Exhibit 10.20  
CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED AS "(CONFIDENTIAL TREATMENT REQUESTED)" IN THE TEXT, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.  
AMIFOSTINE MANUFACTURING AND SUPPLY AGREEMENT  
 This Agreement ("Agreement"), entered into as of the 1st day of January, 2001 (the "Effective Date"), by and between MedImmune Oncology, Inc. (formerly U.S. Bioscience, Inc., hereinafter referred to as "MedImmune Oncology"), a corporation duly formed and existing under the laws of the State of Delaware, having a place of business at One Tower Bridge, 000 Xxxxx Xxxxxx, Xxxx Xxxxxxxxxxxx, Xxxxxxxxxxxx 00000, and PPG Industries, Inc., having a place of business as Xxx XXX Xxxxx, Xxxxxxxxxx, Xxxxxxxxxxxx 00000, XXX, and its wholly-owned subsidiary PPG-Xxxxx, having a place of business at Z.I. la Croix Cadeau, X.X. 00, 00000 Xxxxxxx Xxxxx, Xxxxxx (Individually & Collectively "PPG"), a corporation duly formed and existing under the laws of the State of Pennsylvania.  
WITNESSETH  
 WHEREAS, the parties to this Agreement are parties to a Manufacturing and Supply Agreement between U.S. Bioscience, Inc. and Xxxxx, X.X. (the "Prior Agreement") relating to the manufacture of amifostine;  
 WHEREAS, MedImmune Oncology has certain proprietary technical information (including, without limitation, patents, patent applications and trade secrets) relating to the Product which has been disclosed, in part, to PPG under the terms of the Prior Agreement and which will be disclosed, in part, to PPG under the terms of this Agreement;  
 WHEREAS, the parties desire to have this Agreement supersede the Prior Agreement from and after the Effective Date;  
 WHEREAS, MedImmune Oncology desires to contract with PPG for the continued manufacture of amifostine (hereinafter defined in Section 1.4 and referred to as the "Product"); and  
 WHEREAS, PPG desires to manufacture the Product for MedImmune Oncology and represents that it possesses the requisite expertise, personnel and facilities for the manufacture and supply of Product on the terms and in the quantities contemplated by this Agreement.  
 NOW THEREFORE, in consideration of the foregoing and of the mutual covenants and conditions herein contained, the parties hereby agree as follows:  
ARTICLE I  
DEFINITIONS  
 For purpose of this Agreement:  
 Section 1.1 "cGMPs" shall mean the current Good Manufacturing Practices promulgated by the United States Food and Drug Administration ("FDA") and other applicable government regulatory agencies. MedImmune Oncology shall keep PPG regularly informed about any amendment or modification to relevant portions of its regulatory registrations for the Product.  
 Section 1.2 "Confidential Information" shall have the meaning set forth in Section 7.1.  
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 Section 1.3 "Preparation" and/or "Prepare" shall mean any and all steps and operations required in the sourcing of raw material, synthesis, manufacture, processing, subdividing, quality control, quality assurance, testing, storage and packaging of Product for shipment.  
 Section 1.4 "Product" shall mean Amifostine Drug Substance together with changes, modifications and improvements instituted during the term hereof as described more fully on Exhibit "C" attached and made a part hereof.  
 Section 1.5 "Specifications" shall have the meaning set forth in Section 4.1 hereof.  
 Section 1.6 "Contract Year" shall mean a calendar year under this Agreement.  
ARTICLE II  
SALE AND DELIVERY OF PRODUCT  
 Section 2.1 Subject to the terms and conditions set forth in this Agreement, PPG agrees to Prepare and sell, and MedImmune Oncology agrees to purchase from PPG, the Product as follows:  
Prior to the beginning of each calendar quarter, MedImmune Oncology shall provide to PPG, in writing, a (CONFIDENTIAL TREATMENT REQUESTED) forecast of its requirements for deliveries of the Product during the next (CONFIDENTIAL TREATMENT REQUESTED) (hereinafter the "Delivery Schedule"). The quantities forecast for delivery in the (CONFIDENTIAL TREATMENT REQUESTED) in a Delivery Schedule shall be firm commitments to purchase and sell; and the (CONFIDENTIAL TREATMENT REQUESTED) included in a Delivery Schedule shall be for planning purposes and may be revised up or down by MedImmune Oncology. Exhibit "A" sets forth MedImmune Oncology's non-binding requirements forecast for the Contract Years 2001-2003.  
 Section 2.2 PPG agrees, at the request of MedImmune Oncology, to provide Product at the agreed upon price set forth in the Price Schedule attached hereto as Exhibit "B" and subject to the provisions of Section 3.1.  
 Section 2.3 Subject to Section 2.5, PPG shall provide (CONFIDENTIAL TREATMENT REQUESTED) to (CONFIDENTIAL TREATMENT REQUESTED) of MedImmune Oncology's requirements for the Product, at MedImmune Oncology's option. Subject to Section 2.5, MedImmune Oncology shall purchase from PPG a minimum of (CONFIDENTIAL TREATMENT REQUESTED) to (CONFIDENTIAL TREATMENT REQUESTED) of MedImmune Oncology's global requirements for the Product, provided however, that PPG may elect to qualify a second manufacturing location for production of Product by informing of its intent to do so in writing. Within 90 days of such notification, PPG will provide to MedImmune documentation which describes PPG's qualification protocols and validation plans. PPG and MedImmune will cooperate to complete such qualification in a timely manner. Upon successful qualification of the alternate manufacturing location by MedImmune, MedImmune shall be obligated to purchase (CONFIDENTIAL TREATMENT REQUESTED) of MedImmune Oncology's global requirement for Product.  
 Section 2.4 PPG shall at all times maintain a minimum inventory of at least (CONFIDENTIAL TREATMENT REQUESTED) of the amount of the Product purchased by MedImmune Oncology during the preceding (CONFIDENTIAL TREATMENT REQUESTED). PPG shall at all times maintain a minimum annual capacity reserved for production of the Product for MedImmune Oncology of the quantity of Product specified for delivery in the most recent Delivery Schedule. Notwithstanding anything to the contrary in this Section 2.3, should PPG be required to replace Product pursuant to its obligations in Article 4, PPG may utilize the inventory of the Product even though that may result in a temporary situation in which inventory is less than required by this Section 2.4. PPG shall rebuild the  
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inventory to once again meet the requirements of this Section 2.4 within (CONFIDENTIAL TREATMENT REQUESTED) days of removing Product to use as replacement Product.  
 Section 2.5 If PPG has not qualified an alternative manufacturing site subject to Section 2.3, MedImmune Oncology may qualify an alternative source(s) of supply other than PPG and may secure Product from such alternative source(s) for amounts in excess of (CONFIDENTIAL TREATMENT REQUESTED) of its requirements. MedImmune Oncology shall not make the alternative source(s) MedImmune Oncology's principal supplier of Product unless PPG has materially failed to meet MedImmune Oncology's orders in a period of more than (CONFIDENTIAL TREATMENT REQUESTED) or this Agreement is terminated or has by its terms expired. After (CONFIDENTIAL TREATMENT REQUESTED) in which PPG has materially failed to meet MedImmune Oncology's orders, both parties agree that MedImmune Oncology may use an alternate source to supply MedImmune Oncology's needs until PPG is able to again furnish MedImmune Oncology's needs.  
 Section 2.6 PPG agrees to sell the Product exclusively to MedImmune for pharmaceutical applications. PPG agrees that during the term of this Agreement and for a period of (CONFIDENTIAL TREATMENT REQUESTED) thereafter, it will not compete, or assist third parties to compete, directly or indirectly with MedImmune Oncology in the sale of the Product.  
 Section 2.7 MedImmune Oncology shall submit purchase orders for Product to PPG at least (CONFIDENTIAL TREATMENT REQUESTED) prior to the date of shipment specified therein. MedImmune Oncology's purchase orders shall (i) reference this Agreement; (ii) be submitted in writing; (iii) state the quantity of Product ordered; (iv) specify the delivery location; and (v) state the desired date of shipment. In no event shall the use of any form of purchase order be effective to vary, alter, modify or add to the terms and provisions of this Agreement; nor will the acceptance of any such purchase order have the effect of substituting the provisions set forth on such form for the provisions contained in this Agreement. MedImmune Oncology may reschedule such purchase order no later than (CONFIDENTIAL TREATMENT REQUESTED) prior to the date of scheduled manufacturing. In no event shall MedImmune Oncology's right to reschedule such Purchase Order abrogate any of its obligations under Section 2.1.  
 Section 2.8 PPG shall exercise reasonable, diligent efforts to ship Product in the quantities and on the dates specified in MedImmune Oncology's purchase orders. Sales of Product by PPG to MedImmune Oncology shall be made CIP (as in Incoterms 1990), to MedImmune Oncology's facility in Nijmegen, the Netherlands, or such other location as may be specified by MedImmune Oncology to PPG from time to time hereunder.  
ARTICLE III  
PAYMENT TERMS  
 Section 3.1 The Base Prices to be paid by MedImmune Oncology for quantities of Product purchased pursuant to this Agreement are set forth in Exhibit "B", except for freight and insurance which will be billed (CONFIDENTIAL TREATMENT REQUESTED). The prices set forth on Exhibit "B" shall be subject to the following adjustments, as applicable:  
 PPG and MedImmune Oncology will adjust the prices in Exhibit B such that any benefit or loss due to the change in exchange rate will be shared equally by the parties according to the following:  
Average Exchange Rate ("AER") is defined as the average Euro per US$ exchange rate which has prevailed for the previous (CONFIDENTIAL TREATMENT REQUESTED) prior to the date of invoicing.  
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"Invoice Price" is defined as such:  
For invoices for which the AER is greater than or equal to (CONFIDENTIAL TREATMENT REQUESTED) Euro per US$ and less than or equal to (CONFIDENTIAL TREATMENT REQUESTED) per US$ the Invoice Price is equal to (CONFIDENTIAL TREATMENT REQUESTED) divided by the AER multiplied by the Base Price then in effect  
For invoices for which the AER is greater than (CONFIDENTIAL TREATMENT REQUESTED) the Invoice Price is equal to (CONFIDENTIAL TREATMENT REQUESTED) multiplied by the Base Price then in effect.  
For invoices for which the AER is less than (CONFIDENTIAL TREATMENT REQUESTED) the Invoice Price is equal to (CONFIDENTIAL TREATMENT REQUESTED) multiplied by the Base Price then in effect.  
In summary:  
For AER>(CONFIDENTIAL TREATMENT REQUESTED) Invoice price = (CONFIDENTIAL TREATMENT REQUESTED)× Base Price in effect  
For (CONFIDENTIAL TREATMENT REQUESTED)<AER<(CONFIDENTIAL TREATMENT REQUESTED) Invoice price= (CONFIDENTIAL TREATMENT REQUESTED)/AER × Base Price in effect  
For AER<(CONFIDENTIAL TREATMENT REQUESTED) Invoice price = (CONFIDENTIAL TREATMENT REQUESTED) × Base Price in effect  
 In the event that MedImmune Oncology makes changes to the Specifications which result in material increases in the cost to PPG to Prepare the Product, PPG and MedImmune Oncology shall negotiate in good faith an appropriate and reasonable price adjustment. In the event that the regulatory authorities other than the regulatory authorities of the United States, the EC countries or Japan, require additional cGMP requirements or changes to the Specifications in order to allow commercialization of Product in their respective countries, the parties shall negotiate in good faith an appropriate and reasonable price adjustment relating solely to quantities of Product for which such changes are necessary.  
 In the event that the parties do not agree on such price adjustment, then both parties will appoint a mutually acceptable independent expert whose findings will be binding on both PPG and MedImmune Oncology. Said expert shall transmit to both parties its findings within three months from the date of its appointment. If the parties are unable to agree on an independent expert, the matter shall be settled in accordance with Section 12.3 hereof.  
 Section 3.2 All prices of Product shall be on the basis of (CONFIDENTIAL TREATMENT REQUESTED) as in Incoterms 1990.  
 Section 3.3 The purchase price for Product shall be paid to PPG no later than (CONFIDENTIAL TREATMENT REQUESTED) days after the date of PPG's invoice to MedImmune Oncology. In no event shall PPG invoice MedImmune Oncology for the Product prior to delivery. All invoices from PPG to MedImmune Oncology covering Product shipped to MedImmune Oncology shall be stated in, and all payments to PPG by MedImmune Oncology shall be made in United States Dollars (US$). However, the parties hereto may agree at the beginning of each Contract Year that such invoices and payments will be in European Monetary Units (Euro), provided, however, that said prices may be adjusted by mutual agreement of the parties by an amount sufficient to cover PPG'S currency exchange risk and costs.  
 In the event that the Euro to US$ exchange rate is greater than (CONFIDENTIAL TREATMENT REQUESTED) or less than (CONFIDENTIAL TREATMENT REQUESTED) for  
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more than (CONFIDENTIAL TREATMENT REQUESTED), then either party may request a renegotiation of the Base Prices in Exhibit "B" in writing to the other party. Both parties will commence such negotiations within 30 days of receipt of the written request. If the parties fail to agree to a modification of the base prices within 60 days of commencement of the negotiation, then the dispute will be settled in accordance with Section 12.3.  
 Section 3.4 Payments due to PPG shall be made by wire transfer or by a mutually agreeable method to the bank account of PPG of which PPG shall advise MedImmune Oncology from time to time.  
ARTICLE IV  
MANUFACTURE AND SUPPLY  
 Section 4.1 Prior to the date of the Prior Agreement, MedImmune Oncology (then U.S. Bioscience, Inc.) transferred to PPG, and PPG hereby acknowledges receipt of, copies of MedImmune Oncology's specifications for the manufacture and testing of the Product, and such specifications have been revised from time to time under the Prior Agreement. The current specifications for the Product are attached hereto as Exhibit "C" and made a part hereof (such specifications, as revised in accordance with this Section 4.1, hereinafter being defined as the "Specifications"). The Preparation of the Product shall be carried out by PPG in accordance with applicable cGMPs and established quality standards. The Product shall meet Specifications. MedImmune Oncology shall provide PPG with all revisions to the Specifications in a timely manner after such revisions are approved by MedImmune Oncology, as appropriate, such revisions to be reasonably required for the Product. All revisions or deviations from Specifications for Product must be made in accordance with the Change Control Procedures set forth in Exhibit "D".  
 Section 4.2 PPG shall prepare and make available to MedImmune Oncology for review and comment comprehensive and complete documentation including the Drug Master File(s) with regard to the manufacture and testing of Product which will include, but not be limited to, testing of all raw materials, in-process and finished product applications; and review of master and working batch records for processing and packaging and all supporting analytical documentation. Such documentation shall be in a format consistent with cGMP's or FDA or other regulatory agencies requirements, and shall be prepared with respect to the manufacture of each batch of Product.  
 Section 4.3 PPG shall prepare and maintain a current master production batch record in English. At the time of execution of this Agreement, PPG shall provide MedImmune Oncology with a copy of the then current master production batch record in English. Thereafter, PPG shall provide to MedImmune Oncology any updates of this master record in English within (CONFIDENTIAL TREATMENT REQUESTED) of any such update being submitted. PPG shall not change the master production batch record without the prior written approval of MedImmune Oncology.  
 Section 4.4 For each batch Prepared, PPG shall provide MedImmune Oncology with a certificate of analysis and a certificate of compliance, specifically providing that the Product meets Specifications, in the English language, for the Product no later than (CONFIDENTIAL TREATMENT REQUESTED) after completion of manufacture of such batch.  
 Section 4.5 Within (CONFIDENTIAL TREATMENT REQUESTED) from receipt by MedImmune Oncology of the certificate of analysis for Product set forth in Section 4.4, MedImmune Oncology shall notify PPG in writing whether it approves of the release of Product for shipment. Upon receipt of such notification from MedImmune Oncology, PPG shall within one (1) week ship the certificated amount of Product to MedImmune Oncology's designee.  
 MedImmune Oncology shall confirm to PPG in writing within (CONFIDENTIAL TREATMENT REQUESTED) of arrival of a shipment of Product, the identity and amount of Product received, and  
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condition of the shipment based solely upon a visual inspection. Such MedImmune Oncology confirmation shall not constitute acceptance of the Product, nor shall it be construed as any indication of whether or not the Product conforms to Specifications.  
 Section 4.6 MedImmune Oncology or its designee shall have (CONFIDENTIAL TREATMENT REQUESTED) after shipment to inspect each shipment of Product to determine whether the Product included in such shipment conforms to the Specifications. MedImmune Oncology shall promptly give PPG written notice of any aspect in which Product fails to conform to Specifications. If MedImmune Oncology fails to notify PPG of any nonconformity within such (CONFIDENTIAL TREATMENT REQUESTED) period, MedImmune Oncology shall be deemed to have accepted the Product as shipped, provided, however, that with respect to any nonconformity due to latent defects, MedImmune Oncology shall be entitled to reject the nonconforming Product within (CONFIDENTIAL TREATMENT REQUESTED) after discovering the latent defects. In the event of contestation of quality by MedImmune Oncology as provided in this Section and that such contestation is not accepted by PPG, a sample of the contested batch sealed by PPG in compliance with applicable regulations shall be submitted by PPG to a relevant state approved unrelated and independent laboratory, mutually acceptable to both parties, and the check assay of said laboratory shall be accepted by the two parties as final and binding. The cost of said analysis made by the laboratory shall be borne by the failing party.  
 If any production batches of the Product fail to meet the Specifications as evidenced by the laboratory check assay, MedImmune Oncology shall have the right to return such batches, in which case the cost of the rejected batches (including raw materials, labor, manufacturing overhead and quality control) or, if applicable, the cost of any work (any rework not included in the Drug Manufacturing File must be approved in advance by MedImmune Oncology) will be borne by PPG unless such failure is due to the negligence of MedImmune Oncology. In the event that MedImmune Oncology rejects or returns any batch of Product pursuant to this Section, it shall receive replacement of such batch. In no event shall MedImmune Oncology's damages for rejected Product batches exceed (CONFIDENTIAL TREATMENT REQUESTED).  
 Section 4.7 PPG shall make its best reasonable efforts to replace Product as quickly as possible but in no case more than (CONFIDENTIAL TREATMENT REQUESTED) after notification of MedImmune Oncology of nonconformity pursuant to Section 4.6.  
 Section 4.8 In the event the check assay made by the laboratory as provided in Section 4.6 hereabove concludes the nonconformity of the Product, MedImmune Oncology and PPG shall meet immediately to agree upon the corrective actions, if any, to be implemented. PPG will cease further production of the Product until MedImmune Oncology and PPG formally agree in writing on such corrective actions. PPG may at its own risk continue to produce Product during this period with no obligation to MedImmune Oncology. Should MedImmune Oncology desire to have Product produced while the investigation is in process, MedImmune Oncology will be responsible for the fees for service of PPG whether the batch is accepted or not. Should PPG be required by MedImmune Oncology to produce any experimental batches of Product to elucidate or resolve the source of the batch rejection, xxxxxxxx for these batches will be separate from and exclusive of the fees stated in the attachment.  
 Section 4.9 PPG shall provide access to information and support needed during investigations addressing customer complaints and/or recalls. All documents and updates with regard to the Preparation of the Product which are required by any regulatory agency shall be provided by PPG, and PPG shall submit to all inquiries and inspections by such regulatory agencies. All documents provided by PPG to any regulatory agency shall be provided to MedImmune Oncology in advance, if feasible, and in no case shall such documents be provided to MedImmune Oncology more than two (2) days after such documents are provided to any regulatory agency.  
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 Section 4.10 PPG shall properly dispose of all manufacturing waste and associated contaminated materials in accordance with all applicable laws, including French laws and environmental regulations. Upon MedImmune Oncology's request, PPG shall supply to the FDA or any official government agency an official statement, a model of which is attached hereto as Exhibit "E" stating that PPG is in conformance with relevant environmental regulations. PPG shall provide at the request of MedImmune Oncology from time to time a letter from the appropriate governmental authority certifying that the site is in compliance with environmental laws applicable to PPG.  
 Section 4.11 PPG shall maintain its facilities utilized in the performance of this Agreement or which in any way affect such performance to meet all cGMP requirements.  
ARTICLE V  
STORAGE  
 Section 5.1 PPG shall purchase, receive, test, store and secure all Product and materials used for the Preparation of the Product by means which meet all cGMP requirements.  
ARTICLE VI  
QUALITY CONTROL  
 Section 6.1 PPG shall perform quality control and quality assurance review of all aspects of Product Preparation on an individual batch basis. Such review shall include, but shall not be limited to: raw material handling and testing, manufacturing, including all reprocessing and packaging, in-process and finished product testing. The review shall be made to ensure and certify compliance of all PPG's activities to all Specifications and cGMP requirements for the Product. Such quality control and quality assurance review shall include acceptance and approval of all associated documentation, as more fully set forth in Sections 4.2, 4.3, and 4.4 by PPG on an individual batch basis.  
 Section 6.2 PPG shall keep all samples including raw materials, in process and final Product relating to the manufacture of each batch of the Product in accordance with the cGMP provided said samples do not represent a danger and are in stable substance form.  
 In the event of an investigation or claim from a third party made to MedImmune Oncology, PPG shall, except as provided hereabove, provide MedImmune Oncology on MedImmune Oncology's request, a sample of raw materials, in-process samples and/or final Product from a production batch of the Product only.  
 Upon MedImmune Oncology's request, PPG shall supply to MedImmune Oncology an official statement stating that drug substance reserve samples of Product are kept in compliance with cGMP, except as provided hereabove.  
 Section 6.3 PPG shall promptly notify MedImmune Oncology of any FDA or other regulatory agency inspections, pre-approval inspections, or any other FDA or other regulatory interactions relating to PPG operations and concerning the manufacture of the Product.  
 PPG shall provide MedImmune Oncology with copies of all regulatory inspections and reports, including reports of the FDA, within 48 hours of receipt of such reports by PPG.  
 Section 6.4 Nothing contained in this Article VI shall relieve PPG of its responsibility to Prepare the Product in accordance with the Specifications and to perform the necessary quality control tests and quality assurance review on the Product.  
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ARTICLE VII  
CONFIDENTIALITY—PATENT RIGHTS  
 Section 7.1 MedImmune Oncology and PPG agree that all data disclosed to the other party pursuant to the Prior Agreement or this Agreement or otherwise related to the Preparation or distribution of the Product, except as stated below, is of a most highly confidential nature (the "Confidential Information"), and in accepting such data for its internal use the receiving party has agreed and agrees to use such Confidential Information for no other purpose than in furtherance of the transactions contemplated by this Agreement and to protect and maintain such data in strict confidence and not disclose such data, or any part thereof, to any person, firm or other entity, including but not limited to affiliates and subsidiaries of the receiving party, except to (i) employees of the receiving party, or its affiliates or subsidiaries who are bound by legally enforceable written agreements to keep said data confidential; (ii) any government agency if required by law or regulation in connection with the performance of the terms of this Agreement or in support of regulatory filings; or (iii) third parties upon prior written consent of the disclosing party. The confidentiality provisions set forth herein shall survive termination of this Agreement during a period of five (5) years regardless of the cause of termination. The confidentiality provisions shall apply to Confidential Information except to the extent that:  
(i)  
Information is already or will be properly in the public domain at the time of disclosure;  
  
(ii)  
Information is known to the recipient prior to communication by the disclosing party (or its predecessor) as shall be established by competent proof by the recipient;  
  
(iii)  
Information which is required by law, administrative or judicial order to be disclosed, provided that such disclosure is subject to all applicable governmental or judicial protection available for like material and the recipient notifies the disclosing party in writing in advance of such intended disclosure, promptly after the recipient becomes aware of the disclosure requirement.  
 Section 7.2 PPG agrees that it shall not use or assist or permit any other person or party to use any MedImmune Oncology Confidential Information, marketing data, Preparation, distribution or business information obtained as a result of the transactions hereunder, in any way which interferes with the marketing or sales, by MedImmune Oncology or its duly-appointed agents, employees, representatives, distributors, subsidiaries or affiliates, of the Product subject to this Agreement.  
 Section 7.3 Upon expiration or termination of this Agreement, the receiving party shall return to the disclosing party all originals and copies of manuals, correspondence, documents, records or other confidential written instructions it may have received concerning the Preparation of Product except that the receiving party's Legal Department may retain one set of copies of such materials in its secured records for purposes of defining and/or meeting its obligations of confidentiality hereunder or for use as otherwise contemplated in this Agreement. If equipment was purchased by MedImmune Oncology for projects under this Agreement, said equipment will be returned to MedImmune Oncology upon termination of this Agreement unless otherwise specified. Notwithstanding any other provision of this Agreement and subject to Section 7.4 (iv) hereof, PPG agrees that upon expiration or termination of this Agreement, MedImmune Oncology shall have the full unencumbered right without further payment to use PPG Confidential Information related to the Preparation of the Product to Prepare and have others on its behalf Prepare the Product.  
 Section 7.4 PPG agrees to communicate promptly to MedImmune Oncology any ideas and improvements conceived or made by PPG after the Effective Date arising from PPG's activities under this Agreement and relating to the processing or production of the Product (hereinafter referred to as the "Improvement") under the following conditions.  
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(i)  
All rights and title to Improvements (patented, patentable or unpatentable) which are related to said processing or production without any other foreseeable applications shall be assigned to MedImmune Oncology, without cost to MedImmune Oncology, which shall have the right to utilize such Improvements freely in the process of the Product;  
  
(ii)  
All rights and title to Improvements (patented, patentable or unpatentable) which apply to said processing and production and which have also other applications, and provided that specific know-how of PPG developed prior to the execution date of the Prior Agreement is not contained in said Improvements shall be licensed to MedImmune Oncology without cost to MedImmune Oncology (subject to Section 7.4(iv)), on a perpetual, royalty-free worldwide exclusive basis, to utilize such Improvements freely in the process of the Product only;  
  
(iii)  
A perpetual, royalty-free worldwide exclusive license limited to processing or production of the Product shall be granted by PPG to MedImmune Oncology, without cost to MedImmune Oncology (subject to Section 7.4(iv)), for Improvements (patented, patentable or unpatentable) related to said processing and which also have other application but in which specific PPG's know-how developed prior to the execution date of the Prior Agreement is contained; and  
  
(iv)  
In the event that MedImmune Oncology obtains rights pursuant to Section 7.4(ii) or (iii) to any Improvements that materially reduce the cost of the process of the Product and MedImmune Oncology elects to qualify an alternative source(s) using these rights, then MedImmune Oncology agrees to pay a royalty to PPG for such improvements used by such alternative source. This royalty payment will be negotiated in good faith and mutually agreeable terms and will equal (CONFIDENTIAL TREATMENT REQUESTED). PPG agrees that it will assist in the transfer of the technology with PPG's reasonable out-of-pocket expenses paid by MedImmune Oncology.  
 Section 7.5 All proprietary data, technology and information relating to the use, application or manufacture of Product or any improvement, modification or refinement thereof, whether patented or unpatented, which is developed or acquired by PPG shall be treated as Confidential Information first disclosed and made known to PPG by MedImmune hereunder and shall be maintained and administered by PPG in accordance with the provisions of Sections 7.1, 7.2, 7.3 and 7.4. PPG agrees to do and cause to be done all matters and things as it may reasonably and lawfully be required to do to secure to MedImmune Oncology the full right of use and enjoyment thereof in and for all countries, including any and all measures necessary to insure that title to MedImmune Oncology in and to the aforementioned inventions and other materials shall be full and clear of any claim of any of its present or future employees. PPG also agrees to cooperate with MedImmune Oncology to the full extent necessary in the filing and prosecutions of any patent applications, including the execution of any documents required in connections herewith.  
ARTICLE VIII  
WARRANTIES AND INSPECTION  
 Section 8.1 PPG warrants that it will Prepare and test the Products in accordance with cGMPs and the requirements established for the Product in the Specifications.  
 Section 8.2 MedImmune Oncology or its authorized representatives, upon reasonable notice, shall have the right, at its sole cost and expense, to conduct during normal business hours and days quality assurance audits or other inspections of PPG's facilities to inspect and observe PPG compliance with cGMP, PPG's Preparation, quality control and quality assurance procedures. During such audits MedImmune Oncology shall have access to facilities, equipment and documentation.  
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 Section 8.3 PPG shall make available to MedImmune Oncology during quality assurance audits or other inspections all records and documentation relating to the Preparation and quality control of Product. PPG shall also provide MedImmune Oncology, at MedImmune Oncology's reasonable request, with copies of such records during on-site inspections.  
ARTICLE IX  
FORCE MAJEURE  
 Section 9.1 Neither party shall be liable for failure to perform or for delay in performing any provision of this Agreement that such party is required to perform, if such failure or delay is caused by labor disputes, lack of supply of materials through no fault of such party, an act of God, riot, fire, explosion, flood, hostilities of war, executive legislation or administrative order, restriction or controls of any governmental agency, or other conditions reasonably beyond the control of such party. However, if any such cause results in a delay in performance of this Agreement by either party by more than sixty (60) days, then the parties shall meet and discuss what, if any, modifications of the terms of the Agreement may be required in order to arrive at an equitable solution.  
ARTICLE X  
INDEMNIFICATION  
 Section 10.1 Except as provided in Section 10.2, MedImmune Oncology agrees to indemnify and hold PPG harmless from and against any loss, damage, liability or expense to PPG (including without limitation reasonable attorneys fees) arising out of or in connection with (i) any action, suit, claim, demand or prosecution that may be brought or instituted against PPG based on or arising out of MedImmune Oncology's distribution of Product, and (ii) any recalls involving Product. Notwithstanding harmless PPG to the extent that any such action, suit, claim, demand, or prosecution arises out of PPG's failure to conform to cGMPs or other applicable regulatory standard, or out of PPG's negligence, willful misconduct, or illegal conduct.  
 Section 10.2 PPG agrees to indemnify and hold MedImmune Oncology harmless from and against any loss, damage, liability or expense (including without limitation reasonable attorneys fees) arising out of or in connection with any action, suit, claim, demand or prosecution that may be brought or instituted against MedImmune Oncology resulting from:  
(i)  
Product that materially failed to meet the Specifications at the time of shipment, unless such failure was or reasonably should have been detected by MedImmune Oncology utilizing the testing procedures then in effect on receipt of the Product in compliance with the provisions of Section 4.6;  
  
(ii)  
PPG's negligence or its failure to comply with applicable law or government regulations or cGMP with respect to PPG's responsibilities in the Preparation of Product unless such failure was detected by MedImmune Oncology utilizing the testing procedures then in effect on receipt of the Product in compliance with the provisions of Sections 4.6; or  
  
(iii)  
Breach by PPG of any covenant, representation, or warranty contained in the Agreement unless such failure was detected by MedImmune Oncology utilizing the testing procedures then in effect on receipt of the Product in compliance with the provisions of Sections 4.6.  
 Section 10.3 If any action, suit, claim, demand or prosecution (collectively, an "Action") is brought against a party (the "Indemnitee") in respect of indemnification which may be sought hereunder, the Indemnitee shall immediately notify the party who is to Indemnify (the "Indemnitor") of such Action and shall extend to the Indemnitor the opportunity to defend against such Action, at the Indemnitor's sole expense and through legal counsel reasonably acceptable to Indemnitee, provided that the  
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Indemnitor proceeds in good faith, expeditiously and diligently. Indemnitee shall, at its option and expense, have the right to participate in any defense undertaken by Indemnitor with legal counsel of its own selection. No settlement or compromise of any action may be made by Indemnitee without the prior written consent of Indemnitor.  
ARTICLE XI  
TERM OF AGREEMENT  
 Section 11.1 This Agreement shall come into effect on the Effective Date as set forth at the beginning hereof and shall supersede the Prior Agreement thereafter. Unless earlier terminated in accordance with the provisions hereof, this Agreement shall remain in force until December 31, 2005. This Agreement shall automatically be then extended for consecutive two (2) year periods, unless either party notifies the other, in writing, of its intention not to renew at least (CONFIDENTIAL TREATMENT REQUESTED) prior to the expiration of the initial term of this Agreement or at any time thereafter.  
 Section 11.2 Upon early termination of this Agreement consequent to a failure by PPG, PPG will cooperate fully with MedImmune Oncology to facilitate transfer of all manufacturing aspects, equipment, material, documentation and all other items related to the manufacture of Products to any MedImmune Oncology identified alternative manufacturing site(s). Should MedImmune Oncology be unable to identify, qualify and receive FDA approval of any alternative manufacturing site within the (CONFIDENTIAL TREATMENT REQUESTED) notification period provided in Section 11.1 despite all reasonable efforts and due diligence, PPG will continue to manufacture the Product for an additional (CONFIDENTIAL TREATMENT REQUESTED) grace period or until an appropriate manufacturing site is able to produce the Product, whichever occurs first. PPG's cooperation in facilitating such transfer shall be at no cost to MedImmune Oncology.  
 Section 11.3 Notwithstanding the cause of termination, the foregoing undertakings of confidentiality, non-use and non-competition agreed to in this Agreement shall continue and remain in full force and effect subject to provisions of Section 2.6.  
 Section 11.4 Either party may terminate this Agreement for a material breach by the other party by giving the breaching party written notice, specifying the breach relied on, and giving the breaching party (CONFIDENTIAL TREATMENT REQUESTED) to cure such breach. If the default has not been cured at the end of the (CONFIDENTIAL TREATMENT REQUESTED) period, then, upon notice thereof to the breaching party by the other, this Agreement shall terminate.  
 Section 11.5 In the event of filing of a petition of bankruptcy or insolvency by either party or the appointment of a receiver for property of either party, the other party may immediately terminate this Agreement with no liability whatsoever to the first party, subject however to relevant legislation.  
 Section 11.6 Any termination of this Agreement will have no effect on performance obligations or amounts to be paid which have accrued up to the effective date of such termination.  
ARTICLE XII  
MISCELLANEOUS  
 Section 12.1 The parties hereto undertake to use every reasonable endeavor to carry out the terms and the respective obligations of this Agreement but should the action of their parties or economic conditions outside the control of either party, create a situation in which the effect of any provisions hereof is severely inequitable, then the parties agree to negotiate in good faith for such revision of this Agreement as may be reasonable to reach an equitable resolution, including early termination.  
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 Either party desiring to negotiate for revision in accordance with this Section shall give the other party a statement in writing setting forth the circumstances of the hardship suffered from, with a request for a meeting of representatives at the time and place convenient to such party in a period between thirty (30) and sixty (60) days following the request. The other party shall not withhold its agreement unreasonably.  
 Section 12.2 All notices given or requests made under this Agreement shall be in writing and shall be delivered or mailed by certified or registered mail with a return receipt requested or by a reputable express delivery service to the party for which it is intended at its address as set forth below, or at such other addresses as the addressee may have designated to the other party in writing. Any notice shall be deemed given only upon actual delivery thereof at the proper address.  
All notices to MedImmune Oncology shall be addressed to:  
  
   
   
MedImmune Oncology, Inc.  
 c/o MedImmune, Inc.  
 000 Xxxxxxxx Xxxxx  
 Xxxxxxxxx, XX 00000  
  
   
   
Attn: Senior Director, Materials Management and Contract manufacturing with a copy to the office of the General Counsel, Business Development Dept. located at  
  
   
   
MedImmune, Inc.  
 00 Xxxx Xxxxxxx Xxxx Xxxx  
 Xxxxxxxxxxxx, XX 00000  
  
All notices to PPG shall be addressed to:  
  
   
   
Attn: Business Manager, PPG-Xxxxx US Operations with a copy to the office of the General Counsel  
 PPG Sispy, A Unit of PPG-Industries, Inc.  
 Xxx XXX Xxxxx, 00xx Xxxxx  
 Xxxxxxxxxx, XX 00000 XXX  
 Section 12.3 The parties hereto shall use their best efforts to settle amicably any controversy arising out of this Agreement. Should no amicable settlements be reached, any dispute arising in connection with this Agreement shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The place of arbitration shall be New York, New York. Language of arbitration shall be the English language.  
 Section 12.4 This Agreement shall inure to the benefit of and be binding upon the undersigned parties, their respective legal successors and assigns. This Agreement specifically contemplates that either party shall have the right to assign their rights and duties under this Agreement, subject to prior approval of the other, such approval not to be unreasonably withheld. In the event that this Agreement is assigned to a third party, the assignor shall remain responsible for the performance of the obligations by its assignee herein and the assignor shall remain severally and jointly liable with the assignee for the failure to perform its obligations provided for herein.  
 Section 12.5 PPG shall notify MedImmune Oncology promptly after any change of control of PPG. MedImmune Oncology shall have the right to reasonably terminate this Agreement by notice to PPG within 60 days after receipt of PPG's notice in accordance with the preceding sentence, such termination to take effect 180 days after the change of control. For purposes of this Agreement a "change in control" shall mean (i) a merger, consolidation or combination in which PPG is not the surviving corporation; (ii) a change in ownership such that any person or entity becomes the beneficial  
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owner, directly or indirectly of 50% or more of the combined voting power of PPG's then outstanding voting securities; or (iii) a purchase of the business or assets of PPG necessary to perform the services contracted for hereunder.  
 Section 12.6 This Agreement may not be changed, waived, discharged, or terminated orally, but only by an instrument in writing signed by the parties.  
 Section 12.7 The parties agree that the provision of the Agreement, together with any amendments, schedules and attachments hereto, represent the entire agreement between them with respect to the subject matter hereof and supersede any other agreements or understandings they may have with respect thereto.  
 Section 12.8 This Agreement shall be governed by and construed, interpreted, enforced and applied in accordance with the law of the State of New York.  
 Section 12.9 This Agreement shall be executed in duplicate originals with each party retaining one original for its files.  
 Section 12.10 The invalidity of one or more provisions of this Agreement shall not affect the validity of the Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the parties would not have entered into this Agreement without the invalid provisions.  
 Section 12.11 Should any part of this Agreement be in conflict with any applicable law, all other provisions of this Agreement shall remain in force and the parties hereto shall mutually and in good faith modify the conflicting provisions so as to maintain essentially the spirit hereof and the original will of the parties.  
 Section 12.12 Nothing herein contained shall be deemed to create any relationship in the nature of agency, joint venture, partnership or similar relationship between MedImmune Oncology and PPG. PPG, its agents, employees, and dealer under no circumstances shall be deemed to be agents, or representatives of MedImmune Oncology, nor will any of them have the right to enter into any contracts or commitments in the name of MedImmune Oncology or otherwise bind or commit MedImmune Oncology.  
 Section 12.13 Affirmative Action Notice: PPG is hereby notified that PPG and any subcontractors permitted hereunder may be subject to the provisions of 41 CFR Section 60-1.4, 41 CFR 60-250.4 and 41 CFR Section 60-741.4 with respect to affirmative action program and plan requirements.  
 WITNESS the signatures on behalf of the parties hereto by their duly authorized representatives making this Agreement effective as of the date first set forth above.  
MEDIMMUNE ONCOLOGY, INC. PPG INDUSTRIES, INC.  
  
By:  
/s/ XXXXXX X. XXXXX   
Xxxxxx X. Xxxxx  
   
By:  
/s/ XXXXXX XXX XXXXXX   
Xxxxxx Xxx Xxxxxx  
Title: President Title: Vice President  
Date: 1/24/01 Date: 1/18/01  
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