that Amgen or a Third Party manufacturer has complied with all applicable product specifications, GMP or GDP requirements in manufacturing Ivory. GSK's For Cause Audits will be limited in scope to what is reasonably necessary to confirm that the cause for such audit has been or is being remedied. Any information disclosed to GSK in the course of any audit may only be used for the purposes of such audit. Any audit conducted under this Agreement, the Expansion Agreement or the relevant Ivory supply agreement between Amgen and GSK will be considered an audit conducted under all such agreements. For the purposes of this Section 3.14.4 (Manufacturing), the following will give GSK the right to conduct a For Cause Audit: [*]. The JSC will review events that may give rise to the right to conduct a For Cause Audit if so requested by either Party.

4. COLLABORATION ACTIVITIES – PERFORMANCE STANDARDS

- 4.1. Collaborative Activities. Activities to be undertaken by the Parties hereunder will be conducted in a collaborative manner as determined by the committee or team overseeing such activities, and in accordance with the terms and conditions of this Agreement, as applicable.
- 4.2. Diligence and Performance Standards. Subject to the decisions made by and oversight of the teams and committees established hereunder, each Party will use, and will assure that each of its Affiliates use, Commercially Reasonable Efforts in the performance of its and their activities hereunder. Each Party will conduct, and ensure that each of its Affiliates conduct, all of its and their activities with respect to the promotion and commercialization of Ivory in the Collaboration Scope in accordance with this Agreement, the Brand Plan, applicable Country Plans, accepted national and international pharmaceutical industry codes of practices in and for the Collaboration Territory, and all Applicable Law. Amgen will conduct, and ensure that each of its Affiliates conduct (and, to the extent the Parties may agree in writing that GSK or its Affiliates will conduct any activities with respect to the manufacture, distribution or development of Ivory in the Collaboration Scope, then GSK will conduct, and ensure

that each of its Affiliates conduct), all of its and their activities with respect to the manufacture, distribution and development of Ivory in the Collaboration Scope in accordance with this Agreement and all Applicable Law including GMP and GDP. The Parties will provide each other with all reasonably requested cooperation to enable each of them to comply with Applicable Law and accepted national and international pharmaceutical industry codes of practices, including permitting each Party to verify the other Party's compliance therewith.

- 4.3. Detailing Activities. Each Party's sales representatives will conduct the Detailing activities under this Agreement in accordance with the relevant codes of practice established by the Party employing such representative, and nothing herein will be interpreted to require lower standards of conduct with respect to such sales representatives than those required in the codes of practice established by the Party employing such representatives. In addition:

4.3.1. *Minimum Sales Activities*. Each Country Team will determine, in accordance with the Brand Plan, and will set forth in the applicable Country Plan, the number of: (i) primary care sales representatives to be provided by GSK for Detailing Ivory and a minimum number of Details to be conducted by such sales representatives, and (ii) specialty care sales representatives to be provided by Amgen for Detailing Ivory and a minimum number of Details to be conducted by Amgen. The minimums will be subject to periodic adjustments by the applicable Country Team (subject to approval by the JSC). Unless otherwise determined by the JSC or the relevant Country Team, GSK will Detail at least those primary care prescribers who in the aggregate are expected to prescribe [*] of PMO prescriptions in such country (provided, however, that in [*] GSK will Detail no less than [*], and at least [*] of GSK's Details of Ivory in the Collaboration Territory will be First Position Details; provided, that the [*], unless otherwise determined by the relevant Country Team). The Parties will not Detail Ivory in the Collaboration Scope except as expressly set forth in the Brand Plan (including with respect to Detailing only to those types of healthcare professionals as set forth in the Brand Plan) and the applicable Country Plan and GSK will not promote or Detail Ivory outside the Collaboration Scope. Notwithstanding the foregoing, the Parties agree that to achieve the maximum effect of increasing prescribing preferences of Ivory, the JSC or JBT may determine that there will be sales representatives of each Party that are solely dedicated to Detailing Ivory in the Collaboration Scope, and that, [*].

4.3.2. *Sales Force Minimum*. Each Party will only use its employees to perform sales activities under this Agreement, including as sales representatives and sales managers, and will not utilize a contract sales organization to fulfill its obligations to Detail Ivory in the Collaboration Scope. Each sales representative of GSK that will Detail Ivory and each sales manager for Ivory of GSK will have comparable educational qualifications and experience as Amgen requires for its own sales representatives and sales managers for Ivory; provided, that if GSK requires stricter standards applicable to its sales representatives pursuant to its codes of practice, then those additional standards will also apply

to GSK's sales representatives. All sales representatives of each Party will have, prior to being assigned to Detail Ivory, at least [*] of prior experience promoting and Detailing pharmaceutical products in [*] to being assigned to Detail Ivory and will have received appropriate training on proper marketing and sales techniques to be used in promoting pharmaceutical products in accordance with all Applicable Law and applicable national and international pharmaceutical industry codes of practices. [*]. All sales representatives and sales managers for Ivory of each Party will be subject to a reasonable proficiency examination relevant to Ivory (subject to Applicable Law).

- 4.3.3. *Sales Force Incentive Compensation* Unless otherwise agreed by the Parties, the Parties will provide for incentive compensation for their respective sales representatives Detailing Ivory that is consistent with incentive compensation for successful, first-in-class novel therapeutics at a similar stage in commercialization. In particular, such incentive compensation plans will be structured to ensure that Ivory's weighting is such that the following percentages of total incentive compensation paid to each member of such sales force during each calendar year during the Term will be as follows: [*].
- 4.4. Violation of Laws. Each Party will promptly notify the other Party of any violation of Applicable Law by its personnel with respect to the conduct of activities in the Collaboration Scope under this Agreement. Upon request of the non-notifying Party, the notifying Party will promptly confer with the non-notifying Party regarding any such violation and will promptly take remedial and/or preventative action as may be reasonably required by the JSC with respect thereto. The JSC will have the right to require the removal of any personnel that materially violates Applicable Law or applicable national or international pharmaceutical industry codes of practices from performing activities contemplated under this Agreement with respect to Ivory in the Collaboration Scope.
- 4.5. Use of Affiliates and Third Party Contractors. GSK will perform the Designated GSK Activities itself or through a wholly-owned Affiliate, and any proposed use of a Third Party to conduct Designated GSK Activities will be subject to Amgen's prior written consent, such consent not to be unreasonably withheld. Amgen will perform the Designated Amgen Activities itself or through a wholly-owned Affiliate; provided, that if Amgen wishes to engage a Third Party to conduct Designated Amgen Activities of material strategic importance to the Collaboration Scope, then the applicable Country Team or JSC will discuss the allocation of such Designated Amgen Activity to GSK in accordance with the principles set forth in Section 3.5; provided, that such Country Team or the JSC will not be required to do so for activities it has, prior to the Effective Date, arranged to have performed by Third Parties. The obligations of GSK and Amgen herein also apply to their respective Affiliates.
- 4.6. Affiliates. Each Party will be responsible for compliance by its respective Affiliates with this Agreement and will be responsible for all acts and omissions of such Affiliates as if committed or omitted by the applicable Party.
- 4.7. Management of Personnel. Each Party will have sole authority and responsibility for recruiting, hiring, managing, compensating (including paying for all benefits, wages,

special incentives, workers' compensation and employment taxes), disciplining, firing and otherwise controlling the personnel provided by such Party for performance of its obligations hereunder. Each Party will provide the day-to-day management of its sales representatives and other personnel, including furnishing administrative support, financial resources, equipment and supplies.

- 4.8. COGS. Amgen will supply Ivory for the Collaboration Scope in a manner consistent with its general corporate practice for supply. Amgen will not systematically supply Ivory for the Collaboration Scope from higher-priced Inventory Layers for the purpose of increasing costs chargeable within the Collaboration Scope. Currently, Amgen [*] and Amgen promptly will inform the JSC if the foregoing supply structure changes.

5. UP-FRONT PAYMENT AND MILESTONES

5.1. Payments by GSK.

5.1.1. *Up-Front Payment*. As partial consideration for the rights granted to GSK by Amgen pursuant to the terms of this Agreement, GSK will pay to Amgen a non-refundable, non-creditable payment equal to [*] within ten (10) days after receipt of an invoice after the Effective Date from Amgen, payable by wire transfer of immediately available funds in accordance with wire transfer instructions of Amgen that will be provided in writing to GSK prior to the Effective Date.

5.1.2. *Milestone Payment*. As partial consideration for the rights granted to GSK by Amgen under the terms of this Agreement, GSK will make a first non-refundable, non-creditable payment of [*] to Amgen upon the [*], and a second non-refundable, non-creditable payment of [*] to Amgen upon [*]. Amgen will provide GSK with prompt written notice upon achievement of the milestone. GSK will make the payment associated with the achieved milestone event within sixty (60) days of the date on which GSK receives an invoice from Amgen with respect to such milestone.

- 5.2. Payment Method. Payments pursuant to this Article 5 (Up-Front Payment and Milestones) will be made in accordance with the provisions of Article 7 (Payments).

6. PROFIT/EXPENSE SHARING

- 6.1. Sharing. The Parties will share in profits and losses generated by Ivory in the Collaboration Scope as follows:

6.1.1. *GSK Costs*: Within forty-five (45) days after the end of each calendar quarter GSK will provide Amgen a detailed, itemized report of the costs described in Sections 6.1.1.1 through 6.1.1.5 (collectively, "*GSK Costs*") incurred in such quarter in such format as designated by the JSC. Within five (5) days prior to the end of each calendar quarter GSK will provide Amgen an estimate of GSK Costs incurred and to be incurred in such quarter, and an estimate of GSK Costs to be incurred in the remaining quarters of such calendar year, in each case in such format as designated by the JSC.

- 6.1.1.1. Costs incurred by GSK or its Affiliates in performing activities allocated to GSK pursuant to Section 3.3 (Designated GSK Activities) or 3.1 (Allocation of Operational Responsibility) and not otherwise included in this Section 6.1.1 (GSK Costs);
- 6.1.1.2. Training costs incurred in accordance with Section 3.8 (Training);
- 6.1.1.3. GSK Sales Force Costs incurred in accordance with the Brand Plan and calculated in accordance with Section 6.1.10 (Calculation of Sales Force Costs).
- 6.1.1.4. Defense costs incurred within or materially related to the Collaboration Scope in accordance with Section 9.7 (Defense and Settlement of Third Party Claims of Infringement) or 13.5 (Defense of Third Party Claims) (but, in each case, not including defense costs incurred by GSK in fulfilling its obligations pursuant to Section 13.1 (Indemnity by GSK)), and enforcement (and cooperation) costs within or materially related to the Collaboration Scope incurred in accordance with Section 9.8 (Enforcement); and
- 6.1.1.5. Collaboration Losses.
- 6.1.2. *Amgen Costs*: Within forty-five (45) days of the end of each calendar quarter Amgen will provide GSK a detailed, itemized report of the costs described in Sections 6.1.2.1 through 6.1.2.13 (collectively "*Amgen Costs*") incurred in such format as designated by the JSC. Within five (5) days prior to the end of each calendar quarter Amgen will provide GSK an estimate of Amgen Costs incurred and to be incurred in such quarter, and an estimate of Amgen Costs to be incurred in the remaining quarters of such calendar year, in each case in such format as designated by the JSC. All Amgen Costs incurred on or after [*] will be included in the profit/expense sharing provisions of this Article 6 (Profit/Expense Sharing).
 - 6.1.2.1. Costs incurred by Amgen or its Affiliates in performing activities allocated to Amgen pursuant to Section 3.4 (Designated Amgen Activities) or 3.1 (Allocation of Operational Responsibility) and not otherwise included in this Section 6.1.2 (Amgen Costs);
 - 6.1.2.2. Any amounts paid by Amgen to Third Parties for rights to manufacture, use or sell Ivory in or for the Collaboration Scope to the extent not already included in COGS [*];
 - 6.1.2.3. Costs associated with obtaining, maintaining and renewing Regulatory Filings and Regulatory Approvals pertaining to Ivory;
 - 6.1.2.4. Training costs incurred in accordance with Section 3.8 (Training);
 - 6.1.2.5. Amgen Sales Force Costs incurred in accordance with the Brand Plan and calculated in accordance with Section 6.1.10 (Calculation of Sales Force Costs);
 - 6.1.2.6. COGS associated with Ivory Net Revenues;

- 6.1.2.7. [*] of Qualified Amgen R&D Costs;
- 6.1.2.8. Collaboration Territory R&D Costs;
- 6.1.2.9. Standard Cost of any Samples of Ivory provided in the Collaboration Scope;
- 6.1.2.10. Costs associated with any recalls, returns and withdrawals of Ivory in the Collaboration Scope that are not attributable to Amgen's or its Affiliates' negligence or willful misconduct or Amgen's breach of this Agreement;
- 6.1.2.11. Defense costs incurred within or materially related to the Collaboration Scope in accordance with Section 9.7 (Defense and Settlement of Third Party Claims) or 13.5 (Defense of Third Party Claims) (but, in each case, not including defense costs incurred by Amgen in fulfilling its obligations pursuant to Section 13.2 (Indemnity by Amgen)) and enforcement (and cooperation) costs incurred in accordance with Section 9.8 (Enforcement) within or materially related to the Collaboration Scope;
- 6.1.2.12. Amgen's costs incurred in connection with Prosecution and Maintenance of Ivory Intellectual Property in accordance with Section 9.6 (Prosecution and Maintenance) within or materially related to the Collaboration Scope; and
- 6.1.2.13. Collaboration Losses (except as expressly provided in Section 6.5 (Collaboration Losses)).
- 6.1.3. *FTE Rate*. The FTE Rate used for calculation of costs pursuant to this Article 6 (Profit/Expense Sharing) with respect to any activity will be the relevant FTE Rate for the calendar quarter in which such activity was undertaken.
- 6.1.4. *Income Taxes*. For the avoidance of doubt, income and withholding taxes imposed on either of the Parties hereunder will not be included in cost sharing hereunder.
- 6.1.5. *Exchange Rate*. For purposes of calculating quarterly balancing payments as set forth in Section 6.1.9 (True-Up), Ivory Net Revenues, Amgen Costs and GSK Costs will be converted from local currency (if different from U.S. Dollars) to U.S. Dollars in accordance with Section 16.8 (Currency).
- 6.1.6. *Budget and Overruns*.
 - 6.1.6.1. Preparation; Updating. Promptly after the Country Teams prepare the Country Plans, the JSC will prepare the Collaboration Budget. On an annual basis, commencing with the Collaboration Budget for 2010, the JSC will prepare the Collaboration Budget for the following calendar year based upon the input of the Country Teams and JBT. The Parties agree that each Collaboration Budget covering a calendar year will be [*] subject to mutual agreement of the CRC; provided, that if the CRC cannot mutually agree, then [*] pursuant to Section 6.1.8 (Calculation of Profit (or Loss)). On an annual basis, commencing with the

Development Budget for 2010, the JDC will prepare a Development Budget for the following calendar year (or update the Initial Development Budget for the following year, as applicable). The Parties will promptly provide the JSC and JDC all reasonably requested information to facilitate the preparation or updating of each Collaboration Budget or Development Budget, as applicable, including detailed estimates of GSK Costs and Amgen Costs for the following calendar year.

- 6.1.6.2. Overruns. Each Party will provide prompt, written advance notice to the other Party if it becomes aware of any anticipated costs to be incurred by such Party in excess of the applicable Collaboration Budget or Development Budget. Unless otherwise agreed by the Parties in advance, in writing, costs reported by a Party pursuant to Section 6.1.1 (GSK Costs) or 6.1.2 (Amgen Costs) incurred in excess of [*] of any aggregate amounts budgeted to be incurred by or on behalf of such Party for its activities for such calendar year in the then-current Collaboration Budget or Development Budget will not be included in the calculation of profit (or loss) pursuant to Section 6.1.8 (Calculation of Profit (or Loss)); provided that GSK Costs and Amgen Costs in excess of such amount will be included in the calculation of profit (or loss) pursuant to Section 6.1.8 (Calculation of Profit (or Loss)) [*].
- 6.1.7. *Ivory Net Revenues*. Within forty-five (45) days after the end of each calendar quarter, Amgen will provide GSK with a reasonably detailed report of Ivory Net Revenues for such calendar quarter.
- 6.1.8. *Calculation of Profit (or Loss)*. The total profit (or loss) for a calendar quarter will be calculated by Amgen by first deducting from Ivory Net Revenues for such quarter a percentage of such Ivory Net Revenues equal to the Inventorship Margin, which will be paid to Amgen to reflect Amgen's inventorship of Ivory; and then deducting from the remaining Ivory Net Revenues the GSK Costs and Amgen Costs reported by the Parties pursuant to Sections 6.1.1 (GSK Costs) and 6.1.2 (Amgen Costs). The resulting amount will be the "*Collaboration Profit (Loss)*" for such quarter, which will be shared by the Parties equally.
- 6.1.9. *True-up*. Within ninety (90) days of the end of each calendar quarter, Amgen will calculate and provide to GSK a report of the Collaboration Profit (Loss) for such quarter, and a balancing payment will be made between the Parties such that each Party bears one half of the sum of GSK Costs and Amgen Costs, and each Party receives one half of Ivory Net Revenues, after deducting the amount allocated to Amgen under Section 6.1.8 (Calculation of Profit (or Loss)) above. The net paying Party will make a payment pursuant to this Section 6.1.9 (True-up). Payments pursuant to this Article 6 will be made in accordance with the provisions of Article 7.

- 6.1.10. *Calculation of Sales Force Costs.* Sales force FTE costs for each of the Parties will be determined by including in GSK Costs or Amgen Costs, as the case may be, a pro rata portion of each Party's sales representative's FTE Rate as follows:
- (i) [*] if such sales representative Details only Ivory with the approval of the JSC, (ii) [*] if such sales representative Details two (2) products with Ivory as the First Position Detail or Details only Ivory without the approval of the JSC, (iii) [*] if such sales representative Details two (2) products with Ivory as the Second Position Detail, (iv) [*] if such sales representative Details three (3) or more products with Ivory as the Second Position Detail, and (v) [*] if such sales representative Details three (3) or more products with Ivory as the Third Position Detail. For the avoidance of doubt, if a sales representative Details Ivory in more than one (1) position, then a pro rata share of the foregoing percentages, to be calculated based on the time spent by such sales representative on Detailing Ivory in each such position, will be included in GSK Costs or Amgen Costs, as the case may be. For periods in which sales representatives are performing activities in support of the collaboration but are not Detailing Ivory (e.g., during launch preparation or training), FTE costs will be calculated in accordance with Section 6.4 (Attribution of Costs).
- 6.2. Example. The Profit (Loss) True-up Schedule sets forth an example of calculation and true-up of the quarterly Collaboration Profit (Loss).
- 6.3. Calculation of Net Revenues. In calculating Ivory Net Revenues for the purposes of this Article 6 (Profit/Expense Sharing):
- 6.3.1. *Free Products.* Any disposal of Ivory at no charge for, or use of Ivory without charge in, clinical or preclinical trials, given as free samples, or distributed at no charge to patients unable to purchase the same will not be included in Ivory Net Revenues.
 - 6.3.2. *Bundled Products.* Where Ivory is sold in a Bundle, then for the purposes of calculating the Ivory Net Revenues under this Agreement, such Ivory will be deemed to be sold for an amount equal to $X \div (X + Y) \times Z$, where: X is the average sales price during the applicable reporting period generally achieved for such dosage form of Ivory in the Collaboration Scope; Y is the sum of the average sales price during the applicable reporting period generally achieved in the Collaboration Territory, when sold alone, by each pharmaceutical product in the relevant dosage form included in the Bundle (excluding Ivory); and Z equals the price at which the Bundle was actually sold. In the event that Ivory or one or more of the other pharmaceutical products in the Bundle are not sold separately in the relevant dosage form, the Ivory Net Revenues from the sale of such Bundle will be reasonably allocated between Ivory and the other product(s) in such Bundle based upon their relative values and the JSC will determine an equitable fair market price to apply to such bundled Ivory. Notwithstanding the foregoing, Ivory will not be sold in a Bundle if such sale would violate Applicable Law.
- 6.4. Attribution of Costs. Unless otherwise set forth herein, for costs not specific to the Collaboration Scope or the activities to be performed hereunder (including FTE costs for personnel not solely devoted to Ivory in the Collaboration Scope (but not including sales force FTE costs for sales force Detailing Ivory, which will be calculated in accordance with Section 6.1.10 (Calculation of Sales Force Costs)), the portion of such

costs allocable to the collaboration may be determined based upon percent of effort, resource utilization or other reasonable measure, in each case calculated and allocated in accordance with the applicable Party's accounting procedures, consistently applied. For clarity, no particular cost will be allocated to the collaboration more than once.

- 6.5. Collaboration Losses. Each Party understands the risks attendant to the business of Ivory within the Collaboration Scope. Losses related to the Collaboration Scope that arise out of the development, manufacture, regulatory activities, commercialization or other exploitation of Ivory undertaken by or on behalf of a Party in the exercise of its rights or performance of its obligations under this Agreement in good faith ("*Collaboration Losses*") will be charged to the Collaboration Profit (Loss); provided, that Collaboration Losses will not include Losses that are: [*] will not be Collaboration Losses). If a Party becomes aware of a [*] that would, if successful, result in a Collaboration Loss, such Party will inform the other Party of such [*] as soon as reasonably practicable after it receives notice thereof. [*].

7. PAYMENTS

- 7.1. Appropriate Measure of Value. Each of the Parties acknowledges that the value provided by the other hereunder is comprised of many related items, including performance of various services, access to development and commercial expertise, clinical data and other financial and non-financial consideration and that the amount of the Inventorship Margin, and the ratio of profit and expense sharing set forth herein are intended to capture such value as an aggregate. Therefore the increase, decrease or lapse of any particular items or rights (including Patents), including allocation of operational responsibilities between the Parties, will not affect the amount of such payment, or the ratio of profit and expense sharing and the Parties agree that both the amount and duration of such payment or the ratio of profit and expense sharing are reasonable.
- 7.2. No Other Compensation. Other than as explicitly set forth (and as applicable) in this Agreement, neither Party will be obligated to pay any additional fees, milestone payments, royalties or other payments of any kind to the other hereunder.
- 7.3. Payment Method. All payments made hereunder between the Parties will be made in U.S. Dollars except as set forth in Section 7.5 (Blocked Currency) or as otherwise agreed by the Parties. Each Party will pay all sums due hereunder by wire transfer, or electronic funds transfer (EFT) in immediately available funds. If the EFT option is chosen by Amgen or GSK, a completed electronic funds transfer form will be provided in a timeframe that facilitates timely payment. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments.
- 7.4. Audits. Each Party will keep complete and accurate records pertaining to the activities to be conducted hereunder in sufficient detail to permit the other Party (the "*Auditing Party*") to confirm the accuracy of all payments due hereunder, including the Tail Payments set forth in Section 14.11, and such records will be open (in such form as may be available or reasonably requested) to inspection for [*] following the end of the period to which they pertain. The Auditing Party will have the right, at its own expense to have an independent, certified public accountant, selected by it, perform a review the

records of the other Party (the “*Audited Party*”) applicable to amounts payable hereunder (including any records kept in the ordinary course of the Audited Party’s business) upon reasonable notice, during regular business hours and under reasonable obligations of confidentiality. The report of such accountant will be made available to both Parties simultaneously, promptly upon its completion. The Auditing Party’s right to perform an audit pertaining to any calendar year will expire [*] after the end of such year and the books and records for any particular calendar year will only be subject to one (1) audit. Should an inspection pursuant to this Section 7.4 (Audits) lead to the discovery of a payment discrepancy, then the appropriate Party will pay to the other the amount of the discrepancy (plus, if the error was in favor of the Audited Party, interest accrued at the Contract Interest Rate, compounded annually from the day the relevant payment(s) were due). If a payment discrepancy was greater than [*] of the correct amount for the audited period and the discrepancy was in favor of the Audited Party, then the Audited Party will pay the reasonable out-of-pocket cost of such inspection, but in no case will the costs of an audit pursuant to this Section 7.4 (Audits) be included in GSK Costs or Amgen Costs allocated to the collaboration. This Section 7.4 (Audits) does not apply to or include manufacturing audits or regulatory inspections.

- 7.5. Blocked Currency. If Applicable Law in the Collaboration Territory prevent the prompt remittance of any payments with respect to sales therein, the paying Party will have the right and option to make such payments by depositing the amount thereof in local currency to the other Party’s account in a bank or depository in such country.
- 7.6. Withholding. If Applicable Law requires a Party to pay or withhold Taxes with respect to any payment to be made pursuant to this Agreement, the paying Party will notify the other in writing of such payment or withholding requirements prior to making the payment and provide such assistance to the receiving Party, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in such Party’s efforts to claim an exemption from or reduction of such Taxes. Each Party will withhold any Taxes required by law to be withheld from the amount due, remit such Taxes to the appropriate tax authority, and furnish the other Party with proof of payment of such Taxes promptly following payment thereof. If Taxes are paid to a tax authority, each Party will provide the other such assistance as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid. In the event that the governing tax authority retroactively determines that a payment made by a Party to the other pursuant to this Agreement should have been subject to withholding (or to additional withholding) for Taxes, and such Party (the “*Withholding Party*”) remits such withholding Taxes to the tax authority, the Withholding Party will have the right to offset such amount, including any interest and penalties that may be imposed thereon, against future payment obligations of the Withholding Party under this Agreement (or, at the option of the Withholding Party, the Withholding Party will have the right to invoice the other Party for such amount, and the other Party will pay such amount within sixty (60) days of the receipt of such invoice); provided however, that the Withholding Party may also pursue reimbursement by any other available remedy.
- 7.7. VAT. All payments due a Party pursuant to this Agreement will be paid exclusive of any VAT and other indirect Taxes (which, if applicable, will be payable by the paying

Party upon receipt of a valid VAT invoice). If such amounts of VAT are refunded by the applicable Governmental Authority or other fiscal authority subsequent to payment, the Party receiving such refund will transfer such amount to the paying Party within forty-five (45) days of receipt.

7.8. Late Payment. Any payments or portions thereof due hereunder which are not paid when due will bear interest at the Contract Interest Rate, compounded annually, calculated on the number of days such payment is delinquent. This Section 7.8 (Late Payment) will in no way limit any other remedies available to either Party.

7.9. Change in Accounting Periods. From time to time, either of the Parties may change its accounting and financial reporting practices from calendar quarters and calendar years to fiscal quarters and fiscal years or vice versa. If a Party notifies the other in writing of a change in its accounting and financial reporting practices from calendar quarters and calendar years to fiscal quarters and fiscal years or vice versa, then thereafter, beginning with the period specified in the notice, the Parties will cooperate to determine a way to report and reconcile each Party's accounting periods so as to facilitate payments to be made hereunder.

8. [*]

9. INTELLECTUAL PROPERTY

9.1. Invention Ownership. Each Party will own all right, title, and interest in and to all Inventions that are made by or on behalf of such Party, solely or independent of the other Party, and all intellectual property rights related thereto (including in the case of GSK, GSK Inventions), and any Invention that is jointly made will be owned jointly by the Parties (each a "*Joint Invention*"). Inventorship will be determined according to United States Patent Law (without reference to any conflict of law principles).

9.2. Copyright Ownership; Certain Confidential Information. Except as set forth below, each Party will own all right, title, and interest in and to all Copyrights created pursuant to this Agreement that are authored by or on behalf of such Party, solely or independent of the other Party, and all intellectual property rights related thereto; provided that any Copyrights pertaining to Ivory (including any clinical trial protocols, investigator brochures and informed consent forms, and including the product labeling, package inserts, core data sheet and all marketing and promotional materials and including the Brand Book) will be owned solely by Amgen. The Parties will jointly own all right, title, and interest in and to all Copyrights that are authored by or on the behalf of the Parties jointly; provided that any Copyrights pertaining to Ivory will be owned solely by Amgen whether created jointly by the Parties or by either Party independent of the other Party. In addition, all Confidential Information to the extent pertaining to Ivory will be the Confidential Information of Amgen (and not of GSK), regardless of which Party created such information (and will not be subject to the exclusion under Section 11.1.1 or 11.1.4). Any Copyrights created by GSK or its Affiliates and specified in this Section 9.2 (Copyright Ownership) as being owned by Amgen will be considered a work for hire. To the extent any such Copyright is not considered a work for hire, GSK and/or such Affiliate will assign and does hereby assign to Amgen all of its right, title and interest in and to such Copyright and intellectual property rights therein and

thereto. Each Party will duly execute, acknowledge, and deliver to the other all such further papers, including assignments and applications for copyright registration or renewal, as may be reasonably requested and/or necessary to enable such other Party to publish or protect said Copyrights in any and all countries and to vest title to said Copyrights in such other Party (or its nominees, or its or their successor or assigns) in accordance with this Section 9.2 (Copyright Ownership), and will render such reasonable assistance, at such other Party's expense, as such other Party may reasonably require in any proceeding or litigation involving said Copyrights.

- 9.3. Joint Ownership. Except as expressly provided in this Agreement, it is understood that neither Party will have any obligation to obtain any approval or consent of, nor pay a share of the proceeds to or account to, the other Party to practice, enforce, license, assign or otherwise exploit Inventions or intellectual property (including Copyrights) owned jointly by the Parties hereunder, and each Party hereby waives any right it may have under the laws of any jurisdiction to require such approval, consent or accounting. Each Party agrees to cooperate with the other Party, as reasonably requested, and to take such actions as may be required to give effect to this Section 9.3 (Joint Ownership) in a particular country within the Collaboration Territory.
- 9.4. License Grant by Amgen. Amgen hereby grants and causes its Affiliates to grant to GSK and its Affiliates during the Term a [*] license to Ivory Intellectual Property solely to the extent necessary to Detail Ivory in the Collaboration Scope, conduct the Designated GSK Activities, and exercise and perform GSK's other rights and obligations under the terms of this Agreement.
- 9.5. License Grant by GSK. GSK hereby grants and causes its Affiliates to grant to Amgen and its Affiliates a [*] license under all Know-How and Patents owned or controlled as of the Effective Date or during the Term (including GSK Inventions) by GSK or its Affiliates solely to use, make, have made, sell, offer for sale and import Ivory for all uses, and for performing Amgen's rights and obligations hereunder. Such license is sublicensable by Amgen or its Affiliates solely to Third Parties to whom Amgen or its Affiliates also grant a license to Know-How or Patents owned or controlled by Amgen claiming Ivory, its formulation or the use thereof; provided, that such sublicense will terminate no later than the date on which the license to the Third Party to Amgen Know-How or Patents described above terminates.
- 9.6. Prosecution and Maintenance. Subject to the provisions of Section 2.14 (Patent Coordinators), Amgen will control, itself or through outside counsel, and have final decision making authority (after consultation with GSK in accordance with the terms and conditions of this Agreement) with respect to the Prosecution and Maintenance of the Patents and Product Trademarks within the Ivory Intellectual Property in the Collaboration Territory (the "*Ivory Patents and Trademarks*"), and with respect to preparation and filing for any patent term extensions or similar protections therefor. Through the Patent Coordinators: (i) Amgen will provide GSK with copies of and an opportunity to review and comment upon the text of the applications relating to the Ivory Patents and Trademarks at least [*] before filing; provided, that if it is not reasonably practicable to provide such application in such [*] period, then Amgen will provide either a draft copy of such application or a statement of intent to file such application in such [*] period; (ii) Amgen will provide GSK with a copy of each

submission made to and document received from a patent authority, court or other tribunal regarding any Ivory Patent and Trademark reasonably promptly after making such filing or receiving such document, including a copy of each application for each Ivory Patent and Trademark as filed together with notice of its filing date and application number; (iii) Amgen will keep GSK advised of the status of all material communications, actual and prospective filings or submissions regarding the Ivory Patents and Trademarks, and will give GSK copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (iv) Amgen will consider in good faith GSK's comments on the communications, filings and submissions for the Ivory Patents and Trademarks. With respect to any filings or other materials provided to GSK under this Section 9.6 (Prosecution and Maintenance), Amgen will have the right to redact any manufacturing information and any information relating to any product other than Ivory from any such filings and materials.

- 9.7. Defense and Settlement of Third Party Claims of Infringement. If a Third Party asserts that Patents, Know-How or other rights owned or controlled by it are infringed by the activities hereunder of either of the Parties, then defense of such claim (an "*Infringement Claim*") will be managed in accordance with the provisions of Section 13.5 (Defense of Third Party Claims), with coordination and cooperation between the Defending Party and Assisting Party occurring via the Patent Coordinators. If either Party seeks to initiate a nullification or revocation proceeding against any such Patents, Know-How or other rights in response to prospective or actual Third Party Claims of Infringement, the Parties will coordinate and cooperate in regard to such proceedings in accordance with the procedures set forth in Section 13.5 (Defense of Third Party Claims), with coordination and cooperation between the Defending Party and Assisting Party occurring via the Patent Coordinators.
- 9.8. Enforcement. Except as expressly set forth in this Section 9.7 (Enforcement), each Party will retain all its rights to control the enforcement of its own intellectual property. Amgen will have the sole right to enforce the Ivory Intellectual Property. GSK will reasonably assist Amgen with respect to any such enforcement in the Collaboration Territory, including, in the event that it is determined that the GSK is an indispensable Party to such action, by being named as a Party in such action, and cooperate in any such action at Amgen's request. Without limiting the foregoing, Amgen will keep GSK advised of all material communications, actual and prospective filings or submissions regarding such action, and will provide GSK copies of and an opportunity to review and comment on any such material communications, filings and submissions (provided that Amgen will have the right to redact any manufacturing information and any information relating to any product other than Ivory from any such materials). All Recoveries will be retained by Amgen, but included in Ivory Net Revenues for the period in which such Recovery is made.
- 9.9. Patent Term Extensions. GSK will provide reasonable assistance to Amgen in connection with obtaining supplemental protection certificates for Patents within the Ivory Intellectual Property or otherwise licensed or assigned hereunder as determined by the Patent Coordinators. To the extent reasonably and legally required to obtain any such supplemental protection certificates in a particular country, GSK will make

available to Amgen copies of all necessary documentation to enable Amgen to use the same for the purpose of obtaining the supplemental protection certificates in such country.

9.10. Employee Agreements. Prior to beginning work relating to any aspect of the subject matter of this Agreement and/or being given access to Ivory Intellectual Property or Confidential Information of the other Party, each employee, consultant and/or agent of Amgen and GSK will have signed or will be bound to a commercially reasonable non-disclosure and/or invention assignment agreement. Each Party will be responsible for any compensation or payment to its employees, contractors or agents in connection with the invention of any patent right.

9.11. Trademarks.

9.11.1. *Title.* Amgen will own all right, title and interest in and to the Product Trademarks, and GSK agrees to assign and hereby assigns to Amgen all right title and interest that GSK has or may acquire in connection with the Product Trademarks. All goodwill arising out of the use of the Product Trademarks or otherwise related to Ivory will inure to the benefit of Amgen. GSK will not, and will ensure that its Affiliates do not: (i) challenge any Product Trademark or the registration thereof in any country; (ii) file, register or maintain any registrations for the Product Trademarks, or for any trademarks or trade names that are confusingly similar to any Product Trademark, in any country without the express prior written consent of Amgen, and such permitted registrations (if any) will be filed, registered or maintained by GSK in Amgen's name; or (iii) authorize or assist any Third Party to do the foregoing.

9.11.2. *Required Use and Compliance.*

9.11.2.1. Promotional Materials for Ivory in the Collaboration Scope will display the Amgen Housemarks and the GSK Housemarks to the extent allowed by Applicable Law and in accordance with the Brand Plan. Except for the use of the Amgen Housemarks and the GSK Housemarks as may be expressly set forth in the Brand Plan, each Party will promote Ivory in the Collaboration Scope only under the Product Trademarks.

9.11.2.2. GSK agrees that it and its Affiliates will: (i) ensure that each use of the Product Trademarks and/or the Amgen Housemarks by GSK is accompanied by an acknowledgement that the Product Trademarks and Amgen Housemarks are owned by Amgen; (ii) not use the Product Trademarks or Amgen Housemarks in a way that might materially prejudice their distinctiveness or validity or the goodwill of Amgen therein; and (iii) not use any trademarks or trade names so resembling any of the Product Trademarks or Amgen Housemarks as to be likely to cause confusion or deception. Amgen agrees that it and its Affiliates will ensure that each use of the GSK Housemarks by Amgen is accompanied by an acknowledgement that the GSK Housemarks are owned by GSK.

9.11.3. *Licenses.*

9.11.3.1. **To GSK.** Amgen hereby grants to GSK [*] license to use the Product Trademarks and Amgen Housemarks as set forth in the Promotional Materials and other materials provided to it by Amgen, solely to Detail Ivory in the Collaboration Scope in accordance with the Brand Plan, Country Plans and this Agreement during the period that GSK has rights to Detail Ivory hereunder. GSK's right to use the Product Trademarks and the Amgen Housemarks will terminate, on a country-by-country basis, when GSK's rights to Detail Ivory in such country are terminated or expire. GSK will take all such steps as Amgen may reasonably request to give effect to the termination of the license to the Product Trademarks and Amgen Housemarks in such country and to record any documents that may be required to evidence the termination of such license.

9.11.3.2. **To Amgen.** GSK hereby grants to Amgen a [*] license to use the GSK Housemarks as set forth in the Promotional Materials solely to Detail Ivory in the Collaboration Scope in accordance with the Brand Plan, Country Plans and this Agreement. Amgen's right to use the GSK Housemarks will terminate, on a country-by-country basis, when GSK's rights to promote Ivory in such country are terminated or expire; provided, that the license set forth in this Section 9.11.3.2 (To Amgen) will continue for a period of [*] to permit Amgen to use and distribute its inventory of Promotional Materials containing GSK Housemarks in such country (or, where the on-hand inventory as of such termination or expiration of such Promotional Materials cannot practically be used within such [*] period, such longer period as reasonably necessary to exhaust such Promotional Materials, but in no event longer than [*]), in connection with Amgen's Detailing of Ivory. Amgen will take all such steps as GSK may reasonably request to give effect to the termination of the license to the Collaboration Housemarks in the applicable country and to record any documents that may be required to evidence the termination of such license.

9.11.4. *Respect of Trademarks.* GSK will not have, assert or acquire any right, title or interest in or to any of Product Trademarks or Amgen Housemarks or the goodwill pertaining thereto, and Amgen will not have, assert or acquire any right, title or interest in or to the GSK Housemarks or the goodwill pertaining thereto, in each case by means of entering into or performing under this Agreement, except in each case for the limited licenses explicitly provided in this Agreement.

9.11.5. *Infringement* Amgen will monitor the Product Trademarks against infringing uses within the Collaboration Scope. GSK will give Amgen prompt notice of any infringement or threatened infringement of any of the Product Trademarks of which it becomes aware. Amgen will determine in its sole discretion what action, if any, to take in response to any such infringement or threatened infringement of any Product Trademark.

- 9.12. Community Of Interest. From time-to-time it may be desirable or beneficial to the Parties to share between each other and their respective outside counsel privileged and/or work product information with respect to certain Patents and/or Know-How related to Ivory, and legal matters relating thereto, and that they share a common interest in the prosecution, defense and enforcement of such Patents and Know-How, including such Patents and Know-How owned or controlled by Third Parties. Therefore, the Parties agree to execute the Joint Community Of Interest Privilege Agreement (attached hereto as the Privilege Agreement Schedule) concurrently with this Collaboration Agreement.

10. REGULATORY AND SAFETY

10.1. Regulatory Matters.

- 10.1.1. *Regulatory Communication and Filings.* Amgen will use Commercially Reasonable Efforts to prepare, submit and maintain all Regulatory Filings and to obtain all Regulatory Approvals for Ivory in the Collaboration Scope, including making all Regulatory Filings necessary for the development of Ivory in accordance with the Development Plan. Amgen will use Commercially Reasonable Efforts with respect to all other regulatory matters regarding Ivory in the Collaboration Scope including pricing, reimbursement and health technology assessments. GSK will cooperate with Amgen, at its reasonable request, with respect to any regulatory matters related to Ivory in the Collaboration Scope. Amgen will provide GSK with copies of Regulatory Filings and material communications with Governmental Authorities in the Collaboration Scope prior to submission within a reasonable amount of time to allow GSK to review and comment on such Regulatory Filings and communications, but not less than five (5) days, and Amgen will consider all comments and proposed revisions from GSK in good faith prior to submission. Notwithstanding the foregoing, if exigent action is required with respect to such Regulatory Filing or material communication, and Amgen reasonably believes it is not practicable to provide such Regulatory Filing or communication to GSK in advance of submission without violating Applicable Law or causing a material delay to such Regulatory Filing, communication or receipt of Regulatory Approval, Amgen will instead provide such filing or communication to GSK as soon as reasonably practicable. Amgen will consult with GSK regarding, and keep GSK informed of, the status of the preparation of all Regulatory Filings, Governmental Authority review of Regulatory Filings, and Regulatory Approvals made or obtained by it in the Collaboration Scope.
- 10.1.2. *Regulatory Meetings.* Amgen will consult with GSK reasonably in advance of the date of any anticipated meeting with a Governmental Authority in the Collaboration Scope and will consider in good faith any timely recommendations made by GSK in preparation for such meeting. Amgen will consider in good faith permitting GSK to attend particular meetings between Amgen and the applicable Governmental Authority that pertain to the Collaboration Scope. Where Amgen so agrees, it will request that the applicable Governmental Authority allow at least one (1) GSK representative to

attend, [*] such meetings; provided, that the foregoing will not apply to [*] only (such as interactions with EMEA rapporteurs). Amgen will timely inform GSK of any such meetings. [*] with respect to any such meeting, and will not discuss the contents of any such meeting with any Governmental Authority except as required by Applicable Law or authorized by Amgen in writing.

- 10.1.3. *GSK Obligations.* Except as expressly provided in Section 10.1.1 (Regulatory Communications and Filings) GSK will cooperate with Amgen, at its request, with respect to any regulatory matters related to Ivory. GSK will not without the consent of Amgen or unless so required by Applicable Law (and then only pursuant to the terms of this Section 10.1.1 (Regulatory Communication and Filings)), correspond or communicate with any Governmental Authority, whether within the Collaboration Territory or otherwise, concerning Ivory or otherwise take any action with any Governmental Authority concerning any authorization or permission under which Ivory is sold or any application for the same. Furthermore, GSK will, immediately upon receipt of any communication from any Governmental Authority relating to Ivory, forward a copy (or written description, with respect to any oral communication) of the same to Amgen and respond to all inquiries by Amgen relating thereto. If GSK is advised by its counsel that it must communicate with any Governmental Authority with respect to Ivory or the activities under this Agreement, then GSK will so advise Amgen immediately and, if possible, provide to Amgen in advance for review a copy of any proposed written communication (or written description, with respect to any oral communication) with respect thereto. GSK will comply with any and all reasonable direction of Amgen concerning any meeting or written or oral communication with any Governmental Authority; provided, that GSK will not take direction of Amgen that GSK reasonably believes is not in compliance with Applicable Law. In addition to the foregoing: (i) unless required by Applicable Law, GSK will not disclose any information concerning any adverse drug experience to any Person or Governmental Authority without the prior consent of Amgen; (ii) GSK will utilize the global safety database maintained by Amgen as directed by Amgen from time-to-time; and (iii) Amgen will have the sole discretion to assess all adverse drug experiences and to determine whether any complaint or adverse drug experience must be reported to any Governmental Authority.
- 10.1.4. *Labeling and Packaging Materials.* Amgen will have sole authority and responsibility, and will use Commercially Reasonable Efforts to, seek and/or obtain any necessary governmental approvals of any labeling, package inserts or packaging for Ivory and Promotional Materials, and to determine whether the same requires governmental approval; provided, that Amgen will use Commercially Reasonable Efforts to obtain any Governmental Authority approval required to include the GSK Housemarks on the labeling, packaging and package inserts for Ivory in the Collaboration Scope within [*] of the Effective Date. All filings and communications with Governmental Authorities in connection therewith will remain under the control of Amgen. No labeling, package inserts, or packaging for Ivory may be used or distributed by GSK

unless such labeling, package inserts or packaging has been approved in advance by Amgen. GSK will not modify or alter any labeling, package inserts or packaging for Ivory, without the express prior approval of such modification or alteration by Amgen. Amgen will provide GSK with prompt notice of, and copies of, any changes in the Ivory labeling, package inserts or packaging.

10.1.5. *Regulatory and Safety Information.* Each Party agrees to provide the other with all reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party to comply with any Applicable Law with respect to Ivory, including reporting obligations of Amgen related to Ivory. Such assistance and actions will include, among other things, GSK keeping Amgen informed, commencing immediately upon notification of any action by, or notification or other information which it receives (directly or indirectly) from any Governmental Authority that: (i) raises any concerns regarding the safety or efficacy of Ivory; (ii) indicates or suggests a potential liability for either Party to Third Parties arising in connection with Ivory; or (iii) is reasonably likely to lead to a recall or market withdrawal of Ivory. Concurrently with entry into this Agreement, or promptly after the Effective Date of the Agreement, but not later than sixty (60) days thereafter, the Parties will enter into an agreement pertaining to safety, pharmacovigilance, product complaints and/or the like.

10.2. Brand Security and Anti-Counterfeiting. The Parties will establish contacts for communication regarding brand security issues and will each reasonably cooperate with the other with respect thereto.

10.3. Product Technical Complaints; Recalls; Returns.

10.3.1. *Product Technical Complaints* If GSK (including any GSK sales representative Detailing Ivory) becomes aware of any Product Technical Complaint (as defined below), GSK will submit a written report of such complaint to Amgen within one (1) business day of GSK so becoming aware (along with a sample of the Ivory product involved in the complaint, as soon as (and if) available). GSK will not take any other action in respect of any such complaint without the consent of Amgen unless otherwise required by Applicable Law. As used herein, “*Product Technical Complaint*” means: (i) any complaint that questions the purity, identity, potency or quality of Ivory, its packaging or labeling or the compliance of any batch of Ivory with Applicable Law; (ii) any complaint concerning Ivory being mistaken for, or Ivory’s labeling being applied to, another article; (iii) any bacterial contamination or significant chemical, physical or other change or deterioration in Ivory; (iv) any failure of one (1) or more batches of Ivory to meet the specifications therefor in the applicable Regulatory Approval; or (v) any complaint or evidence of tampering with Ivory. Amgen will use Commercially Reasonable Efforts to address any such Product Technical Complaint with respect to Ivory in the Collaboration Scope.

10.3.2. *Recalls or Other Corrective Action.* Amgen will have the sole right to undertake, and will make all decisions with respect to, any recall, market withdrawals, field alerts or any other corrective action (including letters to

health care professionals) related to Ivory. At Amgen's request, GSK will provide reasonable assistance to Amgen in conducting such recall, market withdrawal or other corrective action in the Collaboration Territory. Without prejudice to Amgen's indemnity obligations pursuant to Section 13.2 (Indemnity by Amgen), Amgen will be under no liability whatsoever to compensate GSK or make any other payment to GSK based on any decision to recall, initiate a market withdrawal, issue a field alert or take any other corrective action with respect to Ivory, unless such action results from Amgen's failure to comply with the terms of this Agreement.

10.3.3. *Returns.* If any quantities of Ivory are returned to GSK, GSK will promptly notify Amgen and ship them to the facility designated by Amgen. GSK, at its option, may advise the customer who made the return that Ivory has been returned to Amgen, but will take no other steps in respect of any return without the consent of Amgen, except as may be expressly authorized by the relevant Country Team.

10.4. Clinical Trial Register. Amgen will use Commercially Reasonable Efforts to publish the results and/or summaries of clinical trials relating to Ivory in the Collaboration Scope on a clinical trial register maintained by it and the protocols of clinical trials relating to Ivory in the Collaboration Scope on www.ClinicalTrials.gov (or an equivalent register in the Collaboration Scope, or as otherwise required by Applicable Law or Amgen's policies). GSK will have the right to publish results and/or summaries [*]. The Parties will cooperate to establish timelines and procedures for JDC review of publications and presentations.

11. CONFIDENTIALITY, PUBLICATIONS AND PRESS RELEASES

11.1. Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [*] thereafter, the receiving Party will keep confidential and will not publish or otherwise disclose or use for any purpose any and all information or materials related to the activities contemplated hereunder and furnished to it by the other Party pursuant to this Agreement (or in the case of GSK, that is created by or on behalf of GSK and owned by Amgen pursuant to Section 9.2 (Copyright Ownership)) that is identified by the disclosing Party as confidential, proprietary or the like or that the receiving Party has reason to believe is confidential based upon its own similar information (collectively, "*Confidential Information*"). For clarity, GSK will have no right to and will not utilize any Confidential Information of Amgen for activities outside the Collaboration Scope or for activities related to products other than Ivory. Notwithstanding the foregoing, Confidential Information will not include any information to the extent that it can be established by written documentation by the receiving Party that such information:

11.1.1. was obtained or was already known by the receiving Party or its Affiliates without obligation of confidentiality as a result of disclosure from a Third Party that the receiving Party did not know was under an obligation of confidentiality to the disclosing Party with respect to such information;

- 11.1.2. was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party through no act or omission of the receiving Party or its Affiliates in breach of this Agreement;
 - 11.1.3. became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliates in breach of this Agreement; or
 - 11.1.4. was independently discovered or developed by the receiving Party or its Affiliates (without reference to or use of Confidential Information of the disclosing Party).
- 11.2. Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) as reasonably necessary in conducting the activities contemplated under this Agreement; (ii) with respect to Confidential Information generated in the course of the activities conducted hereunder, to the extent pertaining specifically to Ivory, for use by Amgen in connection with Ivory outside the Collaboration Scope or disclosure by Amgen to a partner, GSK or licensee for use with respect to Ivory outside the Collaboration Scope; (iii) to the extent such disclosure is to a Governmental Authority as reasonably necessary in filing or prosecuting patent, copyright and trademark applications in accordance with this Agreement, prosecuting or defending litigation in accordance with this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement, filing Regulatory Filings, obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for Ivory, or otherwise required by Applicable Law, provided that if a Party is required by Applicable Law to make any such disclosure of the other Party's Confidential Information it will, except where impracticable for necessary disclosures (for example, in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and, in the case of each of the foregoing exceptions pursuant to this subsection (iii), will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; (iv) to advisors (including lawyers and accountants) on a need to know basis in support of the purposes of this Agreement, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement; and (v) to the extent mutually agreed to by the Parties. Neither Party will disclose Confidential Information of the other Party to its personnel or to an Affiliate except to the extent such personnel or Affiliate needs to know such information for the performance of such Party's activities hereunder.
- 11.3. Confidential Treatment of Terms and Conditions. Neither Party will disclose the terms and conditions of this Agreement except that each Party has the right to disclose the terms and conditions of this Agreement under reasonable and customary obligations of confidentiality (but no less than equivalent obligations to those under which the disclosing Party would disclose its own confidential information of similar type): (i) if required by Applicable Law (including disclosure of a redacted version of this Agreement in a relevant SEC filing); (ii) to Governmental Authorities with authority over such Party that request to review this Agreement in connection with a review, audit or investigation of the operations of such Party by such authority (and provided

that review of the terms of this Agreement are reasonably pertinent to such review, audit or investigation); and (iii) to its attorneys and accountants in support of the purposes of this Agreement. Notwithstanding the foregoing, with respect to complying with the disclosure requirements of any Governmental Authority in connection with any required filing of this Agreement, the Parties will consult with one another concerning which terms of this Agreement will be requested to be redacted in any public disclosure of the Agreement, and in any event each Party will seek reasonable confidential treatment for any public disclosure by any such Governmental Authority.

- 11.4. Press Releases. Notwithstanding Section 11.3 (Confidential Treatment of Terms and Conditions), the Parties will issue a joint press release to announce the execution of this Agreement, which is attached hereto as the Press Release Schedule and is for use in responding to inquiries about the Agreement and will agree on the timing (in accordance with Applicable Law) and method for issuing such press release and any media briefings; thereafter, GSK and Amgen may each disclose to Third Parties (including media interviews and disclosures to financial analysts) the information contained in such press release (but only such information) without the need for further approval by the other, provided that such information is still accurate. Each Party will have the right to issue additional press releases and disclosures in regards to the terms of this Agreement only with the prior written consent of the other Party, such consent not to be unreasonably withheld (or as required to comply with Applicable Law). For any such proposed press release or disclosure, the disclosing Party will provide [*] notice to the other Party and will reasonably consider the other Party's comments that are provided within [*] after such notice, or such shorter notice and comment periods as are reasonably required under the circumstances but not less than [*].
- 11.5. Prior Agreement. This Agreement supersedes the Confidential Disclosure Agreement between the Parties dated January 28, 2009, including any written requests thereunder (the "*Prior Agreement*") with respect to information disclosed thereunder relating to Ivory and activities related thereto. All confidential information exchanged between the Parties under the Prior Agreement will be deemed Confidential Information of the disclosing Party disclosed hereunder and will be subject to the terms of this Agreement.
- 11.6. Publications and Program Information. Except as permitted pursuant to Section 10.4 (Clinical Trial Register), or as agreed by the JBT or JDC, Amgen will have the sole right to publish and make scientific presentations with respect to Ivory, and to issue press releases (except with respect to the terms of this Agreement, which is governed by Section 11.4 (Press Releases) or make other public disclosures regarding Ivory (including with respect to its development, commercialization and regulatory matters), and GSK will not do so without Amgen's prior written consent. Amgen will keep the relevant committee or team informed of its general publication strategy and presentation calendar. In addition, Amgen will deliver to GSK a copy of any proposed written publication or outline of presentation with respect to Ivory in the Collaboration Scope in advance of submission for publication or presentation at least [*] in advance of submission (or, where a copy of such publication or presentation is not available at such time, a draft or outline of such publication or a description of such presentation), and GSK will have the right to: (i) require a delay in submission of not more than [*] to enable patent applications protecting each Party's rights in such information to be filed;

and (ii) prohibit disclosure of any of its Confidential Information in any such proposed publication or presentation. Publications and presentations will be subject to policies established by the Patent Coordinators to ensure appropriate protection of intellectual property rights.

- 11.7. Attorney-Client Privilege. Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges recognized under the Applicable Law of any jurisdiction as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties may become joint defendants in proceedings to which the information covered by such protections and privileges relates and may determine that they share a common legal interest in disclosure between them that is subject to such privileges and protections, and in such event, may enter into a joint defense agreement setting forth, among other things, the foregoing principles but are not obligated to do so.
- 11.8. Injunctive Relief. Given the nature of the Confidential Information and the competitive damage that may result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 11 (Confidentiality, Publications and Press Releases). In addition to all other remedies, a Party is entitled to seek specific performance and injunctive and other equitable relief (without the need to post a bond) as a remedy for any breach or threatened breach of this Article 11 (Confidentiality, Publications and Press Releases).
- 11.9. Additional Permitted Disclosure. [*] will have the right to [*] pursuant to [*].

12. REPRESENTATIONS AND WARRANTIES

- 12.1. Mutual Representations and Warranties. Each of the Parties hereby represents and warrants, as of the Effective Date to the other Party as follows:
- 12.1.1. It is duly organized and validly existing under the Applicable Law of its jurisdiction of incorporation and it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;
- 12.1.2. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of the Agreement, and compliance with its terms and provisions, and the consummation of the transaction contemplated hereby, by such Party will not materially conflict, interfere or be inconsistent with, result in any material breach of or constitute a material default under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor to its knowledge violate any Applicable Law. The person or persons executing this Agreement on such Party's behalf have been duly authorized to do so by all requisite corporate action;

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- 12.1.3. To its knowledge, no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority or under Applicable Law, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed concurrently herewith, or (except for Regulatory Approvals, licenses, clearances and the like necessary for the commercialization, research, development, manufacture, sales or marketing of pharmaceutical products and except for any required filing with the United States Securities and Exchange Commission) for the performance by it of its obligations under this Agreement;
 - 12.1.4. It has not been debarred or the subject of debarment proceedings by any Governmental Authority;
 - 12.1.5. To its knowledge it and its Affiliates have not violated any applicable anticorruption or anti-bribery law or regulation, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the regulations promulgated thereunder (collectively, "*Anticorruption Laws*");
 - 12.1.6. It has established and maintains reasonable internal controls intended to ensure compliance with Anticorruption Laws, including reasonable reporting requirements; and
 - 12.1.7. It has not granted any right to any Third Party relating to any intellectual property or proprietary right licensed, granted or assigned by it to the other Party hereunder that conflicts with the rights licensed, granted or assigned to the other Party hereunder.
- 12.2. Amgen Representations and Warranties. In addition to the representations and warranties set forth in Section 12.1 (Mutual Representations and Warranties) Amgen hereby represents and warrants to GSK that, except as would not be expected to have a material adverse effect on the activities of the Parties hereunder, as a whole, as of the Effective Date: [*]
- 12.3. Amgen Covenants. Amgen hereby covenants to GSK that:
- 12.3.1. It will not [*]
 - 12.3.2. Amgen understands its rights and obligations under this Agreement, and has and will at all times during the Term maintain sufficient resources to fully and diligently perform its obligations hereunder in accordance with the terms and provisions hereof.
- 12.4. GSK Representations and Warranties. In addition to the representations and warranties set forth in Section 12.1 (Mutual Representations and Warranties), GSK hereby represents and warrants to Amgen that, except as would not be expected to have a material adverse effect on the activities of the Parties hereunder, as a whole, as of the Effective Date: [*]
- 12.5. GSK Covenants. GSK hereby covenants to Amgen that:
- 12.5.1. GSK understands its rights and obligations under this Agreement, and has and will at all times during the Term maintain sufficient resources to fully and diligently perform its obligations hereunder in accordance with the terms and provisions hereof; and

12.5.2. It will not [*].

- 12.6. Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 12 (REPRESENTATIONS AND WARRANTIES), GSK AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE COLLABORATION, IVORY INTELLECTUAL PROPERTY, AMGEN HOUSEMARKS, GSK HOUSEMARKS, PRODUCT TRADEMARKS, THIS AGREEMENT, OR ANY OTHER SUBJECT MATTER RELATING TO THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.
- 12.7. Limitation of Liability. NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN, OTHER THAN TO THE EXTENT RESULTING FROM A PARTY'S BREACH OF ARTICLE 8 [*] OR SECTION 11.1 (Confidentiality; Exceptions), IN NO EVENT WILL GSK OR AMGEN BE LIABLE TO THE OTHER OR ANY OF THE OTHER'S AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT. THE FOREGOING SENTENCE WILL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER SECTION 13.1 (INDEMNITY BY GSK), SECTION 13.2 (INDEMNITY BY AMGEN) [*].
- 12.8. Covenants. Each Party hereby covenants to the other Party that, during the Term:
- 12.8.1. it will not grant any right to any Third Party relating to any intellectual property or proprietary right licensed or assigned by it to the other Party hereunder that conflicts with the rights granted to the other Party hereunder;
 - 12.8.2. it will not knowingly use in connection with the research, development, manufacture or commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been debarred or the subject of debarment proceedings by any regulatory agency; and
 - 12.8.3. it will comply with all Applicable Law with respect to their performance of its rights, duties and obligations under this Agreement, including commercialization, manufacturing, research and development and regulatory activities.

13. INDEMNIFICATION AND INSURANCE

- 13.1. Indemnity by GSK. Subject to the remainder of this Article 13 (Indemnification), GSK will defend, indemnify, and hold harmless Amgen, its Affiliates, and their respective directors, officers, employees, agents and representatives (collectively, "*Amgen*

Indemnitees”), at GSK’s cost and expense, from and against any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and attorneys’ fees incurred by or on behalf of any of the indemnitees until such time as the indemnification obligation is acknowledged and assumed hereunder with respect to the applicable claim) (collectively, “*Losses*”) arising out of any Third Party Claims brought against any Amgen Indemnatee to the extent such Losses result from: [*].

13.2. Indemnity by Amgen. Subject to the remainder of this Article 13 (Indemnification), Amgen will defend, indemnify, and hold harmless GSK, its Affiliates, and their respective directors, officers, employees, agents and representatives (collectively, “*GSK Indemnitees*”), at Amgen’s cost and expense, from and against any and all Losses arising out of any Third Party Claims brought against any GSK Indemnatee to the extent such Losses: [*].

13.3. [*].

13.4. Claim for Indemnification. Whenever any Third Party Claim or Loss arises for which a GSK Indemnatee or an Amgen Indemnatee (the “*Indemnified Party*”) may seek indemnification under this Article 13 (Indemnification), the Indemnified Party will promptly notify the other Party (the “*Indemnifying Party*”) of the Third Party Claim or Loss and, when known, the facts constituting the basis for the Third Party Claim; provided that the failure by an Indemnified Party to give such notice or to otherwise meet its obligations under this Section 13.4 (Claim for Indemnification) will not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. The Indemnifying Party will have exclusive control of the defense and settlement of all Third Party Claims for which it is responsible for indemnification and will assume defense thereof at its own expense promptly upon notice of such Third Party Claim. The Indemnified Party will not settle or compromise any Third Party Claim for which it is entitled to indemnification without the prior written consent of the Indemnifying Party, unless the Indemnifying Party is in breach of its obligation to defend hereunder. In no event will the Indemnifying Party settle any Third Party Claim without the prior written consent of the Indemnified Party if such settlement does not include a complete release from liability on such Third Party Claim or if such settlement would involve undertaking an obligation by the Indemnified Party other than the payment of money, would bind or impair the Indemnified Party, or includes any admission of wrongdoing by the Indemnified Party or that any intellectual property or proprietary right of the Indemnified Party is invalid or unenforceable. The Indemnified Party will reasonably cooperate with the Indemnifying Party at the Indemnifying Party’s expense and will make available to the Indemnifying Party reasonably requested information under the control of the Indemnified Party, which information will be subject to Article 11 (Confidentiality, Publications and Press Releases). The Indemnifying Party will permit the Indemnified Party to participate in (but not to control) the Third Party Claim through counsel of its choosing to the extent it has the ability to do so (at the Indemnified Party’s expense). Notwithstanding the foregoing, the Indemnified Party will have the right to employ separate counsel at the Indemnifying Party’s expense and to control its own defense of the applicable Third Party Claim if: (i) there are or may be legal defenses available to the Indemnified Party

that are different from or additional to those available to the Indemnifying Party; or (ii) in the reasonable opinion of counsel to the Indemnified Party, a conflict or potential conflict exists between the Indemnified Party and Indemnifying Party that would make such separate representation advisable; provided that, in no event will the Indemnifying Party be required to pay fees and expenses under this sentence for more than one (1) firm of attorneys in any jurisdiction in any one (1) legal action or group of related legal actions.

- 13.5. Defense of Third Party Claims. Except as otherwise provided in Section 13.4 (Claim for Indemnification), each Party (such Party referred to as the “*Defending Party*”) will have the sole right, but not the obligation, to defend against any Third Party Claims made against it with respect to its activities hereunder. Each Party will notify the other Party (the “*Assisting Party*”) as promptly as practicable if any Third Party Claim is commenced or threatened against it, including any Infringement Claim or any [*]. The Assisting Party will reasonably assist the Defending Party and cooperate in any such litigation at Defending Party’s reasonable request (and the Defending Party will reimburse the Assisting Party’s reasonable costs incurred in connection with such cooperation (subject to Section 6.1.1.4 and 6.1.2.11, to the extent applicable)). The Defending Party will seek and reasonably consider, but is not obligated to follow, the Assisting Party’s comments before determining the strategy for such matter. Without limiting the foregoing, the Defending Party will keep the Assisting Party advised of all material communications, actual and prospective filings or submissions regarding such action, and will provide the Assisting Party copies of and an opportunity to review and comment on any such communications, filings and submissions; provided, that each Party will have the right to redact from any information disclosed to the other hereunder any information relating to a product other than Ivory or relating to the manufacture of Ivory. The Defending Party will control the defense and/or settlement of Third Party Claims at its own expense (subject to Section 6.1.1.4 and 6.1.2.11, to the extent applicable) with counsel of its choice. The Assisting Party will have the right to participate in the defense and/or settlement of such Third Party Claim at its own expense (subject to Section 6.1.1.4 and 6.1.2.11, to the extent applicable) with counsel of its choice. The Defending Party will not settle a Third Party Claim without the prior written consent of the other Party (such consent not to be unreasonably withheld), unless such settlement: [*]. In the event that a Third Party Claim is brought against both of the Parties (a “*Joint Claim*”), then the Parties will determine whether to defend against such Joint Claim, which of the Parties should be the Defending Party or whether the Parties should jointly control such defense and the strategy for such defense. If the Parties determine that there will be one Defending Party for a Joint Claim, then the Assisting Party will have the right to participate in the defense of such Joint Claim through counsel, and at its own expense (subject to Section 6.1.1.4 and 6.1.2.11, to the extent applicable) of its choosing to the extent it has the ability to do so, and may control its own defense of the Joint Claim if there are or may be legal defenses available to the Assisting Party that are different from or additional to those available to the Defending Party, or in the reasonable opinion of counsel to the Assisting Party, a conflict or potential conflict exists between the Assisting Party and Defending Party that would make such separate representation advisable. In the case of an Infringement Claim, the coordination and cooperation set forth in this Section 13.5 (Defense of Third

Party Claims) will be accomplished via the Patent Coordinators. This Section 13.5 (Defense of Third Party Claims) will not apply to employment or similar personnel-related claims.

- 13.6. Insurance. Each of the Parties will, at their own respective expense (and not subject to cost sharing hereunder) procure and maintain during the Term, insurance policies adequate to cover their obligations hereunder and consistent with the normal business practices of prudent pharmaceutical companies of similar size and scope (or reasonable self-insurance sufficient to provide materially the same level and type of protection). Such insurance will not create a limit to either Party's liability hereunder.

14. TERM AND TERMINATION

- 14.1. Term. This Agreement will become effective on the Effective Date and will terminate at the end of the Term unless and until sooner terminated pursuant to any provision of this Agreement.

14.2. Termination for Breach.

14.2.1. In the event of a material breach of this Agreement, the non-breaching Party will have the right to terminate this Agreement (either as a whole or in the country or countries in which such breach occurred, at the terminating Party's option) by written notice to the breaching Party, which notice will specify the nature of such breach in reasonable detail. Such termination will become effective on the date specified in the notice (which will not be earlier than [*] after the delivery thereof to the breaching Party or, in the case of a failure to pay amounts due hereunder, [*]) unless, during the [*] period after delivery of such notice to the breaching Party, the breaching Party has cured such breach to the reasonable satisfaction of the non-breaching Party.

14.2.2. Notwithstanding the provisions of Section 14.2.1, the following will apply in the event of multiple breaches by the same Party: (i) in the event of [*] material breaches of this Agreement by the same Party within a [*] period, the non-breaching Party will have the right to terminate this Agreement by written notice to the breaching Party, which notice will specify the nature of such third breach in reasonable detail, effective (regardless of whether such third breach is cured) as of the date specified in such notice (which will not be earlier than [*] from receipt thereof by the breaching Party), and (ii) if a Party commits at least [*] material breaches of this Agreement and such breaches are with respect to the same obligation or activity hereunder, then the non-breaching Party will have the right, but not the obligation, to call a special meeting of the JDC with respect to development breaches or the JSC with respect to any other breach (a "Special Meeting"), by written notice to the breaching Party. Such notice will state with particularity the obligations that the non-breaching Party believes have not been satisfied and the basis for such belief. The Special Meeting will be convened within ten (10) business days of the breaching Party's receipt of such notice. At the Special Meeting, the JSC or JDC, as applicable, will discuss the non-breaching Party's concerns, the breaching Party's efforts in such area of concerns and any additional actions the breaching Party should take to alleviate

the non-breaching Party's concerns. The JSC or JDC, as applicable, will develop a plan describing the actions that the Parties reasonably believe the breaching Party should take to meet its applicable obligations under the Agreement (the "*Remediation Plan*"); provided, that the Remediation Plan may provide that the non-breaching Party will assume responsibility for such obligation or activity and the breaching Party will cooperate with the non-breaching Party to effect such transition to the non-breaching Party. The applicable Party will perform the actions described in such Remediation Plan in accordance with the timelines, if any, set forth therein. For the avoidance of doubt, if the non-breaching Party chooses not to request a Special Meeting, then such Party may proceed in accordance with Section 14.2.1.

- 14.3. Termination for Insolvency. Either Party will have the right to terminate this Agreement immediately upon written notice, if: (i) the other Party becomes insolvent; (ii) the other Party files a petition in bankruptcy, or if an involuntary petition in bankruptcy is filed against the other Party and such involuntary petition is not dismissed within seventy-five (75) days and the other Party (a) fails to assume this Agreement in any such bankruptcy proceeding within thirty (30) days after filing or (b) assumes and assigns this Agreement to a Third Party, or (iii) a receiver or guardian has been appointed for the other Party who is not discharged within seventy-five (75) days after appointment.
- 14.4. Early Termination by Amgen. Amgen will have the right to terminate this Agreement by [*], such termination to be effective no sooner than January 1, 2021 with respect to either: (i) all countries in the Collaboration Territory; or (ii) one, any or all of the Russian Federation, Mexico, Australia and/or New Zealand. In the event of any such termination, Amgen will pay GSK [*].
- 14.5. Termination Discussion. If the sales of Ivory during any three (3) year period are less than [*] of the total amount forecast for such period (as set forth in the Sales Forecast Schedule) (or if either Party reasonably determines that facts and circumstances pertaining at any time during the Term indicate a very high likelihood that the foregoing will occur, including by reason of label or other access limitations or safety events), then the Parties will meet and discuss whether it may be appropriate to terminate this Agreement, provided that no such termination will be effective unless expressly agreed in writing by the Parties.
- 14.6. Valid Safety Issue. Either Party may terminate this Agreement immediately upon written notice following either: [*]. To be effective, such notice must be given no later than thirty (30) days following the notification by Amgen that such Valid Safety Issue has occurred.
- 14.7. Failure to Supply. GSK may terminate this Agreement on thirty (30) days prior written notice if Amgen is unable to supply for reasons other than Force Majeure, at least [*] of the lower of: (i) the then-current monthly forecast requirements for Ivory in the Collaboration Scope as a whole; and (ii) the actual demand for Ivory in the Collaboration Scope as a whole, in each case for each of [*]. To be effective, such notice must be given no later than thirty (30) days following the sooner of notification by Amgen or GSK otherwise becoming aware that such failure to supply has occurred.

- 14.8. Termination for Challenge. Either Party will have the right to terminate this Agreement by written notice to the other Party, if such other Party, its Affiliates or licensees bring or join any challenge to the validity or enforceability of (i) if Amgen is the challenging Party, any Know-How or Patents licensed to Amgen pursuant to Section 9.5 (License Grant by GSK) (including GSK Inventions); and (ii) if GSK is the challenging Party, any Ivory Intellectual Property (or any intellectual property corresponding to any such Ivory Intellectual Property outside the Collaboration Scope). Notwithstanding the foregoing, nothing in this Section 14.8 (Termination for Challenge) will either: (i) prevent either Party from asserting any defense or counterclaim in an action for infringement of intellectual property, brought against such Party or its Affiliates, or any Third Party that such Party or any of its Affiliates is obligated to indemnify, or responding in any other manner to such an action for infringement; or (ii) allow a Party to terminate this Agreement in the event the other Party asserts any such defense or counterclaim or otherwise responds in any such action for infringement.
- 14.9. Effects of Expiration or Termination Upon the expiration or termination of this Agreement for any reason, the following will apply:
- 14.9.1. *Accrued Obligations*. Expiration or termination of this Agreement for any reason will not release either Party from any liability (including any payment obligations) that, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to activities prior to such expiration or termination.
- 14.9.2. *Promotion Rights; Licenses*. Except as set forth in Section 14.10 (Transition), upon the expiration or termination of this Agreement: (i) GSK's right to promote Ivory in the Collaboration Scope will terminate; (ii) all licenses to GSK hereunder will terminate; and (iii) GSK will immediately cease all of its promotional and marketing activities for Ivory in the Collaboration Territory and discontinue all use of Amgen Housemarks and Product Trademarks. Amgen's right to use the GSK Housemarks pursuant to Section 9.11.3.2 will survive expiration or termination of the Agreement until such time as any existing inventory of labeling, package inserts or outserts, monographs or packaging materials or Promotional Materials for Ivory in the Collaboration Territory that contain the GSK Housemarks have been depleted.
- 14.9.3. *Product Data and Amgen Confidential Information*. GSK will promptly transfer to Amgen, at no cost, copies of all data, reports, records and materials in its possession or control that relate to Ivory ("*Product Data*"). Such Product Data will be in electronic form reasonably usable by Amgen and, if reasonably necessary in connection with Amgen's (or its designee's) further commercialization, development or exploitation of Ivory in the Collaboration Territory, will include original hardcopies or duplicate copies thereof, as required. In addition (without limiting Section 9.2 (Copyright Ownership; Certain Confidential Information)), all Product Data generated by or under authority of [*] hereunder during the term of the Agreement, that solely pertains to [*], will be deemed Confidential Information of [*] following termination of this Agreement. In addition, GSK will promptly return to Amgen, or destroy at Amgen's request, all relevant records and materials in GSK's possession or

control containing Confidential Information of Amgen (provided that GSK may keep: (i) copies of such records as may be required for GSK to comply with Applicable Law; and (ii) one copy of such Confidential Information of Amgen for archival purposes only; provided that, in each case, such copies are Segregated from any [*]).

- 14.9.4. *Return of Samples and Materials.* GSK will promptly return to Amgen, or destroy at Amgen's request (and certify such destruction to Amgen), all Samples, Promotional Materials, sales training materials and any other documents, or materials primarily intended for use in commercialization of Ivory in the Collaboration Territory.
- 14.9.5. *Assignment of Filings and Registrations.* GSK will, at its own expense (other than with respect to any fee payable to the relevant Governmental Authority in connection with the relevant assignment, which will be borne by Amgen), assign to Amgen all Regulatory Filings and Regulatory Approvals in the Collaboration Territory related to Ivory that are in GSK's name (if any), and all trademark and copyright registrations related to Ivory (or to labeling, package inserts or outserts, monographs or packaging materials or Promotional Materials for Ivory) that are in GSK's name, if any. The foregoing is not meant to imply any right of GSK to own any filing or intellectual property except as may be expressly set forth herein or agreed in writing between the Parties.
- 14.9.6. *Survival.* Articles 5 (Up-Front Payments and Milestones) (with respect to periods prior to expiration or termination), 6 (Profit/Expense Sharing) (with respect to periods prior to expiration or termination), 7 (Payments) (with respect to periods prior to expiration or termination), 8 [*] (only with respect to such continuing periods as expressly referenced in such Article), 13 (Indemnification and Insurance) (with respect to periods prior to expiration or termination), and 16 (Miscellaneous) and Sections 3.10 (Promotional Materials) (with respect to the termination of use of and destruction of existing Promotional Materials), 3.11 (Detailing Reports and Audit Rights) (with respect to periods prior to expiration or termination), 3.13 (Samples) (with respect to the return or destruction of Samples), 9.4 (License Grant by Amgen) (with respect to the transition period referenced in Section 14.10 (Transition)), 9.5 (License Grant by GSK), 9.8 (Enforcement) (with respect to enforcement against activities that took place prior to expiration or termination), 9.9 (Patent Term Extensions) (with respect to periods prior to expiration or termination), 9.11.3 (Licenses) (with respect to the transition period referenced in Section 14.10 (Transition) and the sell-off period referenced therein), 10.3 (Product Technical Complaints; Recalls; Returns), 11.1 (Confidentiality; Exceptions), 11.2 (Authorized Disclosure), 11.3 (Confidential Treatment of Terms and Conditions), 11.7 (Attorney-Client Privilege), 11.8 (Injunctive Relief), 11.9 (Additional Permitted Disclosure), 14.8 (Effects of Expiration or Termination), and 14.10 (Transition), 14.11 (Tail Payments) will survive expiration or termination of this Agreement for any reason. Following any such expiration or termination, medical inquiries with respect to Ivory will be referred by GSK to Amgen in accordance with instructions provided by Amgen. Except as otherwise provided in this

Section 14.7 (Effects of Expiration or Termination), all rights and obligations of the Parties under this Agreement will terminate upon expiration or termination of this Agreement for any reason.

- 14.10. Transition. During all applicable notice periods prior to termination under Sections 14.1 (Termination for Breach), 14.3 (Termination for Insolvency), 14.4 (Early Termination by Amgen), 14.7 (Failure to Supply) and 16.9 (Force Majeure) (provided; that with respect to transition following termination pursuant to Section 16.9 (Force Majeure), the Party subject to such Force Majeure [*] will not be liable for activities to the extent prevented from performing such activities due to the Force Majeure [*] giving rise to such termination. GSK will continue to meet its obligations to promote Ivory within the Collaboration Scope, in accordance with the applicable Country Plan and this Agreement, unless otherwise requested by Amgen or agreed by the Parties. Except for termination pursuant to Section 14.4 (Early Termination by Amgen), during such period as the Parties determine is reasonably necessary (up to [*]) following the effective date of such termination, GSK will undertake reasonable efforts to effect a smooth and orderly transition of all commercial activities and responsibilities of GSK under this Agreement to Amgen, as soon as reasonably possible, to enable Amgen to continue the promotion and commercialization of Ivory in the Collaboration Scope after termination. Notwithstanding the foregoing, the Parties will use reasonable efforts to effect the transition as quickly as possible within the time periods referenced above. For the avoidance of doubt, in the case of termination in accordance with Section 14.6 (Valid Safety Issue) GSK will have no obligation to Detail or commercialize Ivory, or take any other action that it reasonably believes presents a safety risk to patients (and GSK's decision to not take such action will not be subject to Amgen's final decision-making authority under Article 2 (Scope and Governance), but will carry out its other obligations pursuant to Section 14.8 (Effects of Expiration or Termination). During any transition period subsequent to the expiration or termination of this Agreement, Amgen will reimburse GSK's reasonable costs incurred at Amgen's request in connection with the transition of responsibilities for Ivory in the Collaboration Scope to Amgen.
- 14.11. Tail Payments. Upon expiration of the Term pursuant to Section 14.1 (Term) Amgen will make a tail payment to GSK in each of the two (2) years of the Tail Period (i.e., 2023 and 2024) (each, a "*Tail Payment*"). Such Tail Payments will be calculated as follows:
- 14.11.1. No later than March 1, 2024, Amgen will pay GSK a Tail Payment in an amount equal to [*].
- 14.11.2. No later than March 1, 2025, Amgen will pay GSK a Tail Payment in an amount equal to [*].
- 14.11.3. "[*]" means [*] of that percentage that is determined by dividing an amount equal to [*] by [*]. If the [*] equals zero (0) or a negative number, then GSK will not be entitled any Tail Payments pursuant to this Section 14.11 (Tail Payment).

14.11.4. An example of the calculation of the payment to be made pursuant to this Section 14.11 (Tail Payment) is set forth on the Tail Payment Schedule. The provisions of Article 7 will apply to the Tail Payments.

14.12. No Limitation of Rights. The rights provided in this Article 14 (Term and Termination) will be in addition and without prejudice to any other rights which the Parties may have with respect to any default or breach of the provisions of this Agreement. Termination is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies at equity or law will remain available to the Parties except as expressly agreed otherwise herein.

15. CHANGE OF CONTROL

15.1. Change of Control of GSK. GSK will give Amgen written notice within five (5) days after the public announcement or disclosure of, or if earlier the signing of any agreement for, a proposed Change of Control of GSK. In the event of the occurrence of, signing of an agreement for, or public announcement or disclosure of, any proposed Change of Control of GSK, Amgen will have the right to [*].

15.2. Change of Control of Amgen. Amgen will give GSK written notice within five (5) days after the public announcement or disclosure of, or if earlier the signing of any agreement for, a proposed Change of Control of Amgen (a "*Change of Control Notice*"). In the event of the occurrence of a Change of Control of Amgen, if the entity acquiring ownership of Amgen is [*] then GSK will have the right to [*].

16. MISCELLANEOUS

16.1. Affiliates. Each Party will have the right to exercise its rights and perform its obligations hereunder through its Affiliates (including by licensing rights hereunder where such rights are held in the name of any such Affiliate); provided that such Party will be responsible for its Affiliates' performance hereunder.

16.2. Arbitration. In the event of any controversy or dispute arising out of or relating to any provision of this Agreement, the construction, validity or breach thereof, the Parties will try to settle the same amicably between themselves. If the Parties fail to settle such matter within thirty (30) days of it having arisen, such matter will be exclusively and finally resolved by binding arbitration under the [*]. The place of the arbitration will be [*] and the language of the arbitration will be English. In the event of a dispute involving the alleged breach of this Agreement, neither Party will have the right to terminate this Agreement until resolution of the dispute pursuant to this Section 16.2 (Arbitration), and any time period for cure will commence only after such resolution. Any disputed performance or suspended performance pending the resolution of a dispute involving the alleged breach of this Agreement that the arbitrator determines to be required to be performed by a Party must be completed within a reasonable time period following the final decision of the arbitrator. The arbitration award will be final and binding upon both Parties and may be entered in any court of competent jurisdiction for enforcement. The arbitrators will have the power to grant monetary damages as well as injunctive or other specific relief. Notwithstanding the foregoing, each Party will have the right to seek, without establishment of the arbitral tribunal, injunctive or other provisional relief from a court of competent jurisdiction that may be

necessary to avoid irreparable harm or preserve the subject matter of a dispute. Each Party will bear its own costs and expenses and attorneys' fees, and the Party that does not prevail in the arbitration proceeding will pay the arbitrator's fees and any administrative fees of arbitration.

- 16.3. Assignment. Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred (whether by operation of Applicable Law, general succession or otherwise) by either Party without the prior written consent of the other Party; provided that either Party may assign this Agreement, or rights and obligations hereunder, without prior written consent to any Affiliate, and Amgen may assign this Agreement without prior written consent in connection with the transfer or sale of all or substantially all of the business of Amgen to which this Agreement relates. Any assignment not in accordance with this Agreement will be void. Subject to the foregoing, the rights and obligations of the Parties under this Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.
- 16.4. Choice of Law. This Agreement will be governed by, and enforced and construed in accordance with, the laws of the State of New York without regard to its conflicts of law provisions. The United Nations Convention for the International Sale of Goods will not apply to the transactions contemplated herein.
- 16.5. Compliance with Applicable Law. No Party will be required by this Agreement to take or omit to take any action in contravention of Applicable Law or applicable national and international pharmaceutical industry codes of practices.
- 16.6. Construction. The definitions of the terms herein will apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation". The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction will be applied in the interpretation hereof. Unless the context requires otherwise: (i) a reference to a Party's costs includes both internal FTE costs at the FTE Rate and reasonable Third Party costs; (ii) any definition of or reference to any agreement, instrument or other document herein will 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 herein or therein); (iii) any reference to any Applicable Law herein will be construed as referring to such Applicable Law as from time to time enacted, repealed or amended; (iv) any reference herein to any person will be construed to include the person's permitted successors and assigns; (v) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof; and (vi) all references herein to Articles, Sections, Schedules or Exhibits, unless otherwise specifically provided, will be construed to refer to Articles, Sections, Schedules or Exhibits of this Agreement. This Agreement has been executed in English, and the English version of this Agreement will control.

- 16.7. Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts will be deemed an original, will be construed together and will constitute one and the same instrument. Signature pages of this Agreement may be exchanged by facsimile or other electronic means without affecting the validity thereof.
- 16.8. Currency. With respect to amounts required to be converted into another currency for calculation or payment, hereunder, such amounts will be converted using a rate of exchange which corresponds to the rate used for conversion between the relative currencies by whichever Party recorded the relevant receipt or expenditure, for the respective reporting period in its books and records that are maintained in accordance with GAAP or IFRS, as the case may be. If a Party is not required to perform such a currency conversion for its GAAP or IFRS reporting with respect to the applicable period, then for such period such Party will make such conversion using the rate of exchange which corresponds to the [*] as published in the Wall Street Journal, Eastern U.S. Edition on the second to last business day of the calendar quarter (or such other publication as agreed-upon by the Parties) in which such receipt or expenditure was incurred.
- 16.9. Entire Agreement. This Agreement, including the attached Appendices, Schedules and Exhibits constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior or contemporaneous negotiations, representations, agreements and understandings regarding the same. Nothing in this Agreement intended to modify, abrogate or eliminate those rights and obligations of the Parties expressly set forth in the Expansion Agreement.
- 16.10. Force Majeure. Neither Party will be liable for delay or failure in the performance of any of its obligations hereunder (other than the payment of money) to the extent such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, earthquakes, labor strikes, acts of war, terrorism or civil unrest ("*Force Majeure*"); provided, that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect); and provided, further that the affected Party uses its Commercially Reasonable Efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and will continue performance with reasonable dispatch whenever such causes are removed. If the performance of any obligation or activity of either Party that is fundamental to the commercial success of Ivory in the Collaboration Scope is prevented by such Force Majeure event for a period of more than [*], then either Party may terminate this Agreement upon [*] written notice, unless such obligation is performed within such [*] notice period. In addition, [*].
- 16.11. Further Assurances. Each Party agrees to do and perform all such further acts and things and will execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.
- 16.12. Headings. Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.

- 16.13. No Set-Off. Except as expressly set forth in Section 6.1.9 (True-Up), Section 7.6 (Withholding) or Section 7.7 (VAT), no Party will have the right to deduct from amounts otherwise payable hereunder any amounts payable to such Party (or its Affiliates) from the other Party (or its Affiliates), whether pursuant to this Agreement or otherwise.
- 16.14. Notices. Any notice required or permitted to be given by this Agreement will be in writing, in English, and will be delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by registered or certified mail addressed as set forth below unless changed by notice so given:

If to Amgen: Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799
Attention: Corporate Secretary
Telephone: 805-447-1000
Facsimile: [*]

If to GSK: GlaxoSmithKline
709 Swedeland Road
P.O. Box 1539
King of Prussia, PA 19406-0939
USA
Attention: Senior Vice President, Worldwide Business Development
Telephone: [*]
Facsimile: [*]

With a copy to:

GlaxoSmithKline
2301 Renaissance Boulevard
Mailcode RN0220
King of Prussia, PA 19406-2772
USA
Attention: Vice President and Associate General Counsel, Business
Development Transactions
Telephone: [*]
Facsimile: [*]

Any such notice will be deemed given on the date delivered. A Party may add, delete (so long as at least one person is remaining), or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 16.14 (Notices).

- 16.15. Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees, or any other legal arrangement that would impose liability upon

one Party for the act or failure to act of the other Party. The Parties will operate their own businesses separately and independently and they will hold themselves out as, act as, and constitute independent contractors in all respects and not as principal and agent, partners or joint venturers. The Parties will each be responsible for fulfilling their own obligations under this Agreement, and they will not have control or responsibility over the actions of the other Party. The Parties will make and receive only such payments as are required under this Agreement for sales and services required hereunder, and will not share in, or participate in, the business operations of the other Party. Neither party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever. Each Party will file all necessary reports, statements, tax returns, information returns and any other filings with the FDA, the Securities and Exchange Commission, U.S. Internal Revenue Service, any regulatory authority or any other Governmental Authority on the basis that is consistent with the terms of this Section.

- 16.16. Severability. To the fullest extent permitted by Applicable Law, the Parties waive any provision of Applicable Law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect or to any extent, then in such respect and to such extent such provision will be given no effect by the Parties and shall not form part of this Agreement. To the fullest extent permitted by Applicable Law, all other provisions of this Agreement shall remain in full force and effect and the Parties will use their commercially reasonable efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the Parties.
- 16.17. [*]
- 16.18. Third Party Beneficiaries. Except as expressly provided with respect to Amgen Indemnitees or GSK Indemnities in Article 13 (Indemnification), there are no Third Party beneficiaries intended hereunder and no Third Party will have any right or obligation hereunder.
- 16.19. Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder will not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof will not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any other occasion. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement will be valid or effective unless in writing and signed by all Parties hereto.

(Signature page follows)

IN WITNESS WHEREOF, the Parties have executed this Collaboration Agreement as of the Effective Date.

GLAXO GROUP LIMITED

By: /s/ PAUL WILLIAMSON
Name: Paul Williamson
Title: Edinburgh Pharmaceutical Industries Limited
Corporate Director

AMGEN INC.

By: /s/ ROBERT A. BRADWAY
Name: Robert A. Bradway
Title: Executive Vice President &
Chief Financial Officer