Exhibit 10.6  
CERTAIN Information Identified by “[\*\*\*]” HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.  
Execution Version  
AGREEMENT FOR THE MANUFACTURE &  
SUPPLY OF CLINICAL TRIAL MATERIAL BY AND BETWEEN  
TAKEDA PHARMACEUTICAL COMPANY LIMITED,  
AND  
MYOVANT SCIENCES LTD.  
DATE: JUNE 7, 2016  
  
  
  
  
AGREEMENT FOR THE MANUFACTURING & SUPPLY OF CLINICAL  
TRIAL MATERIAL  
This Agreement for the Manufacturing & Supply of Clinical Trial Material (the “Agreement”) is made effective as of June 7, 2016 (the “Effective Date”) by and between Takeda Pharmaceutical Company Limited, a company having its principal place of business at 1-1, Xxxxxxxxxx 0-xxxxx, Xxxx-xx, Xxxxx 000-0000, Xxxxx (“Takeda”) and Myovant Sciences Ltd. (f/k/a Roivant Endocrinology Ltd.), an exempted limited company incorporated under the laws of Bermuda, a having its registered office at 0 Xxxxxx Xxxxxx, Xxxxxxxx, Xxxxxxx (“Myovant”). Myovant and Takeda are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”  
RECITALS  
WHEREAS, Takeda’s Affiliate, Takeda Pharmaceuticals International AG (“TPIZ”) and Myovant are parties to that certain License Agreement dated April 29, 2016 (“License Agreement”) pursuant to which TPIZ granted to Myovant a license in the Licensee Territory and the Takeda Territory under certain patents, patent applications, know-how and other proprietary information for the further Development and Commercialization of the TAK-3 85 Licensed Products in accordance with the terms and conditions set forth in the License Agreement;  
WHEREAS, under the License Agreement, Takeda agreed to provide to Myovant the Initial Clinical Supply [\*\*\*] and to manufacture and supply additional amounts of TAK-385 Licensed Compound or TAK-385 Licensed Product, in each case, as required by Myovant to complete the TAK-385 Development Plan, and Myovant agreed to purchase such additional amounts of TAK-385 Licensed Compound and TAK-385 Licensed Product;  
WHEREAS, in accordance with the terms of the License Agreement and on the terms and conditions set out below, Takeda, on behalf of TPIZ, now agrees to provide Drug Substance or Drug Product (as defined below) and Myovant agrees to receive from Takeda, all of Myovant’s requirements for such Drug Substance or Drug Product in order to complete all Clinical Trials contemplated under the TAK-385 Development Plan.  
NOW, THEREFORE, and in consideration of the mutual covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:  
ARTICLE 1  
DEFINITIONS  
The following capitalized terms used in this Agreement shall have the meanings specified below and all other capitalized terms used but not otherwise defined in this Agreement shall have their respective meanings set forth in the License Agreement:  
1.1 “Batch Documentation” means the documentation provided to Myovant at the time of delivery of Drug Substance or Drug Product, as agreed upon by the Parties in the Quality Agreement.  
1.2 “Credit Note” means a credit memo issued by Takeda to Myovant and usable by Myovant as: (i) an offset against amounts payable to Takeda by Myovant or, (ii) if no such amounts are outstanding at the time of termination or expiration of this Agreement, for a refund from Takeda to Myovant which Takeda shall pay to Myovant no later than [\*\*\*] days after any such termination or expiration.  
1.3 “Direct Expenses” means those material and services expenses captured in invoices and the like which are specifically attributable to Manufacture of the Drug Substance or Drug Product, including [\*\*\*].  
1.4 “Drug Product” means a final, unpackaged pharmaceutical product for use solely for administration to humans in Clinical Trials consisting of: (a) the TAK-385 Licensed Product or (b) a placebo version of each formulation of a pharmaceutical product in sub-Section (a), where, in each case, such Drug Product has been Manufactured in accordance with the Specifications and Applicable Laws. The formulations of Drug Product as of the Effective Date are set forth on Exhibit B.  
1.5 “Drug Substance” means the active pharmaceutical ingredient for the TAK-385 Licensed Compound that has been Manufactured in accordance with the Specifications and Applicable Laws.  
  
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1.6 “Indirect Expenses” means labor expenses, including [\*\*\*], and other indirect production expenses such as [\*\*\*], and expenses for process development and analytical methods development, but excluding, in each case, any Direct Expenses.  
1.7 “Initial Shipment” means the Drug Product to be shipped by Takeda promptly after the Effective Date of this Agreement. The number of tablets of Drug Product to be shipped as part of the Initial Shipment is set forth on Exhibit C.  
1.8 “Manufacturing Expenses” means (a) with respect to Drug Substance or Drug Product that is Manufactured by a Third Party the actual purchase price paid by Takeda or its Affiliate to such Third Party for such Drug Substance or Drug Product, and (b) with respect to Drug Substance or Drug Product that is Manufactured directly by Takeda or its Affiliate the Direct Expenses and Indirect Expenses incurred in connection with the Manufacture of the Drug Substance or Drug Product, [\*\*\*], such calculation being based upon accepted industry standards and the applicable Accounting Standard. Manufacturing Expenses shall not include any: [\*\*\*].  
  
1.9 “Permits” means any licenses, permits, registrations, certifications or other approvals from a Governmental Authority.  
1.10 “Project Work Order” shall have the meaning set forth in Section 11.1.  
1.11 “Quality Agreements” means the Quality Assurance Agreements for Drug Product and Drug Substance between the Parties.  
1.12 “Quality Release” means certification by Takeda’s quality control department that Drug Substance or Drug Product Manufactured by or on behalf of Takeda complies with its quality release specifications as confirmed by release testing.  
1.13 “Specifications” means the specifications for the design, composition, manufacture, packaging, and/or quality control of the Drug Substance and Drug Product as set forth in Exhibit A, which may be amended from time-to-time.  
1.14 “Technical Support Services” shall have the meaning set forth in Section 11.1.  
ARTICLE 2  
PRODUCT SUPPLY  
2.1 Purchase and Supply. Subject to the terms and conditions set forth in this Agreement, the License Agreement and the Quality Agreement, Takeda shall supply to Myovant, and Myovant shall obtain from Takeda, all of Myovant’s requirements for any Drug Substance, Drug Product for its use contemplated under the TAK-385 Development Plan.  
2.2 Takeda Reservation of Rights. Any rights of Takeda not expressly granted to Myovant under the provisions of this Agreement, the License Agreement or the Quality Agreement are retained by Takeda.  
2.3 Myovant’s Rights Outside the Licensee Territory. Except as otherwise provided in the License Agreement: (a) Myovant shall, and shall ensure that its Affiliates, Sublicensees and Subcontractors, use the Drug Substance or Drug Product only in the Field in the Licensee Territory, and (b) Myovant shall not, and shall not permit its Affiliates, Sublicensees and Subcontractors to, use the Drug Substance or Drug Product directly or indirectly (i) in the Takeda Territory, or (ii) in a manner that is reasonably likely to directly or indirectly enable a Third Party to use the Drug Substance or Drug Product in contravention of subsection (i) above.  
ARTICLE 3  
MANUFACTURING EXPENSES  
3.1 Drug Substance and Drug Product. Takeda shall provide to Myovant the Initial Clinical Supply [\*\*\*] to Myovant. In the event the Initial Clinical Supply is insufficient to conduct and complete the activities contemplated under the TAK-385 Development Plan, Myovant shall pay [\*\*\*] of the actual Manufacturing Expenses incurred by Takeda in Manufacturing such additional Drug Substance and Drug Product. For the avoidance of doubt, Myovant shall [\*\*\*] Takeda for all Manufacturing Expenses incurred by Takeda related to the re-working or re-processing of any Drug Substance or Drug Product that was manufactured by Takeda prior to the Effective Date of this Agreement.  
  
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3.2 Invoicing. Takeda shall submit an invoice to Myovant within [\*\*\*] days after the end of each Calendar Quarter for all such Manufacturing Expenses incurred by Takeda during the preceding Calendar Quarter and Myovant shall pay such invoice in accordance with Article 12. For the avoidance of doubt, the first invoice submitted by Takeda pursuant to this Section 3.2 may include Manufacturing Expenses incurred by Takeda in furtherance of its Manufacture of additional Drug Substance or Drug Product that was not part of the Initial Clinical Supply.  
ARTICLE 4  
REGULATORY ACTIVITIES AND RESPONSIBILITIES  
4.1 General Obligations of Takeda. Takeda shall, or shall cause its Affiliates or Third Parties on its behalf to, (a) perform its obligations under this Agreement in compliance with all Applicable Laws, including all GMPs, and in accordance with the Quality Agreement, (b) undertake all regulatory activity with respect to the Manufacture of the Drug Substance and Drug Product for use by Myovant in accordance with the License Agreement and as otherwise required by Applicable Laws or Regulatory Authorities. Takeda shall be responsible for maintaining all Permits and establishment fees required by any Regulatory Authority with respect to any Takeda Manufacturing facility where any aspect of the Drug Substance or Drug Product is Manufactured.  
4.2 General Obligations of Myovant. Other than Takeda’s Permits and establishment fees related to Takeda’s manufacturing facilities, Myovant shall obtain and maintain at its expense during the Term all Permits as well as all Regulatory Approvals required for Myovant to use the Drug Substance or Drug Product in accordance with the License Agreement and fulfill its obligations under this Agreement, the License Agreement and the Quality Agreement. Myovant shall, and shall ensure that its Affiliates, Sublicensees and Subcontractors: (a) comply with the requirements and restrictions of any Permits and other Applicable Laws applicable to the use of the Drug Substance or Drug Product in accordance with the License Agreement; (b) use the Drug Substance or Drug Product in compliance with Applicable Laws and the TAK-385 Licensed Product INDs; and (c) comply with Myovant’s obligations under this Agreement.  
4.3 Communication with Regulatory Authorities. All other communications with Regulatory Authorities shall be governed by the License Agreement, including Article 6 of the License Agreement.  
ARTICLE 5  
FORECASTING AND ORDERING  
5.1 Forecasts and Purchase Orders.  
5.1.1 Forecast Issuance and Acceptance. Attached hereto at Exhibit C is Myovant’s forecast of its desired quantities of the Drug Substance and each formulation of Drug Product contemplated under the TAK-385 Development Plan. Within [\*\*\*] Business Days of the Effective Date of this Agreement, Myovant shall submit to Takeda, at the contact information provided below, Myovant’s forecast for its desired quantities of the Drug Substance and each formulation of Drug Product to be delivered to Myovant on a Calendar Quarter-by-Calendar Quarter basis for the first [\*\*\*] Calendar Quarters of the Term (the “Initial Rolling Forecast”). For clarity, the Initial Rolling Forecast shall not include the Initial Shipment. No later than the [\*\*\*] Business Day of each Calendar Quarter during the remainder of the Term, Myovant shall provide to Takeda a rolling forecast for the proceeding [\*\*\*] Calendar Quarters (“Rolling Forecast”). Myovant will submit each Rolling Forecast to the addressee listed below, which Takeda may update or change by providing written notice to Myovant in accordance with Section 18.2 of this Agreement. The Rolling Forecast shall set forth the desired quantity of Drug Substance and each formulation of Drug Product in full lot increments. Takeda will accept each forecast or provide an alternative proposal to Myovant within [\*\*\*] Business Days after receipt of such forecast. Subject to Takeda’s express rights under this Agreement, Takeda will not unreasonably reject any portion of Myovant’s forecasts.  
Takeda Contact: [\*\*\*]  
5.1.2 Binding Quantities. The first [\*\*\*] Calendar Quarters of each Rolling Forecast submitted by Myovant shall constitute a firm order (“Firm Order Period”). The [\*\*\*] Calendar Quarter of each Rolling Forecast shall be binding upon Myovant within plus or minus [\*\*\*] of the amount set forth for such Calendar Quarter in full lot increments (“Binding Order Period”). The final [\*\*\*] Calendar Quarters of each Rolling Forecast shall be non-binding upon Myovant.  
5.1.3 Purchase Orders.  
  
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(a) Issuance and Acceptance. With its submission of the Initial Rolling Forecast, Myovant shall submit a separate purchase order (each, a “Purchase Order”) for each Calendar Quarter of the Firm Order Period as set forth in the Initial Rolling Forecast to Takeda (each a “Purchase Order”). Thereafter, with each Rolling Forecast submitted to Takeda pursuant to Section 5.1.1, Myovant shall submit a Purchase Order for the [\*\*\*] Calendar Quarter of the Rolling Forecast (i.e., the Calendar Quarter for which no Purchase Order was previously submitted). Within [\*\*\*] Business Days of Takeda’s receipt of each Purchase Order, Takeda will accept such Purchase Order by providing a confirmation of receipt of the Purchase Order. To the extent of any conflict between a Purchase Order and this Agreement, this Agreement shall control.  
(b) Deviations from the Firm Order Period. If the quantity set forth in a Purchase Order exceeds the quantity set forth in the corresponding Calendar Quarter of the Firm Order Period, Takeda shall use reasonable efforts to satisfy the amount contained in a Purchase Order; provided, however, that Takeda shall not be in breach of this Agreement if it does not deliver the quantity set forth in a Purchase Order that exceeds the quantity set forth in corresponding Calendar Quarter of the Firm Order Period. For the avoidance of doubt, such reasonable efforts shall not require Takeda to [\*\*\*]. In the event Myovant issues a Purchase Order in a given Calendar Quarter for a quantity of Drug Substance or formulation of Drug Product that is less than the quantity set forth in the corresponding Calendar Quarter of the Binding Order Period, Takeda may deliver, at its discretion, either the quantity set forth in the Purchase Order or the quantity set forth in the corresponding Calendar Quarter of the Binding Order Period; provided that, in either circumstance, Myovant shall [\*\*\*] Takeda for [\*\*\*] of the actual Manufacturing Expenses incurred by Takeda in accordance with Section 3.1. In the event that any Purchase Order quantity deviates from the quantity set forth in the corresponding Calendar Quarter of the Firm Order Period, Takeda shall inform Myovant within [\*\*\*] Business Days after receipt of such Purchase Order of its best estimate of the quantity it anticipates delivering under such Purchase Order, which estimate shall not be binding upon Takeda.  
5.1.4 Initial Shipment. Within [\*\*\*] Business Days of the Effective Date of this Agreement, the Initial Shipment will be delivered to Myovant in accordance with Section 7.3.  
5.2 Delivery. Subject to Section 18.1, Takeda shall supply the Drug Substance and formulation of Drug Product ordered under a Purchase Order by way of delivery pursuant to Article 7. If Takeda is unable to meet the specified delivery date, Takeda shall promptly notify Myovant and provide to Myovant an alternative delivery date which is as close to the original delivery date as reasonably possible. Delivery by Takeda of up to [\*\*\*] of the quantity of Drug Substance or Drug Product in the Purchase Order will be accepted by Myovant in full satisfaction of Takeda’s obligation to supply such Purchase Order, subject to Myovant’s inspection of the Drug Substance or Drug Product in accordance with Section 8.1. Myovant will be invoiced for the actual quantities of the Drug Substance or Drug Product shipped, excluding the Initial Clinical Supply, for which Myovant shall not be charged.  
5.2.1 Testing by Takeda. Prior to delivery by Takeda pursuant to Section 7.1, Takeda shall undertake release testing to obtain a Quality Release for each batch of the Drug Substance or Drug Product that is Manufactured pursuant to a Purchase Order accepted by Takeda.  
5.2.2 Provision of Records. With each batch of Drug Substance or Drug Product delivered by Takeda pursuant to Section 7.1, Takeda shall provide all Batch Documentation for such batch, including a certificate of analysis and certificate of conformance.  
5.3 Notice of Potential Inability to Supply. Takeda shall inform Myovant of any events that may prevent Takeda or its designee from fulfilling its supply obligations with respect to amounts ordered pursuant to any Purchase Order as soon as reasonably practicable after becoming aware of such events. In the event Takeda notifies Myovant of a potential inability to supply a Drug Substance or a formulation of Drug Product, the Parties shall discuss in good faith how to resolve such supply problems. Notwithstanding the foregoing, if Takeda’s inability to fulfill its supply obligation is due to the unavailability of adequate raw materials and/or resources or because the manufacturing capacity for the Drug Substance or Drug Product of Takeda and/or its supplier is such that Takeda and/or its supplier is unable to meet the demand for the Drug Substance or Drug Product requested by Myovant, then [\*\*\*].  
ARTICLE 6  
MANUFACTURING  
6.1 Conformance with cGMP. Takeda shall supply the Drug Substance and Drug Product that conforms to GMPs, Applicable Laws and the TAK-385 Licensed Product INDs. Takeda shall be entitled, at its cost and expense, to modify the Specifications, Manufacturing, and testing processes, in each case, employed with regard to the Manufacture of the Drug  
  
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Substance or Drug Product from time to time, subject to approval, solely to the extent required by Applicable Laws or Regulatory Authorities.  
6.2 Manufacturing by Affiliates and Third Parties. Takeda shall have the right, from time to time, in its sole discretion and following a critical technical risk assessment to use an alternative site for the Manufacture of the Drug Substance or Drug Product or appoint any Affiliate or Third Party to Manufacture or supply the Drug Substance or Drug Product to Myovant hereunder; provided that such site, Affiliate or Third Party has been approved, solely to the extent required by Applicable Law, for such Manufacture by the applicable Regulatory Authorities. Such Manufacturing and supply changes shall not alter the rights, obligations and liabilities of the Parties as set out under this Agreement. Takeda shall promptly notify Myovant if Myovant is required pursuant to Applicable Law to make any changes to the TAK-385 Licensed Product INDs related to the appointment of a Third Party to Manufacture of the Drug Substance or Drug Product.  
6.3 Quality Agreement. Promptly after the Effective Date, the Parties will execute the Quality Agreement.  
ARTICLE 7  
DELIVERY, TITLE AND RISK OF LOSS  
7.1 Shipment Terms; Title; Risk of Loss. Except for the Initial Shipment and as otherwise provided under Article 11 of this Agreement, all Drug Substance and Drug Product will be shipped to Myovant EXW (Incoterms 2010) from Takeda’s designated site, freight collect, by a common carrier designated by Myovant in the Purchase Order, at Myovant’s expense. Title and risk of loss will transfer to Myovant, and delivery shall be deemed to have occurred, when goods are placed at Myovant’s disposal, not cleared for export and not loaded onto any collecting vehicle. Myovant shall procure, at its cost, insurance covering damage or loss to the Drug Substance and Drug Product during shipping.  
7.2 Importer of Record. Except for the Initial Shipment and as otherwise provided under Article 11 of this Agreement, Myovant shall be the “Importer of Record” of all Drug Substance and Drug Product supplied by Takeda under this Agreement. As the Importer of Record, Myovant shall be responsible for all aspects of importing such Drug Substance and Drug Product, including: (a) customs and other regulatory clearance of the Drug Substance and Drug Product; (b) payment of all tariffs, duties, customs, fees, expenses and charges payable in connection with the importation and delivery of the Drug Substance and Drug Product; and (c) keeping all records, documents, correspondence and tracking information required by Applicable Laws arising out of or in connection with the importation or delivery of such Drug Substance and Drug Product.  
7.3 Initial Shipment. The Initial Shipment will be shipped to Myovant DAP (Incoterms 2010) to Myovant’s designated site. Title and risk of loss will transfer to Myovant when the Initial Shipment is available for unloading at Myovant’s designated site. Myovant will be responsible for import clearance of the Initial Shipment.  
ARTICLE 8  
NON-CONFORMING PRODUCT/RETURNS  
8.1 Claims for Detectable Defects. Myovant shall notify Takeda within [\*\*\*] Business Days after receipt of any shipment of the Drug Substance or Drug Product supplied by or on behalf of Takeda of the existence and nature of any defect in or failure of the Drug Substance or Drug Product to comply with Section 4.1 or Section 6.1 at the time of delivery that could have been detected by a reasonable physical inspection of the Drug Substance or Drug Product at the time of delivery (“Detectable Defects”). If such notice is not provided within such [\*\*\*] Business Day period, then such Drug Substance or Drug Product will be deemed to be in compliance with this Agreement, Myovant will be deemed to have accepted the Drug Substance or Drug Product, and Takeda will have no further responsibility for such Detectable Defects. A non-conformity relating to stability of the Drug Substance or Drug Product shall not be considered a Detectable Defect.  
8.2 Claims for Non-Detectable Defects. Myovant shall notify Takeda within [\*\*\*] Business Days upon discovery of any defect in or failure of the Drug Substance or Drug Product to comply with Section 4.1 or Section 6.1 that is not a Detectable Defect. Claims that are submitted by Myovant shall state the nature of the alleged defect, including how such alleged defect was discovered, in detail reasonably sufficient to enable Takeda to identify the nature of the alleged defect or to dispute the same, and to determine that the defect existed at the time of delivery.  
8.3 Provision of Samples. Myovant shall, when notifying Takeda of an alleged defect, provide samples of any allegedly defective Drug Substance or Drug Product and copies of written reports or investigations performed by or on behalf of Myovant on such allegedly defective Drug Substance or Drug Product.  
  
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8.4 Referral to Independent Laboratory. In the event of a dispute between the Parties as to any defect in a Drug Substance or Drug Product, including whether a defect was a Detectable Defect or whether such defect existed at the time of delivery, that cannot be resolved within [\*\*\*] days of a claim being made to Takeda pursuant to Section 8.1 or Section 8.2, the matter shall promptly (but in no case later than [\*\*\*] Business Days after the expiration of such [\*\*\*] day period) be submitted to an independent laboratory to be mutually agreed between the Parties. The independent laboratory will examine the Drug Substance or Drug Product at issue and determine the existence and, if relevant, the timing of any defect in the Drug Product. The decision of the independent laboratory shall be binding on the Parties, except in the case of fraud. Myovant shall bear the costs of the independent laboratory if the independent laboratory finds that the Drug Product or Drug Substance was not defective or that such defect did not exist at the time of delivery. Takeda shall bear the costs of the independent laboratory if the independent laboratory finds that the Drug Product or Drug Substance was defective at the time of delivery.  
8.5 Credit Note; Replacement Product; Defective Product. Following a claim from Myovant pursuant to Section 8.1 or Section 8.2, Takeda’s sole obligation in the event that Takeda accepts Myovant’s claim as valid or the independent laboratory decides in favor of Myovant’s claim, shall be to either, at Takeda’s election: (a) provide Myovant with a Credit Note equal to the actual Manufacturing Expenses paid by Myovant for the defective Drug Substance or Drug Product; or (b) replace the defective Drug Substance or Drug Product as soon as commercially practicable. Any Drug Substance or Drug Product that is agreed or determined to be defective shall be, as directed by Takeda, either destroyed by Myovant or returned to Takeda, in both cases at Takeda’s expense. Except for Takeda’s obligations under Article 10 and Article 16, Takeda shall have no liability for defective Drug Substance or Drug Product other than as provided in this Article 8.  
ARTICLE 9  
STORAGE, HANDLING AND TRANSPORT  
9.1 Takeda’s Responsibilities. The Drug Substance and Drug Product shall be Manufactured by or on behalf of Takeda, stored, handled, packaged, and transported in accordance with the requirements of this Agreement, the Quality Agreement and all Applicable Laws. Takeda shall maintain appropriate quality assurance and quality control standards and record-keeping practices, including systems, resources and procedures in order to satisfy these obligations.  
9.2 Myovant’s Responsibilities. The Drug Substance and Drug Product shall be stored, handled, packaged, and transported in accordance with the requirements of this Agreement, the Quality Agreement and all Applicable Laws. Myovant shall maintain appropriate quality assurance and quality control standards and record-keeping practices, including systems, resources and procedures in order to satisfy these obligations.  
9.3 Myovant Storage, Handling and Transport of Product. Myovant shall obtain at its sole expense all equipment, facilities and personnel necessary for Myovant to store, handle and transport the Drug Substance and Drug Product in accordance with the terms hereof and shall pay all other costs and expenses in connection therewith. If Myovant, for any reason (other than as a result of a claim for a defect pursuant to Section 8.1 or Section 8.2), refuses to take delivery or possession of any Drug Substance or Drug Product, Myovant shall, notwithstanding Section 16.2, promptly upon receipt of an invoice from Takeda, reimburse Takeda for any resulting direct, out-of-pocket, storage, warehousing, handling or transportation fees that Takeda may have incurred prior to such refusal by Myovant.  
9.4 Notice of Inspections by Regulatory Authorities. The Parties’ obligations with respect to any inspections or audits by any Regulatory Authority related to the Drug Substance or Drug Product shall be governed by the Quality Agreement.  
ARTICLE 10  
PRODUCT RECALL  
The Parties’ obligations with respect to a recall of the Drug Substance or Drug Product shall be governed, as applicable, by the Quality Agreement and the License Agreement, including Section 6.4 of the License Agreement.  
ARTICLE 11  
TECHNICAL SUPPORT SERVICES  
11.1 Technical Support Services. Beginning on the Effective Date and continuing until the earliest of the [\*\*\*] anniversary of the Effective Date, the termination of this Agreement or the termination of the License Agreement, upon reasonable request of Myovant, Takeda shall provide Myovant with: (a) reasonable technical assistance to effect the transfer to  
  
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Myovant or its designee of the Takeda Manufacturing Know-How, including the then-current process for the Manufacture of the Drug Substance and Drug Product, and facilitate the implementation of Manufacture of the Drug Substance and Drug Product at the facilities of Myovant or its designee, and (b) other reasonable technical, regulatory and CMC related services in support of the Development of the Licensed Compound and Licensed Product ((a) and (b) collectively, the “Technical Support Services”). Any Technical Support Services provided by Takeda will be documented in work orders, executed by both Parties and substantially in the form attached as Exhibit D (each a “Project Work Order”). Technical Support Services will be provided from Takeda’s or its Affiliates’ facilities unless otherwise expressly set forth in a Project Work Order. Unless otherwise expressly provided in a Project Work Order, any Inventions or other Information arising out of Takeda’s performance of the any Technical Support Services will be governed by Article 13 of this Agreement. In furtherance of the Technical Support Services, the Parties may agree that Takeda will ship small quantities of Drug Substance or Drug Product to Myovant. Unless otherwise agreed by the Parties, any such shipment shall not be subject to Article 7 or Article 8 of this Agreement; rather, the terms of such shipment shall be separately agreed by the Parties and may be stated in the applicable Project Work Order.  
11.2 Reimbursement for Technical Support Services. Myovant shall compensate Takeda for those FTEs providing the Technical Support Services at the FTE Rate, and shall reimburse Takeda for all reasonable documented out-of-pocketed expenses incurred by Takeda to perform Technical Support Services, provided that any such out-of-pocket expenditure over $[\*\*\*] shall be approved in advance by Myovant. Takeda shall invoice Myovant within [\*\*\*] days after the end of each Calendar Quarter for all FTE expenses and Third Party expenses incurred by Takeda during the preceding Calendar Quarter in furtherance of the Technical Support Services, which shall include a tally of FTE hours by individual and date and a brief description of work performed, and Myovant shall pay such invoice in accordance with Article 12.  
ARTICLE 12  
PAYMENT TERMS  
12.1 Payment Terms. Myovant shall pay any amount invoiced by Takeda pursuant to this Agreement that is not disputed in writing by Myovant within [\*\*\*] days after receipt of such invoice. Myovant shall make all payments for invoices issued by Takeda in Japanese Yen via an Automatic Clearing House payment to Takeda’s account designated below or to such other account as Takeda may specify by written notice to Myovant in accordance with Section 18.2.  
 Bank Name:  
 [\*\*\*]  
 Branch:  
 [\*\*\*]  
 Address:  
 [\*\*\*]  
 Account #:  
 [\*\*\*]  
 Beneficiary’s Name:  
 [\*\*\*]  
 Beneficiary’s Address:  
 [\*\*\*]  
 12.2 Taxes. Myovant shall pay any applicable taxes, including [\*\*\*] as a result of payments it makes to Takeda pursuant to this Agreement (“Payments”). All other taxes, including but not limited to [\*\*\*], applicable to payments Myovant makes to Takeda pursuant to this Agreement shall be the sole responsibility of Takeda. Each Party will provide to the other Party any resale exemption, multiple points of use certificates, treaty certification and other exemption information reasonably requested by the other Party.  
12.3 Late Payment. If Myovant does not pay or dispute in writing any invoiced amount within [\*\*\*] days of receipt of such invoice, simple interest shall thereafter accrue on the sum due to Takeda until the date of payment at the per annum rate of [\*\*\*] over the then-current prime rate quoted by Citibank in New York City or the maximum rate allowable by Applicable Laws, whichever is lower.  
ARTICLE 13  
INTELLECTUAL PROPERTY  
Any Inventions or other Information arising in furtherance of this Agreement shall be subject to the Parties’ obligations set forth in the License Agreement, including those set forth in Article 10 of the License Agreement.  
  
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ARTICLE 14  
CONFIDENTIALITY  
A Party’s obligations with respect to any Confidential Information of the other Party received in furtherance of this Agreement shall be governed by the License Agreement, including Article 12 of the License Agreement.  
ARTICLE 15  
REPRESENTATIONS AND WARRANTIES  
15.1 Mutual Representations, Warranties and Covenants. Each Party hereby represents, warrants and covenants to the other Party that:  
15.1.1 Corporate Existence. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated.  
15.1.2 Corporate Power, Authority and Binding Agreement. As of the Effective Date, (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.  
15.1.3 Debarment. Neither it nor any of its Affiliates (a) has been debarred by a Regulatory Authority, (b) is subject to debarment proceedings by a Regulatory Authority or (c) will use, in any capacity, in connection with the activities to be performed under this Agreement, any Person that has been debarred, or who is the subject of debarment proceedings by any Regulatory Authority. If either Party learns that a Person performing on its behalf under this Agreement has been debarred by any Regulatory Authority, or has become the subject of debarment proceedings by any Regulatory Authority, such Party shall promptly notify the other Party and shall prohibit such Person from further performance on its behalf under this Agreement.  
15.2 Takeda Representations, Warranties and Covenants. Takeda hereby represents, warrants and covenants to Myovant that all Drug Substance and Drug Product supplied to Myovant pursuant to this Agreement, upon delivery to Myovant in accordance with Section 7.1:  
15.2.1 will have been Manufactured, tested, released, stored, supplied and otherwise handled in accordance with all Applicable Laws and GMPs), and the TAK-385 Licensed Product INDs;  
15.2.2 will have been Manufactured in facilities that are in compliance with Applicable Laws;  
15.2.3 will have been Manufactured in accordance with the Quality Agreement and will conform with the certificates provided pursuant to the Quality Agreement;  
15.2.4 shall not be adulterated or misbranded within the meaning of the FFDCA; and  
15.2.5 may be introduced into interstate commerce pursuant to the FFDCA.  
15.3 Myovant Representation, Warranties and Covenants. Myovant hereby represents, warrants and covenants to Takeda that:  
15.3.1 it shall discharge its obligations pursuant to this Agreement in accordance with all Applicable Laws; and  
15.3.2 it shall maintain the Drug Substance and Drug Product in a facility that is properly equipped to store the Drug Substance and Drug Product and shall maintain product security measures in accordance with Applicable Law; and  
15.3.3 in the event it formulates the Drug Substance into a pharmaceutical product and packages such Drug Product for use in Development, it shall do so, and shall distribute such Drug Product, in accordance with all Applicable Laws and the TAK-385 Licensed Product INDs.  
  
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15.4 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, THERE ARE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WRITTEN OR ORAL, MADE BY TAKEDA (OR ANY OF ITS AFFILIATES), WITH RESPECT TO THE PRODUCTS OR OTHERWISE, INCLUDING: (A) ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; (B) ANY IMPLIED WARRANTIES ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE IN THE TRADE; (C) ANY WARRANTY OF DESCRIPTION OR OTHERWISE CREATED BY ANY AFFIRMATION OF FACT OR PROMISE OR SAMPLE OR MODEL; OR (D) NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.  
ARTICLE 16  
INDEMNIFICATION; NO CONSEQUENTIAL DAMAGES; INSURANCE  
16.1 Indemnification Under the License Agreement. The Parties agree that the indemnification of any Losses resulting from the Claim of a Third Party will be governed by the License Agreement, including Article 15 thereof.  
16.2 No Consequential or Punitive Damages. NEITHER PARTY HERETO WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER OR FOR ANY LOSS OR INJURY TO THE OTHER PARTY’S PROFITS OR GOODWILL ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. THIS SECTION 16.2 DOES NOT APPLY TO A BREACH OF A PARTY’S OBLIGATIONS UNDER ARTICLE 14 OR TO A PARTY’S OBLIGATIONS PURSUANT TO SECTION 16.1.  
16.3 Insurance. Each Party agrees to procure and maintain in full force and effect during the Term insurance policies in accordance with its obligations under the License Agreement, including Section 15.4 thereof.  
ARTICLE 17  
TERM AND TERMINATION  
17.1 Term. This Agreement shall commence on the Effective Date and shall continue until the termination of the License Agreement (the “Term”); provided, however, that either Party may terminate this Agreement pursuant to the notice periods provided for in Article 13 of the License Agreement.  
17.2 Consequences of Termination.  
17.2.1 Termination of the License Agreement for Takeda Breach. The following provisions shall apply if the License Agreement is terminated by Myovant pursuant to Sections 13.3 (Termination for Material Breach), 13.7 (Termination for Patent Challenge) or 13.8 (Termination for Insolvency) of the License Agreement:  
(a) Myovant may cancel any Purchase Order; and  
(b) Myovant shall have no liability with respect to raw materials on hand or work in progress at Takeda as of the effective date of such termination.  
17.2.2 Other Terminations of the License Agreement. Except for Myovant’s termination of the License Agreement pursuant to Sections 13.3, 13.7 or 13.8 of the License Agreement, the following provisions shall apply if the License Agreement is terminated by either Party:  
(a) Myovant may cancel any Purchase Order;  
(b) Myovant shall promptly, at Myovant’s cost and at Takeda’s election, destroy its remaining inventory of the Drug Substance or Drug Product or return it to Takeda; and  
(c) Myovant shall [\*\*\*] Takeda within [\*\*\*] days of the effective date of termination for all [\*\*\*] Manufacturing Expenses incurred by Takeda on its behalf to meet all Purchase Orders submitted to Takeda on or before the effective date of termination of this Agreement, except to the extent that Takeda, using good faith efforts to do so, is able to incorporate, integrate or otherwise use or sell such components, raw materials or work-in-progress, including any Drug Substance or Drug Product, in the normal course of Takeda’s business operations.  
  
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17.3 Survival of Obligations. Termination or expiration of this Agreement shall not relieve a Party of any obligation to make a payment that was owed prior to or on the effective date of such termination, including amounts invoiced prior to such termination or expiration, nor prejudice either Party’s right to obtain performance of any obligation provided for in this Agreement that expressly survives termination or expiration. All provisions of this Agreement that, in accordance with their terms, are intended to have effect after the expiration or termination of this Agreement shall survive such termination or expiration, including Sections 2.2, 2.3, 3.2, 9.2, 9.3, 11.2, 15.4, 17.3 and 17.4 and Articles 4 (solely to the extent necessary to fulfill any obligation to a Regulatory Authority after termination or expiration), 8, 10, 12, 14, 16 and 18.  
17.4 Remedies. Except as otherwise expressly provided herein, exercise by a Party of its rights under this Article 17 shall not limit remedies which may otherwise be available to a Party in law or equity.  
ARTICLE 18  
GENERAL PROVISIONS  
18.1 Force Majeure Event. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of such prevention to the other Party. Such excusal shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to mitigate the condition. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder at the time of such Force Majeure because of such Force Majeure. If a Force Majeure persists for more than [\*\*\*] days, the Parties will discuss in good faith the modification of the Parties’ obligations under this Agreement in order to mitigate the delays caused by such Force Majeure.  
18.2 Notices. Any notice, request, or other communication permitted or required under this Agreement will be in writing, will refer specifically to this Agreement and will be hand delivered or sent by a recognized overnight delivery service, expenses prepaid, or by facsimile (with transmission confirmed), to the following addresses or to such other addresses as a Party may designate by written notice in accordance with this Section 18.2:  
If to Takeda:  
Takeda Pharmaceutical Company Limited  
0-0, Xxxxxxxxxx 0-xxxxx,  
Xxxx-xx, Xxxxx 540-8645  
Attention: Vice President, Production Control Department  
Facsimile: (x00) 0-0000-0000  
Copy to:  
Takeda Pharmaceuticals U.S.A., Inc.  
Xxx Xxxxxx Xxxxxxx  
Xxxxxxxxx, XX 00000  
Attention: General Counsel, Legal Department  
Facsimile: 000-000-0000  
If to Myovant:  
Myovant Sciences Ltd.  
Clarendon Xxxxx  
0 Xxxxxx Xxxxxx  
Xxxxxxxx XX 00  
Xxxxxxx  
Xxxxxxxxx: Corporate Secretary  
Copy to:  
Myovant Sciences, Inc.  
000 Xxxx 00xx Xxxxxx  
0xx Xxxxx  
Xxx Xxxx, XX 00000  
  
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Attention: SVP, Finance & Operations  
18.3 Dispute Resolution. Any dispute, controversy, or claim between the Parties that may arise from time to time pursuant to this Agreement relating to either Party’s rights or obligations hereunder that is not resolved through good faith negotiation between the Parties shall be resolved in accordance with Article 14 of the License Agreement.  
18.4 Audits. Each Party will maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of any amounts due under this Agreement. In accordance with Section 9.6 of the License Agreement, each Party shall have the right to have an independent certified public accountant verify the accuracy of the calculation of such amounts due under this Agreement. In addition, in accordance with the Quality Agreement, Myovant shall have the right, upon at least [\*\*\*] Business Days’ notice to Takeda, and such date to be reasonably agreed upon by the Parties, either by itself or through independent outside auditors or consultants, not more than [\*\*\*] per Fiscal Year during the Term of this Agreement, unless reasonable cause is shown, to inspect and audit, at its sole expense and during normal business hours and in a manner that does not interfere unreasonably with operations, any areas in Takeda’s Manufacturing facility or any other facilities of Manufacturer or its Affiliates in which any portion of the Manufacturing, packaging or other activities with respect to any Drug Substance or Drug Product is performed. The information obtained during the course of such audit shall be considered Confidential Information and subject to Section 3.4 (Subcontractors) and the provisions of Article 12 (Confidentiality) of the License Agreement.  
18.5 Relationship of the Parties. It is expressly agreed that Takeda, on the one hand, and Myovant, on the other hand, will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Takeda nor Myovant will have the authority to make any statements, representations or commitments of any kind, or to take any action which will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party will be employees of that Party and not of the other Party and all expenses and obligations incurred by reason of such employment will be for the account and expense of such Party.  
18.6 Designation of Affiliates. Each Party may discharge any obligations and exercise any rights hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party’s obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party’s Affiliate of any of such Party’s obligations under this Agreement will be a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party’s Affiliate.  
18.7 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other except that: (a) each Party may assign its rights and obligations under this Agreement in whole or in part to one or more of its Affiliates without the consent of the other Party; and (b) each Party may assign this Agreement in connection with the sale or other transfer of all or substantially all of the assets of the business to which this Agreement relates (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transaction), but, with respect to assignment by Myovant, only if such assignment is consistent with Sections 5.5 and 5.6 of the License Agreement. Any successor or assignee of rights or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights or obligations. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 18.7 will be null, void and of no legal effect.  
18.8 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision will be considered severed from this Agreement and will not serve to invalidate any remaining provisions hereof. The Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.  
18.9 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.  
  
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18.10 Construction; Rules of Construction. Interpretation of this Agreement will be governed by the following rules of construction: (a) words in the singular will be held to include the plural and vice versa, and words of one gender will be held to include the other gender as the context requires; (b) references to the terms “Section”, “Exhibit”, or “Schedule” are to a Section, Exhibit, or Schedule of this Agreement unless otherwise specified; (c) the terms “hereof”, “hereby”, “hereto”, and derivative or similar words refer to this entire Agreement; (d) references to “$” or “Dollars” will mean the currency of the United States; (e) the word “including” and words of similar import when used in this Agreement will mean “including without limitation,” unless otherwise specified; (f) the word “or” will not be exclusive; (g) references to “written” or “in writing” include in electronic form; (h) the titles and headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement; (i) each of the Parties has participated in the negotiation and drafting of this Agreement and if an ambiguity or question of interpretation should arise, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or burdening either Party by virtue of the authorship of any of the provisions in this Agreement or any interim drafts of this Agreement; (j) the word “shall” will be construed to have the same meaning and effect as the word “will”; (k) references to “days” will mean calendar days, unless otherwise specified; and (l) a reference to any Person includes such Person’s successors and permitted assigns.  
18.11 Further Assurance. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof.  
18.12 Governing Law. This Agreement was prepared in the English language, which language will govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof will be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.  
18.13 Entire Agreement. This Agreement, including the Exhibits and Schedules hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change, or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the event of any inconsistency between this Agreement and the Licensee Agreement, unless expressly stated to the contrary herein, the terms contained in the License Agreement will control. In the event of any inconsistency between the body of this Agreement and the Exhibits or Schedules to this Agreement or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibit, Schedule or subsequent ancillary agreement, the terms contained in this Agreement will control.  
18.14 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Agreement may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures will be deemed to bind each Party hereto as if they were the original signatures.  
[Signature Page Follows]  
  
  
12  
  
  
THIS AGREEMENT FOR THE MANUFACTURE & SUPPLY OF CLINICAL TRIAL MATERIAL IS EXECUTED by the authorized representatives of the Parties as of the Effective Date.  
 MYOVANT SCIENCES LTD.  
 TAKEDA PHARMACEUTICAL  
COMPANY LIMITED  
 Signature:  
 /s/ Xxxxxxxx X. Xxxxx  
 Signature:  
 /s/ X. Xxxxx  
 Name:  
 Xxxxxxxx X. Xxxxx  
 Name:  
 Xxxxxx Xxxxx  
 Title:  
 Head, Global Transactions & Risk  
 Title:  
 Head of Pharmaceutical Technology  
 Management  
 R&D Laboratories, CMC Center  
 Date:  
 June 7, 2016  
 Date:  
 June 8, 2016  
  
  
13  
  
  
EXHIBIT A  
Specifications for Drug Substance and Drug Product  
[Appears on following page]  
  
A-1  
  
  
Specifications of TAK-385 Drug Substance  
[\*\*\*]  
Specifications of TAK-385 Drug Product, T4-B 40 mg and 120 mg Tablets  
[\*\*\*]  
Specifications of XXX-000 XxxxxxxX0-X 40 mg Tablets  
[\*\*\*]  
  
  
A-2  
  
  
EXHIBIT B  
Formulations of Drug Product  
[Appears on following page]  
  
B-1  
  
  
TAK-385 Tablet Formulations  
[\*\*\*]  
  
  
  
B-2  
  
  
EXHIBIT C  
  
Initial Rolling Forecast  
  
Myovant Forecast of Desired Quantities of Drug Substance and Formulation of Drug Product  
  
[\*\*\*]  
  
C-1  
  
  
EXHIBIT C\_A  
  
[\*\*\*]  
  
  
C-2  
  
  
EXHIBIT D  
Project Work Order  
This Project Work Order (the “PWO”), effective as of [DATE] (the “PWO Effective Date”), is incorporated into and shall be governed by the Agreement for the Manufacturing & Supply of Clinical Trial by and between Takeda Pharmaceutical Company Limited and Myovant Sciences Ltd., (“Myovant”), dated of June 7, 2016. For the purposes of this PWO, “Takeda” shall mean Takeda Pharmaceutical Company Limited or the Takeda Affiliate that signs this PWO. Capitalized but undefined terms shall have the meanings first ascribed to them in the Agreement.  
1.  
Description of Services:  
2.  
Project Start Date:  
3.  
Estimated Completion Date:  
4.  
Description of Services:  
5.  
Company Purchase Order No.:  
6.  
Fees. In consideration for Takeda’s performance of the Services under this PWO, Myovant shall compensate Takeda on an hourly basis as invoiced by Takeda using the following rate(s):  
FTE Rate: amount of [\*\*\*] for an FTE per Calendar Year.  
7.  
Expenses. Myovant shall reimburse Takeda for reasonable out-of-pocket expenses actually incurred by Takeda in connection with the Services. For this PWO, Takeda’s reimbursable out-of-pocket expenses for performing the Services shall not exceed $[\*\*\*] without Myovant’s prior written consent.  
8.  
Payment Terms and Schedule. Takeda shall invoice Myovant on a Calendar Quarter basis for fees and expenses incurred in performing the Services. Invoices shall be sent via e-mail in pdf format, to xxxxxxxxxx@xxxxxxx.xxx (Attn: Myovant).  
Myovant shall pay all undisputed amounts set forth on Takeda’s invoices within [\*\*\*] days after receipt. Any amount invoiced by Takeda that is not disputed in writing by Myovant within [\*\*\*] days after receipt of Takeda’s invoice for such amount will be deemed to be accepted by Myovant.  
  
D-1  
  
  
MYOVANT SCIENCES LTD.  
 TAKEDA PHARMACEUTICAL  
COMPANY LIMITED  
 Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
  
D-2  
  
  
FIRST AMENDMENT  
TO THE  
AGREEMENT FOR THE MANUFACTURE & SUPPLY OF CLINICAL TRIAL MATERIAL  
This First Amendment to the Agreement for the Manufacture and Supply of Clinical Trial Material (the “Amendment”) is entered into effective August 19, 2016 (the “Amendment Date”) by and between Myovant Sciences Ltd. (“Myovant”) and Takeda Pharmaceutical Company Limited (“Takeda”). Each of Myovant and Takeda may be referred to individually herein as a “Party” and jointly as the “Parties”.  
WHEREAS, Myovant and Takeda are parties to that certain Agreement for the Manufacture and Supply of Clinical Trial Material dated June 7, 2016 (the “Supply Agreement”); and  
WHEREAS, Myovant and Takeda wish to clarify certain matters relating to the Supply Agreement;  
NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Myovant and Takeda, intending to be legally bound, hereby agree as follows:  
1.  
Capitalized terms used herein and not otherwise defined shall have the meaning ascribed in the Supply Agreement.  
2.  
Section 17.1 of the Supply Agreement is hereby superseded and replaced in its entirety to read as follows:  
17.1 Term. This Agreement shall commence on the Effective Date and shall continue until the termination of the License Agreement, unless terminated earlier in accordance with subsection (a) or (b) below (the “Term”).  
(a)  
Termination for Material Breach.  
(i)Either Party (the “Non-Breaching Party”) may terminate this Agreement in its entirety in the event the other Party (the “Breaching Party”) has materially breached this Agreement and such material breach has not been cured (A) within [\*\*\*] Business days of receiving notice thereof with respect to any breach of any undisputed payment obligation under this Agreement and (B) within [\*\*\*] days of receiving notice thereof with respect to any other breach (as applicable, the “Cure Period”). The written notice describing the alleged material breach will provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement pursuant to this Section 17.1 will become effective at the end of the Cure Period, unless the Breaching Party has cured any such material breach prior to the expiration of such Cure Period.  
(ii)If the Parties reasonably and in good faith disagree as to whether there has been a material breach, including whether such breach was material and whether such breach has been cured, the Party that disputes whether there has been a material breach may contest the allegation in accordance with Article 14 of the License Agreement. The Parties agree that the failure to deliver at least [\*\*\*] of any Drug Substance or Drug Product ordered via a Purchase Order issued in accordance with Section 5.1.3 in any [\*\*\*] month period shall be deemed a material breach of this Agreement; provided that Myovant can establish that such delivery shortfall caused, or is reasonably likely to cause, a material delay in the timelines contemplated in the then-current Development Plan. Notwithstanding anything to the contrary contained in this Section 17.1, the Cure Period for any Dispute will run from the date that written notice was first provided to the Breaching Party by the Non-Breaching Party through the resolution of such Dispute pursuant to Article 14 of the License Agreement, and it is understood and acknowledged that, during the pendency of a Dispute pursuant this Section 17.1, all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement.  
(iii)If Myovant terminates this Agreement pursuant to this Section 17.1(a) for Takeda’s material breach, then Section 17.2.1 of this Agreement shall apply. If Takeda terminates this Agreement pursuant to this Section 17.1(a) for Myovant’s material breach, then Section 17.2.2 of this Agreement shall apply, except that Myovant shall not be permitted to cancel any pending Purchase Orders where Takeda either: (1) has Manufactured the Drug Product or Drug Substance to be delivered pursuant to the Purchase Order prior to the effective date of the termination, or (2) cannot, despite good faith efforts, re-allocate to a different program any Manufacturing slot that was scheduled to be used for a pending Purchase Order.  
(b)  
Termination for Convenience. Myovant may terminate this Agreement at will, in its sole discretion, on not less than [\*\*\*] prior written notice to Takeda. If Myovant terminates this Agreement pursuant to this Section  
  
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17.1(b), then Section 17.2.2 of this Agreement shall apply; except that Myovant shall not be permitted to cancel any Purchase Orders where [\*\*\*].  
3.  
Except as expressly set forth herein, all terms and conditions of the Supply Agreement remain in full force and effect.  
4.  
This Amendment may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Amendment may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures will be deemed to bind each Party hereto as if they were the original signatures.  
  
2  
  
  
This Amendment is accepted and agreed by the Parties through their duly authorized representatives below as of the Amendment Date.  
 TAKEDA PHARMACEUTICALS COMPANY LIMITED  
 MYOVANT SCIENCES LTD.  
 By:  
 /s/ Xxxxxx Xxxxx  
 By:  
 /s/ Xxxxxxxx X. Xxxxx  
 Name:  
 Xxxxxx Xxxxx  
 Name:  
 Xxxxxxxx X. Xxxxx  
 Title:  
 Japan Head of Formulation Development, Pharmaceutical Sciences  
 Title:  
 Head, Global Transactions & Risk Management  
  
  
3