

EX-10.80 6 dex1080.htm COLLABORATION AGREEMENT

Exhibit 10.80

Execution Copy

Collaboration Agreement
By and Between
Amgen Inc.
and
Daiichi Sankyo Company, Limited
Dated
July 11, 2007

CONFIDENTIAL

Amgen Contract #200710717

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

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Collaboration Agreement

This Collaboration Agreement (this “*Agreement*”) is entered into as of the 11th day of July, 2007 (the “*Effective Date*”) by and between Amgen Inc., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, CA 91320-1799 (“*Amgen*”) and Daiichi Sankyo Company, Limited, a Japanese corporation with a principal place of business at 3-5-1 Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426 (“*Collaborator*”). Amgen and Collaborator are sometimes referred to herein individually as a “*Party*” and collectively as the “*Parties*.”

Recitals

WHEREAS, Amgen is a global biotechnology company that conducts pharmaceutical research, development, manufacturing and commercialization;

WHEREAS, Amgen is developing Dmab (as defined below) for the potential treatment of osteoporosis, cancer, rheumatoid arthritis, and other diseases and conditions;

WHEREAS, Amgen wishes to partner with Collaborator for the development and commercialization of Dmab in the Territory (as defined below) in accordance with the terms and conditions hereof;

WHEREAS, Collaborator has existing development and commercialization capabilities in the Territory;

WHEREAS, Collaborator wishes to partner with Amgen with respect to the development and commercialization of Dmab in the Territory in accordance with the terms and conditions hereof;

WHEREAS, the Parties have disputes [*] of various patents relating to [*] owned by each of the Parties [*] (collectively the “*Patent Disputes*”); and

WHEREAS, the Parties wish to [*] settle the Patent Disputes on a world-wide basis.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, the Parties hereto agree as follows:

1. DEFINITIONS

- 1.1. “*Affiliate*” shall mean any corporation or other entity which directly or indirectly controls, is controlled by or is under common control with a Party, for so long as such control exists. For the purposes of this Section 1.1 (“*Affiliate*”), “control” shall mean: (i) in the case of any corporate entity, direct or indirect ownership of more than fifty percent (50%) of the stock having the right to vote for the election of directors thereof; or (ii) in the case of any non-corporate entity, direct or indirect ownership of more than fifty percent (50%) of the equity or income interest therein.
- 1.2. “*Aggregate Maximum*” shall have the meaning set forth in Section 8.8.2 (Maximum Payments).
- 1.3. “*Agreement*” shall have the meaning set forth in Page 3, Paragraph 1.

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- 1.4. “*Amgen Additional Indication*” shall have the meaning set forth in Section 6.2.1 (Amgen Developed Indications).
 - 1.5. “*Amgen Assumed Item*” shall have the meaning set forth in Section 10.3.1.2 (Amgen [*] Prosecution).
 - 1.6. “*Amgen Development Costs*” shall mean Amgen’s (and its Affiliates’) fully-burdened, world-wide development costs [*] related to development of Dmab, as more specifically set forth in the Development Costs Schedule.
 - 1.7. “*Amgen Development Data*” shall mean the preclinical and clinical data generated by or on the behalf of Amgen or its Affiliates (both within and outside the Territory) in the course of its preclinical and clinical development of Dmab, both before and after the Effective Date of this Agreement.
 - 1.8. “*Amgen Indemnitees*” shall have the meaning set forth in Section 14.1 (Indemnity).
 - 1.9. “*Amgen Net Sales*” shall mean Net Sales in the Territory made by or on the behalf of Amgen, its Affiliates or licensees. Amgen Net Sales shall not include sales made to, by or on behalf of Collaborator.
 - 1.10. “*Annual Maximum*” shall have the meaning set forth in Section 8.8.2 (Maximum Payments).
 - 1.11. “*Bundle*” shall mean Dmab sold together with another pharmaceutical compound for a single price.
 - 1.12. “*Calendar Quarter*” shall mean a three-month period beginning on January, April, July or October 1st.
 - 1.13. “*Calendar Year*” shall mean a one-year period beginning on January 1st and ending on December 31st.
 - 1.14. “*Change of Control*” shall mean, with respect to a Party, the occurrence of any of the following events: [*].
 - 1.15. “*Claims*” shall have the meaning set forth in Section 14 (Indemnification).
 - 1.16. “*Collaboration*” shall mean the activities conducted by the Parties hereunder with respect to the development and commercialization of Dmab in the Territory, as described in more detail herein.
 - 1.17. “*Collaborator*” shall have the meaning set forth in Page 3, Paragraph 1.
 - 1.18. “*Collaborator Development Data*” shall mean the preclinical and clinical data generated by or on behalf of Collaborator or its Affiliates in the course of its preclinical (if any) and clinical development of Dmab, on or after the Effective Date of this Agreement.
 - 1.19. “*Collaborator Indemnitees*” shall have the meaning set forth in Section 14.1 (Indemnity).
 - 1.20. “*Collaborator Indications*” shall mean: (i) any and all uses for Oncology indications being developed by Amgen outside the Territory; (ii) any and all uses for the treatment, palliation, prevention or prophylaxis of osteoporosis or rheumatoid arthritis; and (iii)

any other indications that have been added to the definition of Collaborator Indication pursuant to Sections 6.2.1 (Amgen Developed Indications) or 6.2.2 (Collaborator Proposed Indications).

- 1.21. “*Collaborator Net Sales*” shall mean Net Sales made by or on behalf of Collaborator, its Affiliates or licensees in the Territory.
- 1.22. “*Commercialization Committee*” shall mean the committee established by the Parties to oversee and coordinate the commercialization of Dmab in the Territory.
- 1.23. “*Competing Product*” shall mean: (i) any [*], [*],[*]; and (ii) any product that, as a therapeutic mechanism of action,[*]. Competing Product shall not include Dmab.
- 1.24. “*Competing Program*” shall mean the [*], in the Territory, of any Competing Product. Notwithstanding the foregoing, [*] of a Competing Product in the Territory [*]of such Competing Product [*] shall not be considered a Competing Program.
- 1.25. “*Competing Transaction*” shall mean any transaction entered into by a Party or its Affiliate after the Effective Date whereby a Third Party that is engaged in a Competing Program becomes an Affiliate of such Party.
- 1.26. “*Competing Transaction Affiliates*” shall mean those entities that become Affiliates of a Party by virtue of a Competing Transaction.
- 1.27. “*Competing Transaction Party*” shall mean the Party that enters into a Competing Transaction.
- 1.28. “*Confidential Information*” shall have the meaning set forth in Section 11.1 (Confidentiality; Exceptions).
- 1.29. “*Contract Interest Rate*” shall mean [*] plus the [*] rate effective for the date that payment was due, as published by The Wall Street Journal, Eastern U.S. Edition, on the date such payment was due (or, if unavailable on such date, the first date thereafter on which such rate is available), or, if lower, the maximum rate permitted by Law.
- 1.30. “*Control*” shall mean, with respect to any Information or intellectual property, that the applicable Party owns or has a license to such Information or intellectual property and has the ability to grant to the other Party access to and a license or sublicense (as applicable) under such Information or intellectual property as set forth herein without violating the terms of any agreement with any Third Party as of the time such Party would first be required hereunder to grant such access and license or sublicense, or requiring any payment under any agreement with any Third Party.
- 1.31. “*Defending Party*” shall have the meaning set forth in Section 10.4 (Defense and Settlement of Third Party Claims).
- 1.32. “*Development Committee*” shall mean the committee established by the Parties to oversee and coordinate the development of Dmab in the Territory.
- 1.33. “*Divest*” shall mean, with respect to any Competing Program, the sale, exclusive license or other transfer of all of the right, title and interest in and to such Competing Program, including technology, intellectual property and other assets materially relating thereto, to an independent Third Party, without the retention or reservation of any rights or interest (other than solely an economic interest) in such Competing Program by the Competing Transaction Party or its Affiliates.

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- 1.34. “*Dmab*” shall mean Amgen’s proprietary product denosumab, a fully human monoclonal antibody that targets the receptor activator of nuclear factor Kappa B Ligand. [*].
- 1.35. “*Effective Date*” shall have the meaning set forth in Page 3, Paragraph 1.
- 1.36. “*Federal Court*” shall have the meaning set forth in Section 16.11 (Jurisdiction and Venue).
- 1.37. “*First Commercial Sale*” shall mean the first sale of Dmab following Regulatory Approval by or on the behalf of Amgen or Collaborator, or its or their respective Affiliates or licensees.
- 1.38. “*Force Majeure*” shall have the meaning set forth in Section 16.8 (Force Majeure).
- 1.39. “*FTE*” shall mean the equivalent of the work of one employee full time for one year (consisting of at least a total of 45.5 weeks or 1,820 hours per year (excluding vacations and holidays)). Overtime, and work on weekends, holidays and the like shall not be counted with any multiplier (e.g., time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution.
- 1.40. “*FTE Rate*” shall mean \$[*] per full-time employee per year (as of the Effective Date), increasing by [*] ([*]%) of the then-current FTE Rate on January 1st of 2008 and each subsequent Calendar Year.
- 1.41. “*GAAP*” shall mean either Japanese or U.S. generally accepted accounting principles, consistently applied, as used by a Party to record the relevant transaction.
- 1.42. “*Governmental Authority*” shall mean any government administrative agency, commission or other governmental authority, body or instrumentality, or any federal, state, local, domestic or foreign governmental regulatory body.
- 1.43. “*Indemnified Party*” shall have the meaning set forth in Section 14.2 (Claim for Indemnification).
- 1.44. “*Indemnifying Party*” shall have the meaning set forth in Section 14.2 (Claim for Indemnification).
- 1.45. “*Information*” shall mean all tangible and intangible techniques, information, technology, practices, trade secrets, inventions (whether patentable or not), methods, knowledge, know-how, conclusions, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms.
- 1.46. “*Joint Patents*” shall mean any invention, patent or patent application jointly owned by the Parties pursuant to Section 10.1 (Ownership).
- 1.47. “*Law*” shall mean, individually and collectively, any and all laws, ordinances, rules, directives and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.
- 1.48. “*Licensed Amgen Know-How*” shall mean Information in Amgen’s (or its Affiliate’s) possession and Control, as of the Effective Date or thereafter during the Term, that is reasonably necessary for Collaborator to develop or commercialize Dmab in the Territory in the Collaborator Indications. Licensed Amgen Know-How shall include

Amgen Development Data that is reasonably necessary for Collaborator to develop or commercialize Dmab in the Territory in the Collaborator Indications. Licensed Amgen Know-How does not include Amgen manufacturing information.

- 1.49. “*Licensed Amgen Patents*” shall mean those patents and patent applications set forth on the Licensed Amgen Patents Schedule, as well as any continuation, divisional, substitution, continuations-in-part, reissue, reexamination, provisional and converted provisional applications thereof [*]. For purposes of determining whether a patent application falls within this definition, a patent application shall be considered “infringed” if its pending claims would be infringed if issued as then currently set forth in the patent application.
- 1.50. “*Licensed Amgen Trademarks*” shall mean any trademark rights Controlled by Amgen in the Territory on or after the Effective Date and corresponding to any trademarks adopted by Amgen for use with Dmab outside the Territory (not including any corporate or house marks, and not including any such marks to the extent such marks would conflict with any right of any Third Party inside the Territory).
- 1.51. “*Licensed Collaborator Know-How*” shall mean Information in Collaborator’s (or its Affiliate’s) possession and Control, as of the Effective Date or thereafter during the Term, that is reasonably necessary for Amgen to develop or commercialize Dmab within or outside the Territory in any indication. Licensed Collaborator Know-How shall include Collaborator Development Data that is reasonably necessary for Amgen to develop or commercialize Dmab within or outside the Territory in any indication.
- 1.52. “*Licensed Collaborator Patents*” shall mean those patents and patent applications set forth on the Licensed Collaborator Patents Schedule, as well as any continuation, divisional, substitution, continuations-in-part, reissue, reexamination, provisional and converted provisional applications thereof [*]. For purposes of determining whether a patent application falls within this definition, a patent application shall be considered “infringed” if its pending claims would be infringed if issued as then currently set forth in the patent application.
- 1.53. “*Licensed Collaborator Trademarks*” shall mean any trademarks adopted by Collaborator for use with Dmab in the Territory in the Collaborator Indications (not including any corporate or house marks).
- 1.54. “*Losses*” shall have the meaning set forth in Section 14.1 (Indemnity).
- 1.55. “*MHLW*” shall mean the Japanese Ministry of Health, Labour and Welfare, and any successor agency thereto.
- 1.56. “*Net Sales*” shall mean with respect to a given period, the gross invoiced sales price for Dmab sold by or for a Party, its Affiliates or licensees hereunder to Third Parties (not including such Party’s licensees hereunder, unless and to the extent such licensee is the end-user of such Dmab) during such period, less the total of the following charges or expenses, as determined in accordance with GAAP:
- 1.56.1. Trade, cash, prompt payment and quantity discounts;
- 1.56.2. Returns, allowances, rebates, chargebacks and payments to government agencies;

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- 1.56.3. Retroactive price reductions;
 - 1.56.4. Fees paid to distributors, wholesalers, selling agents (excluding any sales representatives of a Party or any of its Affiliates), group purchasing organizations and managed care entities;
 - 1.56.5. Credits and allowances for product replacement, whether cash or trade; and
 - 1.56.6. Non-recoverable sales taxes, excise taxes, tariffs and duties (excluding taxes when assessed on income derived from sales); in each case, to the extent related to sales of Dmab in the Territory and actually given.
- 1.57. “*Oncology*” shall mean any and all uses for the treatment, palliation, prevention or prophylaxis of cancer or other uncontrolled cell proliferation (including myeloma), and the treatment, palliation, prevention or prophylaxis of the effects of cancer or cancer treatment.
- 1.58. “*Ongoing Oncology Study*” shall have the meaning set forth in Section 4.7 (Global Development).
- 1.59. “*Party/Parties*” shall have the meaning set forth in Page 3, Paragraph 1.
- 1.60. “*Patent Disputes*” shall have the meaning set forth in the recitals.
- 1.61. “*Payee Party*” shall mean the Party receiving or entitled to receive a payment pursuant to Article 8 (Payment).
- 1.62. “*Payor Party*” shall mean the Party making or obligated to make a payment pursuant to Article 8 (Payment).
- 1.63. “*Prior Agreement*” shall have the meaning set forth in Section 11.4 (Prior Agreement).
- 1.64. “*Publishing Party*” shall have the meaning set forth in Section 11.5 (Publications).
- 1.65. “*Quarterly Maximum*” shall have the meaning set forth in Section 8.8.2 (Maximum Payments).
- 1.66. “*Reasonably Diligent Efforts*” shall mean, with respect to a Party, the application of a level of resources, efforts and urgency to develop and commercialize Dmab consistent with such Party’s practices in pursuing the development and commercialization of its other high-value pharmaceutical products with similar value and market potential to Dmab in light of its characteristic features, target indication, competitiveness and sales volume, but in no event less than the high professional standards and level commonly applied by other pharmaceutical companies to their high-value pharmaceutical products. For clarity, it is understood that Reasonably Diligent Efforts shall not take into account: (i) any other pharmaceutical product such Party is then discovering, researching, developing, manufacturing or commercializing outside the Collaboration, alone or with one or more collaborators; or (ii) the payments required to be made by such Party to the other Party pursuant to this Agreement.
- 1.67. “*Recall*” means a “recall” (as per Article 70 of the Japanese Pharmaceutical Affairs Law) or “market withdrawal” (as per Article 77-4-3 of the Japanese Pharmaceutical Affairs Law) of Dmab or any lots thereof.

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- 1.68. “*Recoveries*” shall mean all cash amounts (plus the fair market value of all non-cash consideration) received by a Party from a Third Party in connection with the final judgment, award or settlement of any enforcement with respect to any Licensed Amgen Patent, Licensed Amgen Trademark, Licensed Amgen Know-How, Licensed Collaborator Patent, Licensed Collaborator Trademark, Licensed Collaborator Know-How, or Joint Patent, each of the foregoing in the Territory.
- 1.69. “*Regulatory Approval*” shall mean the product-specific approvals necessary for the distribution, use and sale of Dmab.
- 1.70. “*Regulatory Filing*” shall mean any filing with any Governmental Authority with respect to the development, marketing, commercialization or reimbursement of Dmab.
- 1.71. “[*]” shall mean clinical development that, as reasonably demonstrated by [*], either: (i) is [*]; or (ii) [*].
- 1.72. “*Reviewing Party*” shall have the meaning set forth in Section 11.5 (Publications).
- 1.73. “*Settled Patents*” shall mean all patents and patent applications set forth on the Settled Patents Schedule, as well as any continuation, divisional, substitution, continuations-in-part, reissue, reexamination, provisional and converted provisional applications thereof, as well as any patent or patent application [*] as well as any continuations, divisionals, substitutions, continuations-in-part, reissues, reexaminations, provisional and converted provisional applications thereof.
- 1.74. “*Sites*” shall have the meaning set forth in Section 4.18 (Transition in Oncology Development).
- 1.75. “*SOPs*” shall have the meaning set forth in Section 4.16 (Recalls).
- 1.76. “*SPC*” shall mean any patent term extension or related extension of rights, including supplementary protection certificates and similar rights.
- 1.77. “*State Court*” shall have the meaning set forth in Section 16.11 (Jurisdiction and Venue).
- 1.78. “*Taxes*” shall mean any tax, excise or duty, other than taxes upon income.
- 1.79. “*Term*” shall mean the period beginning on the Effective Date and ending on [*], any sooner termination of this Agreement pursuant to Article 15 (Term and Termination) or, in the event of a written extension to this Agreement, such date as specified therein.
- 1.80. “*Termination Date*” shall have the meaning set forth in Section 15.3.1.
- 1.81. “*Territory*” shall mean Japan.
- 1.82. “*Territory IP*” shall have the meaning set forth in Section 10.5.1 (In Territory).
- 1.83. “*Territory Patents and Trademarks*” shall have the meaning set forth in Section 10.3.1.1 (Collaborator [*] Prosecution).
- 1.84. “*Third Party*” shall mean any entity other than a Party or an Affiliate of a Party.
- 1.85. “*Transition Period*” shall have the meaning set forth in Section 15.5 (Transition Period).

1.86. “VAT” shall mean any value added tax.

1.87. *Additional Definitions.* Each of the following capitalized terms shall have the meanings set forth in the corresponding Sections of this Agreement indicated in the table below:

| Definition | Section |
|-------------------------------|--|
| “Amgen” | <i>Preamble</i> |
| “Amgen K.K.” | <i>Section 3.7.1</i> |
| “Amgen Royalty Percentage” | <i>Section 15.3.5</i> |
| “Drug Product” | <i>Schedule: Supply Agreement Term Sheet</i> |
| “Oncology Approval” | <i>Section 8.1.2</i> |
| “Partnering Share Percentage” | <i>Section 15.3.5</i> |
| “Prior Agreement” | <i>Section 11.4</i> |

2. COLLABORATION SCOPE AND GOVERNANCE

- 2.1. Conduct of the Collaboration. The Parties shall cooperate to develop and commercialize Dmab in the Territory, in accordance with the terms and conditions of this Agreement.
- 2.2. Ex-Territory Activities. The Parties acknowledge that no rights are granted hereunder to Collaborator with respect to any country outside the Territory, and that Collaborator shall have no authority with respect to the research, development, manufacture or commercialization of Dmab outside the Territory. Amgen shall have the sole right to research, develop, manufacture and commercialize Dmab outside the Territory.
- 2.3. Activities in Competition with the Collaboration. Except as set forth in Sections 2.4 (Post-Effective Date Affiliates) and 2.5 (Termination or Divestiture), during the Term, [*] shall, itself or through its Affiliates, conduct, participate in, or advise, assist or enable any Third Party to conduct or participate in, any Competing Program.
- 2.4. Post-Effective Date Affiliates. In the event that either Party enters into a Competing Transaction then the Competing Transaction Party shall provide notice to the other Party, within five (5) business days of the closing of the Competing Transaction, specifying the identity of the Competing Transaction Affiliate(s) and describing in reasonable detail, to the extent permitted by Law and without disclosing any proprietary information, the Competing Program and its focus. During the pendency of any potential Competing Transaction, and until the provisions of Section 2.5 (Termination or Divestiture) are effectuated, the Competing Transaction Party shall ensure that information and materials relating to the Collaboration are not shared with or used for the benefit of, and are sequestered from, such Competing Transaction Affiliate(s).

- 2.5. Termination or Divestiture. The notice provided pursuant to Section 2.4 (Post-Effective Date Affiliates) shall include a notification as to whether the Competing Transaction Party intends to: (i) Divest the Competing Program, in which case the Competing Transaction Party shall hold separate such Competing Program (including ensuring that no personnel working directly on the Collaboration works on a Competing Program (and vice versa), and ensuring that information from the Collaboration is sequestered from personnel working directly on the Competing Program (and vice versa)) and use its commercially reasonable, good-faith efforts to Divest such Competing Program; in the foregoing case, the Competing Transaction Party and its Affiliates (including Competing Transaction Affiliates) shall not assert any intellectual property or proprietary right of the Competing Program to obstruct the Parties' (or their Affiliates' or sublicensees') efforts under the Collaboration or Amgen's (or its Affiliates' or sublicensees') efforts with respect to Dmab outside the Territory during such divestiture period; (ii) terminate such Competing Program, in which case the Competing Transaction Party shall terminate all activities of such program within one hundred and twenty (120) days of the closing of the Competing Transaction, during which period the Competing Transaction Party shall hold separate such Competing Program (including ensuring that no personnel working directly on the Collaboration works on a Competing Program (and vice versa), and ensuring that information from the Collaboration is sequestered from personnel working directly on the Competing Program (and vice versa)); in the foregoing case, the Competing Transaction Party and its Affiliates (including Competing Transaction Affiliates) shall not assert any intellectual property or proprietary right of the Competing Program to obstruct the Parties' (or their Affiliates' or sublicensees') efforts under the Collaboration or Amgen's (or its Affiliates' or sublicensees') efforts with respect to Dmab outside the Territory during such termination period or thereafter; or (iii) if Collaborator is the Party providing such notice, [*] pursuant to Section [*] unless the Competing Program constituted the majority of the assets acquired by Collaborator in the Competing Transaction in which case such [*]; during the pendency of such termination and any transition pursuant to Section 15.5 (Transition Period), Collaborator shall hold separate such Competing Program (including ensuring that no personnel working directly on the Collaboration works on a Competing Program (and vice versa), and ensuring that information from the Collaboration is sequestered from personnel working directly on the Competing Program (and vice versa)). In the event the Competing Transaction Party selects option (i) and fails to complete such divestiture within one year of the closing of the Competing Transaction, then such Party shall be deemed to have chosen option (ii), effective as of such one year anniversary, and shall promptly comply with the requirements of such subsection (ii), above.
- 2.6. Governance. The Collaboration shall be governed by a Development Committee and a Commercialization Committee, which shall coordinate and oversee the development and commercialization, respectively, of Dmab in the Territory. Each such committee shall be formed promptly following the Effective Date.
- 2.7. Membership. Each of the committees shall be comprised of three (3) members appointed by Amgen, and three (3) members appointed by Collaborator. Each committee shall be led by two (2) co-chairs, one (1) appointed by each of the Parties.

Each of the committees shall have the right to delegate any of its responsibilities to one or more subcommittees as it determines appropriate.

- 2.8. Replacement of Members. Each Party shall have the right to replace its committee members or co-chairs by written notice to the other Party. In the event any committee member or co-chair becomes unwilling or unable to fulfill his or her duties hereunder, the Party that appointed such member shall promptly appoint a replacement by written notice to the other Party.
- 2.9. Input from other Personnel. Any committee member shall have the right to solicit input or assistance from any other personnel of the Party that appointed such member.
- 2.10. No Authority to Amend or Modify. Notwithstanding anything herein to the contrary, no committee shall have any authority to amend, modify or waive compliance with this Agreement.
- 2.11. Development Committee. The Development Committee shall be responsible for: (i) reviewing and approving development plans (and changes thereto) for Dmab in the Territory prior to adoption of such plans or changes by a Party; (ii) providing for communication and discussion between the Parties to optimize the efficacy and safety of the development of Dmab in the Territory; (iii) reviewing and monitoring the activities and progress against the development plans, including site enrollment, patient enrollment, progress of trials and data received; (iv) communicating with the Commercialization Committee regarding the interrelationship between development activities and potential commercialization of Dmab in the Territory; (v) monitoring and reporting on the competitive landscape for Dmab in the Territory (in consultation with the Commercialization Committee); and (vi) communicating with the Parties regarding all of the foregoing.
- 2.11.1. *Meetings*. The Development Committee shall meet quarterly in person or telephonically (with at least two meetings per Calendar Year being in person), more frequently as may be required by ongoing development activities, or as otherwise agreed by the Parties. Any in-person meetings shall be held on an alternating basis between Collaborator's and Amgen's facilities, unless otherwise agreed by the Parties. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend Development Committee meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings as reasonably required to resolve particular matters requested by such Party by at least five (5) business days written notice to the co-chair appointed by the other Party.
- 2.11.2. *Reporting*. Each Party shall keep the Development Committee fully and promptly informed of progress and results of development activities for which it is responsible or that it is permitted to conduct hereunder through its members on the Development Committee and as otherwise provided herein, including by promptly providing copies of all clinical data and results for Dmab as reasonably requested by the other Party. Each Party shall fully inform the Development Committee with respect to all relevant facts and activities regarding any Dmab

development matter reasonably requested by any member thereof. At least five (5) business days prior to the first Development Committee meeting of each Calendar Quarter, each Party shall deliver to the Development Committee a written summary of development activities conducted hereunder and material clinical data and results received by each such Party since the last such report.

2.11.3. *Development Plans.* At least five (5) business days prior to the first Development Committee meeting of each Calendar Year, Collaborator (and, during the transition period referenced in Section 15.5 (Transition Period) and any other period during which Amgen is developing any Amgen Additional Indication in the Territory, Amgen) shall provide the Development Committee a copy of its proposed development plan for Dmab in the Territory for the next four Calendar Quarters for the Development Committee's review, comment and approval (with Collaborator and Amgen (should Amgen be developing any Amgen Additional Indication in the Territory) each having its own development plan (either by indication or for all indications for which it is responsible in the Territory)). In addition, should a Party seek to make material changes to an approved development plan, then at least five (5) business days prior to the next meeting of the Development Committee it shall provide the Development Committee any proposed changes to the previously approved development plan for the Development Committee's approval.

2.11.4. *Decision Making.* The Development Committee shall strive to reach consensus on decisions, taking into account the views of each committee member. In the event the committee fails to reach consensus, the committee [*] determination unless the decision relates primarily to [*], in which case the committee [*] determination (in all cases subject to [*]).

2.12. Commercialization Committee. The Commercialization Committee shall be responsible for: (i) reviewing and approving commercialization plans (and changes thereto) for Dmab in the Territory prior to adoption of such plans or changes by a Party; (ii) communicating with the Development Committee regarding the interrelationship between development activities and potential commercialization of Dmab in the Territory; (iii) reviewing and monitoring the activities and progress against the commercialization plans; (iv) monitoring and reporting on the competitive landscape for Dmab in the Territory; (v) establishing appropriate processes for coordinating review of promotional materials for the Territory to ensure compliance with Law and industry best practices; (vi) overseeing the trademark and publication strategies for the Territory; and (vii) communicating with the Parties regarding all of the foregoing.

2.12.1. *Meetings.* The Commercialization Committee shall meet quarterly in person or telephonically (with at least two meetings per Calendar Year being in person), more frequently as may be required by ongoing commercialization activities, or as otherwise agreed by the Parties. Any in-person meetings shall be held on an alternating basis between Collaborator's and Amgen's facilities, unless otherwise agreed by the Parties. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend Commercialization Committee

meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings as reasonably required to resolve particular matters requested by such Party by at least five (5) business days written notice to the co-chair appointed by the other Party.

- 2.12.2. *Reporting.* Each Party shall keep the Commercialization Committee fully and promptly informed of progress and results of commercialization activities in the Territory for which it is responsible or that it is permitted to conduct hereunder through its members on the Commercialization Committee and as otherwise provided herein. Each Party shall fully inform the Commercialization Committee with respect to all relevant facts and activities regarding any Dmab commercialization matter reasonably requested by any member thereof. At least five (5) business days prior to the first Commercialization Committee meeting of each Calendar Quarter, each Party shall deliver to the Commercialization Committee a written summary of commercialization activities conducted hereunder by each such Party since the last such report.
- 2.12.3. *Commercialization Plans.* At least five (5) business days prior to the first Commercialization Committee meeting of each Calendar Year, Collaborator (and should Amgen be commercializing any Amgen Additional Indication in the Territory, Amgen) shall provide the Commercialization Committee a copy of its proposed commercialization plan for Dmab in the Territory for the next four Calendar Quarters for the Commercialization Committee's review, comment and approval (with Collaborator and Amgen (should Amgen be commercializing any Amgen Additional Indication in the Territory) each having its own commercialization plan (either by indication or for all indications for which it is responsible in the Territory)). In addition, should a Party seek to make material changes to an approved commercialization plan, then at least five (5) business days prior to the next meeting of the Commercialization Committee it shall provide the Commercialization Committee any proposed changes to the previously approved commercialization plan for the Commercialization Committee's approval.
- 2.12.4. *Decision Making.* The Commercialization Committee shall strive to reach consensus on decisions, taking into account the views of each committee member. In the event the committee fails to reach consensus, the committee [*] determination unless the decision relates primarily to [*], in which case the committee [*] determination.

3. GRANT OF LICENSE

- 3.1. Licensed Amgen Patents. Amgen hereby grants Collaborator [*] (except as otherwise expressly set forth herein (such exception to include the transition periods described in Section 4.18 (Transition in Oncology Development) and Section 15.5 (Transition Period))) right and license during the Term, subject to the terms and conditions hereof, solely to develop, commercialize, use and sell Dmab in the Territory for the

Collaborator Indications under the Licensed Amgen Patents. Such license shall include the right to sublicense only as set forth in Section 3.5 (Collaborator Sublicensing).

- 3.2. Licensed Amgen Know-How. Amgen hereby grants Collaborator [*] right and license during the Term, subject to the terms and conditions hereof, to utilize the Licensed Amgen Know-How solely for the purpose of supporting its development, commercialization, use and sale of Dmab in the Territory for the Collaborator Indications. Such license shall include the right to sublicense only as set forth in Section 3.5 (Collaborator Sublicensing).
- 3.3. Licensed Collaborator Patents. Collaborator hereby grants Amgen [*] right and license under the Licensed Collaborator Patents, subject to the terms and conditions hereof, solely to develop, commercialize, make, have made, use, import, sell and offer for sale [*] for all uses. Such [*] shall be subject to a retained exclusive right in the Territory during the Term solely for Collaborator to develop, commercialize, use and sell Dmab in the Territory for the Collaborator Indications. Such license shall include the right to sublicense [*] provided, however, that: (i) any sublicensee shall be required to enter into a written agreement obligating it to maintain the confidentiality of the Confidential Information of Collaborator; (ii) Amgen shall be responsible for any disclosure of the Confidential Information of Collaborator by such sublicensee in violation of the provisions of Article 11 (Confidentiality and Publications); (iii) no such sublicense shall operate to excuse Amgen's compliance with its obligations hereunder; (iv) to the extent that such sublicense grants rights with respect to the Territory, it shall require such sublicensee to comply with the obligations and prohibitions of this Agreement relevant to the right(s) sublicensed; and (v) Amgen shall be responsible for a breach by such sublicensee of any such obligations or prohibitions. For the avoidance of doubt, Collaborator is retaining the right to develop, commercialize, make, have made, use, import, sell and offer for sale products and services other than [*] under the Licensed Collaborator Patents and no rights with respect to products and services other than [*] are granted to Amgen hereunder.
- 3.4. Licensed Collaborator Know-How. Collaborator hereby grants Amgen [*] right and license, subject to the terms and conditions hereof, to utilize the Licensed Collaborator Know-How solely for the purpose of supporting its development, commercialization, manufacture, use and sale of [*]: (x) in the Territory, outside the Collaborator Indications during the Term and for all uses thereafter; and (y) outside the Territory for all uses both during the Term and thereafter. Such license shall include the right to sublicense [*] provided, however, that (i) any sublicensee shall be required to enter into a written agreement obligating it to maintain the confidentiality of the Confidential Information of Collaborator; (ii) Amgen shall be responsible for any disclosure of the Confidential Information of Collaborator by such sublicensee in violation of the provisions of Article 11 (Confidentiality and Publications); (iii) no such sublicense shall operate to excuse Amgen's compliance with its obligations hereunder; (iv) to the extent that such sublicense grants rights with respect to the Territory, it shall require such sublicensee to comply with the obligations and prohibitions of this Agreement relevant to the right(s) sublicensed; and (v) Amgen shall be responsible for a breach by such sublicensee of any such obligations or prohibitions. Notwithstanding the foregoing, the license granted in this Section 3.4 (Licensed Collaborator Know-How) shall be exclusive to the extent the relevant Licensed Collaborator Know-How is developed in the course of the Collaboration.

- 3.5. Collaborator Sublicensing. Collaborator shall have the right to sublicense the rights granted it hereunder only with Amgen's prior written consent, which Amgen may withhold or condition in its sole discretion. Any permitted sublicensee shall be required to enter into a written agreement obligating it to maintain the confidentiality of the Confidential Information of Amgen and Collaborator shall be responsible for any disclosure of the Confidential Information of Amgen by such sublicensee in violation of the provisions of Article 11 (Confidentiality and Publications). In addition, such written agreement shall require such sublicensee to comply with the obligations and prohibitions of this Agreement relevant to the right(s) sublicensed, and Collaborator shall be responsible for a breach by such sublicensee of any such obligations or prohibitions. No sublicense shall operate to excuse Collaborator's compliance with its obligations hereunder. Collaborator shall have the right to distribute Dmab in the Territory through reputable distributors.
- 3.6. Provision of Know-How. Following the Effective Date, the Parties shall cooperate to establish procedures for the provision of Licensed Amgen Know-How to Collaborator and Licensed Collaborator Know-How to Amgen. During the Term, Amgen shall use reasonable efforts to provide all material Licensed Amgen Know-How to Collaborator, and Collaborator shall use reasonable efforts to provide all material Licensed Collaborator Know-How to Amgen. In any event, each of the Parties shall provide to the other any Licensed Amgen Know-How or Licensed Collaborator Know-How (respectively) as the other Party shall reasonably request. Notwithstanding the foregoing, Amgen shall have no obligation to provide manufacturing information to Collaborator and neither Party shall have an obligation to provide information relating to any product other than Dmab.
- 3.7. Trademarks.
- 3.7.1. *Grant to Collaborator*. Amgen hereby grants Collaborator [*] (except as otherwise expressly set forth herein (such exception to include Amgen's co-promotion rights pursuant to Section 5.2 (Amgen Co-Promotion Right) and the transition period described in Section 15.5 (Transition Period)) right and license during the Term, subject to the terms and conditions hereof, solely to develop, commercialize, use and sell Dmab in the Territory in the Collaborator Indications under the same Licensed Amgen Trademarks as used by Amgen in the corresponding indications outside the Territory. Such license shall include the right to sublicense only as set forth in Section 3.5 (Collaborator Sublicensing). Such license is subject to Amgen's retained right to utilize such Licensed Amgen Trademarks in the Territory outside Collaborator Indications. The Parties acknowledge that the use of the Licensed Amgen Trademarks in the Territory may have commercial value to Collaborator, and that Collaborator shall have the right to commercialize Dmab in the Collaborator Indications in the Territory under the same Licensed Amgen Trademarks as utilized for such indications by Amgen outside the Territory. Should the Parties desire that a different trademark be used for Collaborator Indications in the Territory, or if

additional trademarks to those used outside the Territory are otherwise required, the Parties shall consult and agree upon an additional or replacement trademark (or trademarks). Upon Amgen's request, Collaborator shall include an Amgen trademark designated by Amgen to Collaborator in writing (e.g., "Amgen" or "Amgen K.K.") on all packaging, labeling, promotional and marketing materials for Dmab in equal prominence to those of Collaborator. Collaborator shall utilize those Amgen trademarks as requested by Amgen to the extent that Amgen provides the necessary trademark approvals within thirty (30) days of request by Collaborator for such approval. Amgen hereby grants Collaborator a non-exclusive right and license, with the right to sublicense as set forth in Section 3.5 (Collaborator Sublicensing), during the Term, subject to the terms and conditions hereof, to use such marks solely for such purpose.

3.7.2. *Grant to Amgen.* Collaborator hereby grants Amgen a [*] license during the Term to use Licensed Collaborator Trademarks to the extent Amgen desires or may be required to utilize the same in connection with its development and commercialization of Dmab in the Territory hereunder[*]. Subject to the foregoing, such license shall include the right to sublicense [*]. Any sublicensee shall be required to enter into a written agreement obligating it to comply with the provisions of Section 3.8 (Trademark Quality Standards). No such sublicense shall operate to excuse Amgen's compliance with its obligations hereunder. To the extent that such sublicense grants rights with respect to the Territory, it shall require such sublicensee to comply with the obligations and prohibitions of this Agreement relevant to the right(s) sublicensed, and Amgen shall be responsible for a breach by such sublicensee of any such obligations or prohibitions. Upon any termination or expiration of this Agreement, Collaborator shall, upon Amgen's request but at no charge, promptly assign the Licensed Collaborator Trademarks (and the associated goodwill) to Amgen.

3.8. Trademark Quality Standards. Each Party shall (i) maintain such reasonable quality standards for the Licensed Amgen Trademarks (with respect to Collaborator) or the Licensed Collaborator Trademarks (with respect to Amgen) as it maintains for its own trademarks of a similar nature and shall comply with the other Party's reasonable specifications and usage standards supplied to it in writing (and as may be updated by written notice from time to time); (ii) not use any Licensed Amgen Trademark (with respect to Collaborator) or Licensed Collaborator Trademark (with respect to Amgen) in a manner that suggests any connection with any product other than Dmab or any service; and (iii) not use or display the Licensed Amgen Trademarks (with respect to Collaborator) or the Licensed Collaborator Trademarks (with respect to Amgen) in any manner that might dilute, tarnish, disparage or reflect adversely on the other Party or such marks. Prior to using any Licensed Amgen Trademark (with respect to Collaborator) or Licensed Collaborator Trademark (with respect to Amgen), the Parties shall agree upon a guideline for use of such trademarks, including the review procedure and timing. From time to time, upon request by a Party, the other Party shall provide copies of the usage of the Licensed Amgen Trademarks (with respect to Collaborator) or Licensed Collaborator Trademarks (with respect to Amgen) used in the marketing or promotion of Dmab in order to review such usage. Amgen agrees that it shall not seek

to register or obtain ownership rights in any Licensed Collaborator Trademark (or confusingly similar trademark) and Collaborator agrees that it shall not seek to register or obtain ownership rights in any Licensed Amgen Trademark or any trademark used by Amgen in connection with Dmab outside the Territory in any indication (or confusingly similar trademark to any of the foregoing).

- 3.9. Retained Rights and Limitations. No rights are granted to Collaborator hereunder to Licensed Amgen Patents, Licensed Amgen Know-How or Licensed Amgen Trademarks outside the Collaborator Indications, or outside the Territory. No rights are granted to Collaborator hereunder to make or have made Dmab or any other product. No rights are granted herein to Collaborator to control the research, development or commercialization of Dmab outside the Territory. No rights to either Party's patents, trademarks or other proprietary rights are granted pursuant to this Agreement except as expressly set forth herein, and all other rights are reserved.

4. DEVELOPMENT AND REGULATORY APPROVAL

- 4.1. Responsibility for Development in Collaborator Indications. Collaborator shall develop Dmab in Collaborator Indications in the Territory in accordance with the then-current development plan approved by the Development Committee for such Collaborator Indications. Collaborator's responsibility with respect to Collaborator Indications in the Territory shall include: (a) filing for and seeking Regulatory Approval in the name of Collaborator from the relevant Governmental Authorities; (b) identifying and carrying out all major development tasks to be conducted prior to submission of filings for Regulatory Approval of Dmab in the Territory for a particular Collaborator Indication and any post-approval activities to be conducted for any such Collaborator Indication; (c) identifying key development objectives, expected associated resources, risk factors, timelines, decision points and relevant decision criteria; (d) carrying out all aspects of all clinical trials necessary to obtain Regulatory Approval in the name of Collaborator in the Territory for each Collaborator Indication pursued (including post-approval clinical studies) including, but not limited to, (i) designing study protocols; (ii) establishing/contracting with clinical trial sites, investigators and clinical research organizations, (iii) enrolling clinical trial subjects, (iv) organizing investigator meetings, scientific meetings, advisory panel workshops and regulatory meetings, and (v) analyzing and summarizing clinical trial results; (e) performing any other additional clinical research in support of the clinical development of Dmab; (f) forecasting clinical manufacturing production requirements; and (g) reporting on study design, study outcome, other communications and regulatory filings to the appropriate Governmental Authority. Collaborator shall be solely responsible for its costs incurred in its development of Dmab.
- 4.2. Preclinical Development in Collaborator Indications. Notwithstanding the provisions of Section 4.1 (Responsibility for Development in Collaborator Indications), Amgen shall be responsible for performing (itself or through a subcontractor) any preclinical research that is required (as reasonably demonstrated by written communication from or written meeting minutes of discussions with the relevant Governmental Authority) in order to conduct development of Dmab in one or more Collaborator Indications in the Territory in accordance with this Agreement. [*]. Such research shall be conducted in

accordance with a research plan to be agreed in writing by Amgen and Collaborator. Notwithstanding the foregoing, should [*] is likely to [*], then it shall notify [*]. In such case, [*]. Upon the request of either Party, the Parties shall [*], and should such [*], then [*] in accordance with Section [*].

- 4.3. [*]. Should Collaborator determine to [*] of Dmab for the [*] (including with respect to [*] and including [*]), Collaborator shall give Amgen prompt prior written notice thereof. The Parties shall promptly meet to discuss [*] and Collaborator shall, thereafter, have the right to [*] in accordance with such [*] unless [*] that [*] that such [*] would [*] of Dmab [*]. In such event the Parties [*]. Notwithstanding the above, if such development [*], then Collaborator [*] in accordance with [*]. Prior to any such [*], and Collaborator shall [*] as requested by Amgen [*]. Notwithstanding the foregoing, should [*] is likely to [*] of Dmab [*], then Amgen shall notify Collaborator of the same. In such case, Collaborator shall [*]. Upon the request of either Party, the Parties shall meet to discuss [*] and, should the Parties [*], and should [*], [*] shall have the right to [*] in accordance with [*].
- 4.4. Development in Combination or Outside Territory. Collaborator shall not, without Amgen's prior express written consent, conduct any development of Dmab outside the Territory, or conduct any development of Dmab in combination with any other pharmaceutical product.
- 4.5. Responsibility for Development in Amgen Additional Indications. Amgen shall develop Dmab for any Amgen Additional Indication(s) then under development by Amgen in the Territory in accordance with the then-current development plan approved by the Development Committee for such indications. Amgen's responsibility with respect to Amgen Additional Indications in the Territory shall include: (a) filing for and seeking Regulatory Approval in the name of Amgen from the relevant Governmental Authorities; (b) investigating additional indications for which Dmab will be developed; (c) identifying and carrying out all major development tasks to be conducted prior to submission of filings for Regulatory Approval for Dmab for a particular indication and any post-approval activities to be conducted for any such indication; (d) identifying key development objectives, expected associated resources, risk factors, timelines, decision points and relevant decision criteria; (e) carrying out all aspects of all clinical trials necessary to obtain Regulatory Approval in the name of Amgen for each indication pursued (including post-approval clinical studies) including, but not limited to, (i) designing study protocols; (ii) establishing/contracting with clinical trial sites, investigators and clinical research organizations, (iii) enrolling clinical trial subjects, (iv) organizing investigator meetings, scientific meetings, advisory panel workshops and regulatory meetings, and (v) analyzing and summarizing clinical trial results; (f) performing any other additional clinical and preclinical research in support of the clinical development of Dmab; (g) forecasting clinical manufacturing production requirements; and (h) reporting on study design, study outcome, other communications and regulatory filings to the appropriate Governmental Authority. Subject to Section 4.18 (Transition in Oncology Development) and Section 8.8 (Development Cost Sharing) Amgen shall be solely responsible for its costs incurred in its development of Dmab in the Territory.

- 4.6. Development Outside the Territory. Amgen shall have the sole right to manage and conduct the development of Dmab outside the Territory in all indications. The foregoing is without prejudice to Collaborator's payment obligations pursuant to Section 8.8 (Development Cost Sharing).
- 4.7. Global Development. The Parties acknowledge that it may be in their mutual interests to integrate Collaborator's development of Dmab within the Territory into Amgen's global development plan for Dmab for a particular Collaborator Indication. The Parties agree to discuss in good faith where it may be appropriate to so include such development, and the relevant cost-sharing that will be applicable thereto. As requested by either Party, the Parties shall meet and confer in good faith as to the feasibility and potential efficiency gains of cooperating to integrate Collaborator's development of Dmab for [*] in the Territory into Amgen's global development plan for such indication. The Parties acknowledge that one ongoing study within Oncology, a study of [*], the "*Ongoing Oncology Study*"), currently includes sites both inside and outside the Territory. The Ongoing Oncology Study is a global registration trial intended to support a filing for approval in the United States and Europe, as well as in the Territory. After the Effective Date, the management of those sites shall be addressed as provided in Section 4.18 (Transition in Oncology Development), and shall be conducted strictly in accordance with Amgen's global procedures and protocol for such trial, as in effect at the relevant time, as communicated by Amgen to Collaborator (and/or any relevant contract research organization). If Amgen elects to [*] that would be likely to [*] in the Territory, the Parties will discuss [*] and will discuss [*] in the Territory.
- 4.8. Sharing of Regulatory Filings. Each of the Parties will disclose to the other a draft copy of any Regulatory Filing in the Territory in the original language no less than thirty (30) days prior to filing it with a Governmental Authority. Each Party will consider in good faith any comments made by the other Party with respect to such filings. Each Party shall, no less frequently than quarterly, and more often as reasonably requested by the other Party, provide to the other Party (in such format as reasonably requested) all material preclinical and clinical data arising out of or relating to Dmab in trials thereof in the Territory (and outside the Territory, for Amgen) (or such subset of such data as the Parties may agree). Each of the Parties shall maintain a database which contains all clinical trial data accumulated from all clinical trials of Dmab in the Territory (in a computer readable format reasonably requested by Amgen). Upon the request of either Party, the other Party shall provide a right of reference to any requested Regulatory Filings or Regulatory Approvals in the Territory, and Amgen shall provide the same such right of reference to Collaborator with respect to such Regulatory Filings and Regulatory Approvals outside the Territory, in each case as reasonably necessary for the requesting Party's development or commercialization of Dmab as permitted hereunder (or, with respect to Amgen, manufacture of Dmab). Notwithstanding the foregoing, Amgen shall not be required to provide to Collaborator nor to allow Collaborator to access (but shall provide a right of reference as set forth in Section 4.15.3 (Amgen Cooperation) to the extent necessary) Amgen's manufacturing information with respect to Dmab or any sections of any such Regulatory Filing related thereto and neither Party shall have an obligation to provide information relating to any product other than Dmab.

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- 4.9. Clinical Supply. Collaborator shall obtain its requirements of Dmab for use in clinical development from Amgen, and shall [*] provision of such clinical supply. Amgen shall use reasonably diligent efforts to provide Collaborator with such supply in a form materially the same as the form of clinical supply used by Amgen outside the Territory (i.e. with respect to formulation, presentation, raw materials, diluent and components). Should Collaborator request Amgen to provide clinical supply that materially varies from that used by Amgen outside the Territory, Collaborator and Amgen shall meet to discuss in good faith the best approach with respect to such request. Collaborator shall provide Amgen, at least thirty (30) days prior to the start of each Calendar Quarter, a rolling, one-year forecast for its requirements of clinical Dmab supply. Amgen shall use its reasonable efforts to satisfy such need, and shall promptly notify Collaborator of any difficulty foreseen in doing so. In such event, the Parties shall meet promptly to discuss how to best address such situation.
- 4.10. Quality Agreement. Promptly following the Effective Date, the quality assurance departments of Amgen and Collaborator will develop and agree upon a quality agreement governing the quality and specifications of clinical Dmab to be supplied hereunder including with respect to product quality and product complaints (to the extent not covered in a separate safety agreement entered into pursuant to Section 4.13 (Safety Agreement)) with respect to Dmab. The quality agreement will be documented in writing, and routinely updated by mutual written agreement of the Parties.
- 4.11. Transfer of Regulatory Filing. Promptly after the Effective Date, Amgen shall transfer to Collaborator all Regulatory Filings in the Territory with respect to Dmab in Collaborator Indications.
- 4.12. Transfer of Regulatory Matters. Collaborator shall not transfer title in, fail to maintain or otherwise attempt in any manner to dispose of any Regulatory Filings or Regulatory Approvals or other governmental licenses, approvals or certificates for Dmab in the Territory without the prior written approval of Amgen.
- 4.13. Safety Agreement. Promptly following the Effective Date, the safety departments of Amgen and Collaborator will develop and agree upon safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning adverse events with respect to Dmab sufficient to permit each Party, its Affiliates, permitted sublicensees and licensees to comply with Law, including, to the extent applicable, those obligations contained in U.S. Food and Drug Administration (or any successor agency) and MHLW regulations. The safety data exchange procedures will be documented in writing, and promptly updated if required by changes in Law or by agreement of the Parties.
- 4.14. Adverse Event Reporting. Each Party shall inform the other Party of any adverse event with respect to Dmab of which it becomes aware in a timely manner commensurate with the seriousness of the adverse event. Each Party shall be responsible for reporting to the MHLW all adverse events with respect to Dmab (whether within or outside the Territory), to the extent required by and in accordance with Law. Each Party will ensure that its Affiliates, permitted sublicensees and licensees, as applicable, comply with all such reporting obligations. Each Party will designate a safety liaison to be responsible for communicating with the other Party regarding the reporting of adverse events with respect to Dmab.

4.15. Communications.

4.15.1. *Collaborator Responsibility.* Collaborator shall have exclusive responsibility for all correspondence and for any official communication (except as Amgen may be required by Law or a Governmental Authority to communicate) regarding Dmab in Collaborator Indications with applicable Governmental Authorities in the Territory (other than with respect to manufacturing). Collaborator will supply to Amgen a copy of: (i) all such correspondence and communications to any such Governmental Authority at least ten (10) business days prior to provision of such correspondence or communication to such Governmental Authority (or as promptly as possible where exigent circumstances make such provision impractical); and (ii) all such correspondence and communications from any such Governmental Authority within (10) business days of receipt of any such correspondence. Collaborator shall consider in good faith any comments or suggestions made by Amgen with respect to any such communication. Amgen shall reasonably cooperate with Collaborator in responding to any inquiry made by a Governmental Authority in the Territory regarding Dmab in Collaborator Indications, and Collaborator shall reimburse all reasonable, documented, out-of-pocket expenses incurred by Amgen in connection therewith. Amgen shall be entitled to observe and participate in any discussions between Collaborator and any Governmental Authority, and Collaborator shall give Amgen ten (10) business days prior written notice thereof (or prompt written notice, if ten (10) business days notice is impractical). Should Collaborator be unable to solicit Amgen's participation in any such discussion (as, for example, with respect to a call or visit to Collaborator by such Governmental Authority without notice), then Collaborator shall provide Amgen prompt written notice of such communication with a summary of the discussion.

4.15.2. *Amgen Responsibility.* Amgen shall have exclusive responsibility for all correspondence and for any official communication (except as Collaborator may be required by Law or a Governmental Authority to communicate) regarding Dmab in Amgen Additional Indications with applicable Governmental Authorities in the Territory and with applicable Governmental Authorities in all indications outside the Territory. Amgen shall have exclusive responsibility for all correspondence and for any official communication with Government Authorities in and outside the Territory regarding manufacture of Dmab. With respect to the Territory, Amgen will supply to Collaborator a copy of: (i) all such correspondence and communications (other than those related to manufacturing or relating to Amgen proprietary manufacturing information) to any such Governmental Authority at least ten (10) business days prior to provision of such correspondence or communication to such Governmental Authority (or as promptly as possible where exigent circumstances make such provision impractical); and (ii) all such correspondence and communications (other than those related to manufacturing or relating to Amgen proprietary manufacturing information) from any such Governmental Authority within (10)

business days of receipt of any such correspondence. Amgen shall consider in good faith any comments or suggestions made by Collaborator with respect to any such communication. Collaborator shall be entitled to observe and participate in any discussions between Amgen and any Governmental Authority in the Territory (other than those related to manufacturing or to Amgen proprietary manufacturing information), and Amgen shall give Collaborator ten (10) business days prior written notice thereof (or prompt written notice, if ten (10) business days notice is impractical). Should Amgen be unable to solicit Collaborator's participation in any such discussion (as, for example, with respect to a call or visit to Amgen by such Governmental Authority without notice), then Amgen shall provide Collaborator prompt written notice of such communication with a summary of the discussion. With respect to correspondence and communication with Governmental Authorities outside the Territory: (i) Amgen shall use reasonable efforts to provide Collaborator copies of material written correspondence, and summaries of material non-written communication, as reasonably necessary to permit Collaborator to comply with its relevant regulatory obligations; and (ii) Amgen shall discuss with Collaborator Amgen's experience in seeking Regulatory Approvals outside the Territory and shall provide that information (including selected correspondence and materials) it reasonably believes would be helpful in Collaborator's establishment of its strategy for development and regulatory activities with respect to Dmab in the Territory (provided that Amgen shall not be required to disclose competitively sensitive information). Should Amgen fail to provide Collaborator with any of the foregoing information (other than competitively sensitive information), Collaborator shall have the right to request the same from Amgen, and Amgen shall promptly provide such correspondence or summaries to Collaborator (other than competitively sensitive information).

- 4.15.3. *Amgen Cooperation – Manufacturing Information.* Upon Collaborator's request, Amgen will reasonably cooperate with Collaborator to make and provide copies of any direct communications by Amgen either to or from the Governmental Authorities having jurisdiction in the Territory regarding the manufacture of any Dmab by Amgen for supply to Collaborator; provided, however, that Amgen's obligation to provide Collaborator with manufacturing and process information is limited to the circumstance where the information is reasonably required for Collaborator to carry out its development and commercialization responsibilities, or access to such information is required by Law or a Governmental Authority having jurisdiction in the Territory; but Collaborator shall only be entitled to use such information to the extent required by such Law or Governmental Authority or to the extent reasonably required to carry out its development and commercialization responsibilities hereunder. Amgen shall have the right to instead provide any such manufacturing information directly to the relevant Governmental Authority (including by provision of a drug master file) if such provision will satisfy such requirement (in order to better protect the confidentiality of such information).

- 4.16. Recalls. The Parties shall exchange their internal standard operating procedures as to product recalls (“SOPs”) reasonably promptly after the Effective Date and thereafter reasonably promptly after such SOPs are approved or modified. If either Party becomes aware of information about quantities of Dmab supplied by Amgen to Collaborator which may not conform to the specifications for Dmab then in effect, or for which there are potential adulteration, misbranding and/or other issues regarding safety or effectiveness, or for which Dmab itself is the subject of a Recall in the Territory, it shall promptly so notify the other Party and the Party having the right to control such a Recall pursuant to subsection 4.16.1 (Collaborator Right) or 4.16.2 (Amgen Right) shall have the right to take immediate action with notice to the other Party when the regulatory timeframes or public safety considerations so require. The Parties will meet (in person, by telephone or otherwise) to discuss the circumstances of any potential Recall and to consider appropriate courses of action, which courses of action with respect to a Recall shall be consistent with the internal SOP of the Party having the right to control such Recall pursuant to subsection 4.16.1 (Collaborator Right) or 4.16.2 (Amgen Right), and the other Party shall make available to the Party having the right to control such Recall all pertinent records which the Party having the right to control such Recall may reasonably request to assist in effecting any Recall (provided, however, Amgen shall be obligated to provide manufacturing information to Collaborator only to the extent necessary for Collaborator to conduct such Recall, and Amgen shall also have the right to instead provide any such manufacturing information directly to the relevant Governmental Authority (including by provision of a drug master file) if such provision will satisfy such requirement (in order to better protect the confidentiality of such information). In the event of an order of a Governmental Authority having jurisdiction in the Territory mandating a Recall, the Party having the right to control such a Recall pursuant to subsection 4.16.1 (Collaborator Right) or 4.16.2 (Amgen Right) shall promptly comply with such order with written notice to the other Party.
- 4.16.1. *Collaborator Right*. Collaborator shall have the sole right to control a Recall of Dmab in Collaborator Indications in the Territory. Collaborator shall maintain complete and accurate records of any Recall it has the right to control pursuant to this Section 4.16 (Recalls) for such periods as may be required by Law, but in any event for no less than [*].
- 4.16.2. *Amgen Right*. Amgen shall have the sole right to control a Recall of Dmab outside Collaborator Indications in the Territory (and outside the Territory in all indications). Amgen shall maintain complete and accurate records of any Recall it has the right to control pursuant to this Section 4.16 (Recalls) for such periods as may be required by Law, but in any event for no less than [*].
- 4.17. Cooperation Generally. Subject to the oversight of the Development Committee, the Parties shall provide each other with any cooperation reasonably requested by the other with respect to the development of Dmab in the Territory.
- 4.18. Transition in Oncology Development. Notwithstanding anything in this Agreement to the contrary, the Parties shall cooperate with respect to the conduct of the Ongoing Oncology Study in the Territory as follows: The Parties have [*] to the Ongoing Oncology Study [*] such Ongoing Oncology Study [*] and the Parties both recognize

[*] Amgen shall [*] the Ongoing Oncology Study. To the extent Amgen is [*] Collaborator, [*] of the Ongoing Oncology Study [*]. If [*], Amgen and Collaborator shall [*]. Amgen shall have the right to continue to [*] until Amgen and Collaborator [*]. From and after the Effective Date, Collaborator shall [*] the Sites [*] and [*] as may be agreed hereunder (including the [*]). As provided in Section 4.7 (Global Development), the Ongoing Oncology Study shall be conducted strictly in accordance with Amgen's global development plan and protocols for such trials, as in effect at the relevant time, as communicated by Amgen to Collaborator [*].

5. COMMERCIALIZATION

- 5.1. Operational Control in Collaborator Indications. Collaborator shall have operational responsibility for commercialization of Dmab in the Territory in Collaborator Indications. Collaborator shall commercialize Dmab in all Collaborator Indications in the Territory in accordance with the then-current commercialization plan approved by the Commercialization Committee. Collaborator shall promote and commercialize Dmab using only professional and well-trained employees of Collaborator, and shall not utilize a contract sales organization in connection with Dmab without Amgen's prior written approval. Subject to the foregoing, with respect to Collaborator Indications in the Territory, Collaborator's responsibilities shall include: (a) determination of commercial strategies (e.g., strategies for branding, product positioning, pre-launch activities (e.g., market research), launch and post-launch marketing and promotion, pricing and reimbursement and field sales force optimization); (b) determination of packaging and labeling (provided, however, that Amgen shall have the right to participate in any discussions with Governmental Authorities with respect to labeling in accordance with Section 4.15.1 (Collaborator Responsibility)); (c) creation of promotional materials regarding Dmab which are intended for distribution to Third Parties (including medical professionals) and to Collaborator's sales force (subject to Section 3.8 (Trademark Quality Standards)); (d) determining and conducting promotion activities; and (e) conducting sales, distribution and medical affairs activities, including booking sales (i.e., recognizing all revenues), taking orders and distributing, contracting, handling of returns, handling all aspects of order processing, invoicing and collecting, warehousing, documenting inventory and receivables and collecting prescription tracking, call reporting, handling data regarding sales to hospitals and other end users and handling all other customer service-related functions. Collaborator shall be solely responsible for its costs incurred in its commercialization of Dmab.
- 5.2. Amgen Co-Promotion Right. Amgen shall have the right, upon [*] written notice [*] to co-promote Dmab in one or more Collaborator Indications in the Territory at any time [*]. Collaborator shall provide Amgen any information reasonably requested by Amgen to allow Amgen to consider whether to exercise such option. Should Amgen elect to co-promote Dmab in one or more Collaborator Indications in the Territory, it shall elect to provide up to [*] percent ([*]%) of the details for such indication, and Amgen's notice of exercise of its option shall specify the percentage of total details (up to such maximum) that Amgen desires to perform for such indication. The Parties shall cooperate to allocate details between them on an equitable basis in good faith, taking into account geography, settings, provider category and detailing position, as well as

Amgen's sales force composition and strategic focus in the Territory so as not to unreasonably interfere with Collaborator's commercialization activities hereunder. Collaborator shall pay Amgen [*]. Amgen shall have the right to terminate its co-promotion activities by ninety (90) days notice to Collaborator, and the Parties shall cooperate to transition such activities to Collaborator with a minimum of disruption. At the request of either Party, the Parties shall enter into a written agreement detailing the terms and conditions of such co-promotion effort.

- 5.3. Operational Control in Amgen Additional Indications. Amgen shall have operational responsibility for commercialization of Dmab in the Territory in any Amgen Additional Indications in accordance with the then-current commercialization plan approved by the Commercialization Committee. Amgen shall promote and commercialize Dmab using only professional and well-trained employees of Amgen, and shall not utilize a contract sales organization in connection with Dmab without Collaborator's prior written approval. Subject to the foregoing, with respect to any Amgen Additional Indications being commercialized in the Territory, Amgen's responsibilities shall include: (a) determination of commercial strategies (e.g., strategies for branding, product positioning, pre-launch activities (e.g., market research), launch and post-launch marketing and promotion, pricing and reimbursement and field sales force optimization); (b) determination of packaging and labeling (provided, however, that Collaborator shall have the right to participate in any discussions with Governmental Authorities with respect to labeling in accordance with Section 4.15.2 (Amgen Responsibility)); (c) creation of promotional materials regarding Dmab which are intended for distribution to Third Parties (including medical professionals) and to Amgen's sales force (subject to Section 3.8 (Trademark Quality Standards)); (d) determining and conducting promotion activities; and (e) conducting sales, distribution and medical affairs activities, including booking sales (i.e., recognizing all revenues), taking orders and distributing, contracting, handling of returns, handling all aspects of order processing, invoicing and collecting, warehousing, documenting inventory and receivables and collecting prescription tracking, call reporting, handling data regarding sales to hospitals and other end users and handling all other customer service-related functions. Except as set forth in Section 5.2 (Amgen Co-Promotion Right), Amgen shall be solely responsible for its costs incurred in its commercialization of Dmab.
- 5.4. Commercialization Outside the Territory. Amgen shall be solely responsible for the commercialization of Dmab for all indications outside the Territory and the costs thereof, and Collaborator shall have no rights with respect thereto.
- 5.5. Compliance with Laws, Regulations and Guidelines. Each Party agrees to comply with Law with respect to the development and commercialization of Dmab in the Territory. Neither Party shall be required to undertake any activity relating to the commercialization of Dmab in the Territory that it believes, in good faith, may violate any Law.
- 5.6. Cooperation Generally. Subject to the oversight of the Commercialization Committee, the Parties shall cooperate generally with respect to the commercialization of Dmab in the Territory.

6. COLLABORATOR AND AMGEN ADDITIONAL INDICATIONS

- 6.1. Reasonably Diligent Efforts. Collaborator shall use Reasonably Diligent Efforts to develop, obtain Regulatory Approval for and commercialize Dmab in all Collaborator Indications in the Territory, and it shall be a material breach of this Agreement for Collaborator to fail to do so. The Parties acknowledge that [*]. With respect to the development of Dmab [*], Reasonably Diligent Efforts shall be [*].
- 6.2. Additional Indications.
- 6.2.1. *Amgen Developed Indications*. Within ninety (90) days of Amgen's written request, Collaborator shall inform Amgen in writing of whether or not it intends to develop and commercialize Dmab in the Territory in an indication which is then subject to clinical development by Amgen outside the Territory, but other than a Collaborator Indication. Amgen shall provide Collaborator with all information reasonably requested by Collaborator reasonably necessary to enable Collaborator to make such determination. Should Collaborator elect in writing to do so during such ninety (90) day period, then such indication shall, from that point forward, be a Collaborator Indication. Should Collaborator notify Amgen that it does not intend to so develop and commercialize Dmab for such indication (or fail to timely respond to Amgen's request), then such indication shall become an "Amgen Additional Indication."
- 6.2.2. *Collaborator Proposed Indications*. Should Collaborator wish to develop or commercialize Dmab in the Territory in an indication other than a Collaborator Indication or an Amgen Additional Indication, it shall request Amgen's written approval thereof and the Parties shall discuss in good faith expansion of the definition of Collaborator Indications to include such indication. Collaborator shall provide Amgen any information reasonably requested by Amgen in order to allow Amgen to understand the circumstances and relevant factors with respect to such request. Amgen shall approve the expansion of such definition unless Amgen reasonably believes that [*]. Should the Parties so agree in writing, then such indication shall, from such point forward, be a Collaborator Indication. Any such approved development shall be subject to [*]. Collaborator shall not [*].
7. **MANUFACTURE AND SUPPLY**
- 7.1. Manufacturing Rights. No rights are granted to Collaborator hereunder to manufacture Dmab or to obtain Dmab from any entity other than Amgen or its designee. Collaborator shall not manufacture Dmab or obtain Dmab from any entity other than Amgen or its designee.
- 7.2. Supply Agreement. The Parties (or their Affiliates) intend to enter into a supply agreement for the commercial supply of Dmab (materially consistent with the Supply Agreement Term Sheet Schedule attached hereto) subsequent to the Effective Date, and shall, upon the request of either Party, negotiate in good faith to do so. In the event of any conflict between this Agreement and such supply agreement, this Agreement shall control.

- 7.3. Responsibility for Regulatory Filings with Respect to Manufacturing. Amgen shall be solely responsible for the preparation and submission of all regulatory filings required to be filed with any Governmental Authority in the Territory with respect to the manufacture of Dmab provided to Collaborator by Amgen pursuant to the supply agreement to be entered into by the Parties pursuant to Section 7.2 (Supply Agreement) (including with respect to the use of any contract manufacturer to produce such Dmab). Collaborator shall provide Amgen any cooperation reasonably requested by Amgen in connection with any such filings, and Amgen shall reimburse all reasonable, documented, out-of-pocket expenses incurred by Collaborator in connection with such cooperation.

8. PAYMENT

- 8.1. License Payments by Collaborator. In consideration of the rights granted by Amgen to Collaborator hereunder, Collaborator shall make the following payments to Amgen;
- 8.1.1. *License Fee.* Collaborator shall pay Amgen a non-refundable, non-creditable license fee in the amount of \$20,000,000 within ten (10) days after the Effective Date.
- 8.1.2. *Milestone Payments.* In addition to the license fee, Collaborator shall pay Amgen the following non-refundable, non-creditable development and commercial milestone payments as set forth below, in each case within thirty (30) days after the occurrence of the corresponding event:

| <u>Milestone Event</u> | <u>Payment Amount</u> |
|------------------------|-----------------------|
| [*] | \$ [*] |
| [*] | \$ [*] |
| [*] | \$ [*] |

- 8.2. License Payments by Amgen. In consideration of the licenses granted by Collaborator to Amgen pursuant to Sections 3.3 (Licensed Collaborator Patents) and 3.4 (Licensed Collaborator Know-How) hereunder, Amgen shall make the following payments to Collaborator:
- 8.2.1. *License Fee.* Amgen shall pay Collaborator a non-refundable, non-creditable license fee in the amount of \$[*] within ten (10) days after the substantial completion of the transfer from Collaborator to Amgen of the documents, filings and other information, certificates, instruments and documents related to the Licensed Collaborator Patents as required pursuant to Section 10.2.1.

8.2.2. *Milestone Payments.* Amgen shall pay Collaborator the following non-refundable, non-creditable milestone payments as set forth below, in each case within thirty (30) days after the first occurrence of the following events with respect to Dmab:

| <u>Milestone Event</u> | <u>Payment Amount</u> |
|--|-----------------------|
| The sooner to occur of: (i) Regulatory Approval of Dmab [*]; and (ii) Regulatory Approval of Dmab [*]. | \$ [*] |
| The sooner to occur of: (i) Regulatory Approval of Dmab [*] in [*]; and (ii) Regulatory Approval of Dmab [*] in [*]. | \$ [*] |

8.2.3. *Maintenance Payments.* In order to maintain the license rights granted by Collaborator to Amgen pursuant to Sections 3.3 (Licensed Collaborator Patents) and 3.4 (Licensed Collaborator Know-How), Amgen shall be required to make maintenance fee payments as set forth in the table below. Should Amgen fail to make any such payment when due, Collaborator shall have the right to terminate the licenses granted to Amgen pursuant to such Sections 3.3 (Licensed Collaborator Patents) and 3.4 (Licensed Collaborator Know-How) by thirty (30) days written notice to Amgen, as Collaborator's sole and exclusive remedy with respect to such failure to pay. Such termination shall be automatically effective as of the thirty-first (31st) day following Amgen's receipt of such notice unless Amgen has cured by making the required payment within such thirty (30) day period, in which case such termination notice shall be of no force or effect. As of the effective date of termination of Amgen's licenses pursuant to such Sections 3.3 (Licensed Collaborator Patents) and 3.4 (Licensed Collaborator Know-How), Amgen's payment obligations pursuant to this Section 8.2 (License Payments by Amgen) shall terminate.

| <u>Maintenance Payment Amount</u> | <u>Payment Due Date</u> |
|-----------------------------------|-------------------------|
| \$ [*] | [*] |
| \$ [*] | [*] |
| \$ [*] | [*] |

8.2.4. *Payments Survive.* The Parties acknowledge that Amgen's payment obligations pursuant to this Section 8.2 (License Payments by Amgen) are in consideration of Collaborator's grants of license to Amgen pursuant to Sections 3.3 (Licensed Collaborator Patents) and 3.4 (Licensed Collaborator Know-How), which licenses are perpetual and irrevocable (except as set forth in Section 8.2.3 (Maintenance Payments)) and which survive any termination of this Agreement. The payment obligations of this Section 8.2 (Amgen Payments) shall therefore likewise survive any such termination or expiration of this Agreement (without prejudice to Collaborator's termination rights pursuant to Section 8.2.3 (Maintenance Payments)); and without prejudice to the last sentence of Section 8.2.3 (Maintenance Payments)).

8.3. Royalty Payments.

8.3.1. *Collaborator Payments to Amgen.* Collaborator shall pay Amgen the following royalty amounts with respect to annual Collaborator Net Sales during the Term:

| <u>Annual Net Sales Amount</u> | <u>Royalty Percentage</u> |
|---|---------------------------|
| That portion of aggregate annual Collaborator Net Sales (across all indications) less than \$[*] | [*]% |
| That portion of aggregate annual Collaborator Net Sales (across all indications) equal to or in excess of \$[*] | [*]% |

8.3.2. *Calculation of Royalty Tiers.* A fiscal year beginning on April 1st and ending on March 31st shall be used for the purposes of calculating annual Collaborator Net Sales in the determination of royalty amounts payable pursuant to Section 8.3.1 (Collaborator Payments to Amgen).

8.3.3. *Amgen Payments to Collaborator.* Amgen shall pay Collaborator [*]% of Amgen Net Sales during the Term as royalty amounts.

8.3.4. *No Royalty on Amgen Sales Outside Territory.* For the avoidance of doubt, no royalty and, except as expressly provided in Section 8.2.2 (Milestone Payments), no other payments shall be owed by Amgen to Collaborator with respect to development, receipt of any Regulatory Approval, or sales of Dmab by or on the account of Amgen, its Affiliates or licensees outside the Territory for any indication.

8.4. Appropriate Measure of Value. Each of the Parties acknowledges that the value provided by the other hereunder is comprised of many related items, including intellectual property of various types, access to development and commercial expertise, clinical data and other financial and non-financial consideration and that the royalties set forth in Section 8.3 (Royalty Payments) are intended to capture such value as an aggregate. Therefore the increase, decrease or lapse of any particular items or rights shall not affect the amount of such royalty, and the Parties agree that both the amount and duration of the royalties set forth in this Section are reasonable.

8.5. Calculation of Net Sales. In calculating Net Sales:

8.5.1. *Free Products.* Any disposal of Dmab at no charge for, or use of Dmab without charge in, clinical or preclinical trials, given as free samples, or distributed at no charge to patients unable to purchase the same shall not be included in Net Sales.

8.5.2. *Bundled Products.* Where Dmab is sold in a Bundle, then for the purposes of calculating the Net Sales under this Agreement, such Dmab shall be deemed to be sold for an amount equal to $(X \div Y) \times Z$, where: X is the average sales price during the applicable reporting period generally achieved for Dmab in the Territory; Y is the sum of the average sales price during the applicable reporting period generally achieved in the Territory, when sold alone, by each pharmaceutical product included in the Bundle; and Z equals the price at which the Bundle was actually sold. In the event that Dmab or one or more of the

other pharmaceutical products in the Bundle are not sold separately, the Parties shall confer in good faith to determine an equitable fair market price to apply to such bundled Dmab.

- 8.6. Reports. Beginning with the Calendar Quarter after the First Commercial Sale of Dmab in the Territory and thereafter for each Calendar Quarter in which royalties are payable until the expiration of the Payor Party's obligation to pay royalties hereunder, royalty payments and reports of the sale of Dmab for each Calendar Quarter will be calculated and delivered by the Payor Party to the Payee Party under this Agreement within forty-five (45) days of the end of each such Calendar Quarter. In addition, such reports for the first Calendar Quarter of each Calendar Year shall be delivered by the Payor Party to the Payee Party within five (5) business days of the end of such Calendar Quarter using the best estimate of the Payor Party, with a final report (and the accompanying royalty payments) sent no later than forty-five (45) days of the end of such Calendar Quarter. Each payment of royalties will be accompanied by a report of Net Sales of Dmab stating: (a) Net Sales of Dmab by or on behalf of the Payor Party during the applicable Calendar Quarter (detailed with gross invoiced amounts, deductions and Net Sales); and (b) a calculation of the royalty payment due from the Payor Party hereunder for such Calendar Quarter. Any reports which contain currency conversions shall provide the details and background information used to calculate such conversions.
- 8.7. No Wrongful Reductions. The Payor Party shall not attempt to reduce compensation rightly due to the Payee Party hereunder by shifting compensation otherwise payable to the Payor Party from a Third Party with respect to Dmab to another product or service for which no royalties are payable by it hereunder.
- 8.8. Development Cost Sharing. In addition to the other payments referenced herein, Collaborator shall pay to Amgen a share of Amgen Development Costs including those for the third Calendar Quarter of 2007 and thereafter:
- 8.8.1. Amounts. Collaborator's share of Amgen Development Costs shall be as set forth in the below table, subject in each case to the maximum amounts described in Section 8.8.2 (Maximum Payments):

| <u>Calendar Year</u> | <u>Collaborator Share</u> |
|----------------------|---------------------------|
| 2007-2009 | [*]% |
| 2010 and thereafter | [*]% |

- 8.8.2. Maximum Payments. Notwithstanding the foregoing, Collaborator's payment obligations pursuant to this Section 8.8 (Development Cost Sharing) shall be subject to a maximum payment as set forth below for each Calendar Year (each, an "Annual Maximum"). In addition, total, aggregate amounts payable by Collaborator pursuant to this Section 8.8 (Development Cost Sharing) shall not exceed \$[*] (the "Aggregate Maximum"). In the event the amount otherwise payable in a Calendar Quarter ("Q1; Q2; Q3 or Q4", as appropriate) would exceed: [*] (the "Quarterly Maximum") then Collaborator shall pay only such Quarterly Maximum. Since there will be only two quarterly payments by Collaborator in 2007 (due to the Effective Date of this Agreement occurring

during Q3 of 2007), the Quarterly Maximum for Q3 of 2007 shall be [*] of the Annual Maximum for 2007, and the Quarterly Maximum for Q4 of 2007 shall be the Annual Maximum for 2007 less the amount paid by Collaborator pursuant to this section for Q3 of 2007. No [*] the Annual Maximum for a particular Calendar Year nor [*] the Quarterly Maximum for a particular Calendar Quarter shall [*]. No amounts in excess of the Aggregate Maximum shall be payable by Collaborator pursuant to this Section 8.8 (Development Cost Sharing).

| <u>Calendar Year</u> | <u>Annual Maximum</u> |
|----------------------|---------------------------|
| 2007 | \$ [*] |
| 2008 | \$ [*] |
| 2009 | \$ [*] |
| Aggregate Maximum | \$ [*] |

8.8.3. *Reports.* Within thirty (30) days of the end of each Calendar Quarter, Amgen shall provide Collaborator with a report specifying in reasonable detail the Amgen Development Costs incurred or paid by Amgen in such Calendar Quarter, as well as any other costs for which Amgen is entitled reimbursement hereunder (such as those incurred pursuant to Section 4.18 (Transition in Oncology Development)). In addition, for the first Calendar Quarter of each Calendar Year Amgen shall provide Collaborator a non-binding estimate of Collaborator's share of Amgen Development Costs, as well as any other costs for which Amgen is entitled reimbursement hereunder (such as those incurred pursuant to Section 4.18 (Transition in Oncology Development)) for such Calendar Quarter within five (5) business days of the end of such Calendar Quarter. Amgen Development Costs may be attributed by Amgen to either the Calendar Quarter in which they are paid or incurred, but no amount shall be attributed to more than one Calendar Quarter.

8.8.4. *Payments.* Collaborator shall pay Amgen its share of Amgen Development Costs in accordance with Section 8.10 (Payment Method) within thirty (30) days of receiving Amgen's report pursuant to Section 8.8.3 (Reports). For the avoidance of doubt, except as expressly set forth in Section 15.3.3 (Development Cost Share), Collaborator's payment obligation with respect to Amgen Development Costs shall remain in effect until the Aggregate Maximum has been paid in full.

8.8.5. *Example.* The Development Costs Example Schedule sets forth an example of the calculation of Collaborator's share of Amgen Development Costs.

8.9. No Other Compensation. Other than as explicitly set forth (and as applicable) in this Agreement, neither Party shall be obligated to pay any additional fees, milestone payments, royalties or other payments of any kind to the other under this Agreement.

8.10. Payment Method. All payments made hereunder between the Parties shall be made in U.S. Dollars except as set forth in Section 8.13 (Blocked Currency). The Payor Party shall pay all sums due hereunder by check, wire transfer, or electronic funds transfer

(EFT) in immediately available funds. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments. Regardless of the amounts of any royalties or other payments due under this Agreement or any other agreement between the Parties or their Affiliates, all amounts payable under this Agreement shall be paid in full (subject to Section 8.15 (Withholding) and Section 8.16 (VAT)).

- 8.11. Change in Accounting Periods. From time to time, either Party may change its company-wide (or Territory-wide) accounting and financial reporting practices from Calendar Quarters and Calendar Years to fiscal quarters and fiscal years or vice versa. If a Party notifies the other of a change in its accounting and financial reporting practices from Calendar Quarters and Calendar Years to fiscal quarters and fiscal years or vice versa, then thereafter, beginning with the period specified in the notice, the payment, reporting and other obligations of such Party hereunder related to Calendar Quarters and Calendar Years shall be deemed satisfied by compliance therewith in accordance with the new reporting periods (fiscal reporting periods or calendar reporting periods, as the case may be) instead of the previously utilized reporting periods. The Parties shall cooperate in good faith to minimize any disruption caused by any such change. Notwithstanding the foregoing, any change in Collaborator's accounting periods shall not affect the timing or amount of Collaborator's payment obligations pursuant to Section 8.8 (Development Cost Sharing).
- 8.12. Audits. The Payor Party shall keep complete and accurate records pertaining to the development and sale of Dmab in the Territory in sufficient detail to permit the Payee Party to confirm the accuracy of all payments due hereunder, and such records shall be open (in such form as may be available or reasonably requested by a certified public accountant in accordance with this Section 8.12 (Audits)) to inspection for [*] following the end of the period to which they pertain. The Payee Party shall have the right, at its own expense, to have an independent, certified public accountant, selected by such Payee Party review the records of the Payor Party upon reasonable notice (which shall be no less than thirty (30) days prior written notice) and during regular business hours. Upon request, the accountant shall execute a confidentiality agreement reasonably required by the Payor Party. The report of such accountant shall be made available to both Parties simultaneously, promptly upon its completion. The Payee Party's audit rights with respect to any Calendar Year shall expire [*] after the end of such year and the books and records for any particular Calendar Year shall only be subject to one (1) audit. Should the inspection lead to the discovery of a discrepancy to the Payee Party's detriment, then the Payor Party shall pay to the Payee Party the amount of the discrepancy plus interest accrued at the Contract Interest Rate, compounded daily from the day the relevant payment(s) were due. Should the inspection lead to the discovery of a discrepancy to the Payor Party's detriment, then the Payee Party shall pay to the Payor Party the amount of the discrepancy without interest. The Payee Party shall pay the full cost of the inspection unless the discrepancy is to the Payee Party's detriment and is greater than [*] percent ([*]%) of the amount actually paid for the audited period, in which case the Payor Party shall pay the cost of such inspection.
- 8.13. Blocked Currency. If at any time legal restrictions in the Territory prevent the prompt remittance of any payments with respect to sales therein, the Payor Party shall have the

right and option to make such payments by depositing the amount thereof in local currency to the Payee Party's account in a bank or depository in the Territory.

- 8.14. Taxes. All Taxes levied on account of a payment made by a Payor Party to a Payee Party pursuant to this Agreement will be the responsibility of and paid by the Payee Party or shall be subject to the withholding and remittance provisions of Section 8.15 (Withholding).
- 8.15. Withholding. In the event that Laws require a Payor Party to withhold Taxes with respect to any payment to be made by such Party to the Payee Party pursuant to this Agreement, the Payor Party will withhold such Taxes from the amount due and furnish the Payee Party with proof of payment of such Taxes. The Payor Party will provide reasonable assistance to the Payee Party in its efforts to claim an exemption of Taxes, obtain a refund of Taxes withheld, or obtain a credit with respect to such Taxes paid. In order for the Payee Party to secure an exemption from, or a reduction in, any withholding of Taxes, the Payee Party shall provide to the Payor Party such forms as reasonably required for each type of payment to be made pursuant to the Agreement for which an exemption from, or a reduction in, any withholding of Taxes is claimed. Each Party shall provide the other any cooperation reasonably requested to minimize any withholding obligation (e.g., by providing the necessary tax forms upon request).
- 8.16. VAT. All payments due a Payee Party from a Payor Party pursuant to this Agreement shall be paid exclusive of any VAT (which, if applicable, shall be payable by the Payor Party upon receipt of a valid VAT invoice).
- 8.17. Late Payment. Any payments or portions thereof due hereunder which are not paid when due shall bear interest at the Contract Interest Rate, compounded daily, calculated on the number of days such payment is delinquent. This Section 8.17 (Late Payment) shall in no way limit any other remedies available to either Party.
- 8.18. Third Party Royalties. Except as expressly set forth in Sections 8.15 (Withholding) and 8.16 (VAT), neither Party shall have the right to make any deduction from amounts otherwise payable pursuant to this Agreement on account of any royalty or other amount payable to any Third Party.

9. SETTLEMENT OF PATENT DISPUTES

- 9.1. Settlement. The Parties hereby intend that this Agreement fully and finally dispose, compromise and settle any and all patent disputes between Collaborator and its Affiliates, and its and their successors and assigns, and Amgen and its Affiliates, and its and their successors and assigns, with respect to the Settled Patents. [*] In consideration of this settlement, the Parties hereby agree as follows: Collaborator covenants that neither it, its Affiliates nor sublicensees, nor its or their successors or assigns will [*] the Territory. Collaborator, for itself, its Affiliates and each of its and their successors and assigns, hereby [*] the Territory. Amgen covenants that neither it, its Affiliates nor sublicensees, nor any of its or their successors or assigns will initiate or file, or request, assist or cause any Third Party to [*] the Territory. Amgen, for itself, its Affiliates and each of its and their successors and assigns, hereby [*] the Territory. The foregoing [*] in this Section 9.1 (Settlement) are subject to the Parties' respective rights to control preparation, filing (including filing for correction of claims or specifications),

prosecution, maintenance, defense (including responses to patent office communications, office actions, oppositions, interferences and challenges) and enforcement of the Settled Patents as specified in Article 10 (Intellectual Property) (following expiration or termination of this Agreement, as may be modified by the provisions of Article 15 (Term and Termination)), and the exercise of a Party's rights in accordance with Article 10 (Intellectual Property) (as may be so modified following expiration or termination of this Agreement) shall not be deemed a breach of the [*] under this Section 9.1 (Settlement).

10. INTELLECTUAL PROPERTY

10.1. Ownership. Except to the extent expressly specified to the contrary in this Agreement: (i) each Party shall retain and own all right, title, and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created solely by such Party; (ii) the Parties shall jointly own all right, title, and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created jointly by the Parties and, subject to the provisions of this Agreement (including those licenses granted pursuant to Article 3 (Grant of License)), neither Party shall have any duty to account or obtain the consent of the other Party (such consent deemed given hereunder) in order to exploit or license such intellectual property rights; and (iii) inventorship and authorship of any invention or work of authorship conceived or created by either Party, or jointly by the Parties, shall follow the rules of the U.S. Patent and Trademark Office and the Laws of the United States (without reference to any conflict of law principles).

10.2. Transition and Cooperation.

10.2.1. *Transition*. [*] The Parties shall cooperate to promptly transition such documents, filings and other information, execute all agreements, certificates, instruments and documents, and take such other actions, in each case as necessary or reasonably requested by the other Party to effectuate such transition of control consistent with this Article 10 (Intellectual Property).

10.2.2. *Cooperation*. Each Party shall provide the Party in control [*] and the controlling Party shall reimburse the assisting Party's reasonable, documented out-of-pocket expenses incurred in connection therewith. Without limiting the foregoing, if reasonably necessary for standing or to satisfy other requirements to file, pursue or maintain an action in accordance with this Article 10 (Intellectual Property), a non-controlling Party will join such action at the controlling Party's request, and the controlling Party shall reimburse the non-controlling Party's reasonable, documented out-of-pocket expenses incurred in connection therewith. Each Party shall, upon the request of the other Party, execute all agreements, certificates, instruments and documents necessary to enable the requesting Party to evidence, register, protect or perfect its rights hereunder, including short-form licenses and other documents necessary to register its licenses with the United States Patent and Trademark Office, and corresponding offices in other countries.

10.3. Prosecution and Maintenance.

10.3.1. *In Territory.*

10.3.1.1. *Collaborator* [*] *Prosecution.* Collaborator shall control, itself or through outside counsel reasonably acceptable to the Parties and directed by Collaborator, the preparation, filing (including filing for correction of claims or specifications), prosecution, maintenance and defense (including responses to patent office communications, any office actions, oppositions, interferences and challenges (whether before a patent authority or judicial body) related thereto) in the Territory [*] at Collaborator's expense, as well as preparation and filing for any patent term extensions or similar protections therefor.[*]

10.3.1.2. *Amgen* [*] *Prosecution.* [*] Amgen may, upon written notice to Collaborator and at Amgen's sole cost, control the preparation, filing (including filing for correction of claims or specifications), prosecution, maintenance and defense (including responses to patent office communications, any office actions, oppositions, interferences and challenges related thereto) of such item within the Territory Patents and Trademarks thereafter in accordance with this Section 10.3.1.2 (Amgen [*] *Prosecution*) (any item so assumed, an "*Amgen Assumed Item*"). Amgen shall control, itself or through outside counsel reasonably acceptable to the Parties and directed by Amgen, the preparation, filing (including filing for correction of claims or specifications), prosecution, maintenance and defense (including responses to patent office communications, any office actions, oppositions, interferences and challenges related thereto) of Amgen Assumed Items in the Territory, at Amgen's expense, as well as preparation and filing for any patent term extensions or similar protections therefor.[*].

10.3.2. *Outside Territory.* Amgen shall control and be solely responsible for the preparation, filing (including filing for correction of claims or specifications), prosecution, maintenance, defense (including responses to patent office communications, any office actions, oppositions, interferences and challenges (whether before a patent authority or judicial body) related thereto) and all other actions with respect to its patent rights, trademark rights and other intellectual property outside the Territory, at its sole cost and expense. Amgen shall control and be solely responsible for the preparation, filing (including filing for correction of claims or specifications), prosecution, maintenance, defense (including responses to patent office communications, any office actions, oppositions, interferences and challenges (whether before a patent authority or judicial body) related thereto) and all other actions with respect to [*].

10.4. Defense and Settlement of Third Party Claims. If a Third Party asserts that a patent right or other right owned by it is infringed by the manufacture, use, sale or importation [*] by a Party (the "*Defending Party*"), the Defending Party shall have the sole right to defend against any such assertions at its sole cost. If such Third Party asserts that a patent right or other right owned by it is infringed by the manufacture, use, sale or

importation [*] by both of the Parties, then the Parties shall meet and confer, and both Parties shall have the sole right to defend against any such assertions with respect to its activities at their respective sole cost. The other Party shall assist the Defending Party and cooperate in any such litigation at the Defending Party's request, and the Defending Party shall reimburse such other Party any reasonable, documented, out-of-pocket costs incurred in connection therewith. Subject to such control, the other Party may join any defense and settlement pursuant to this Section 10.4 (Defense and Settlement of Third Party Claims), with its own counsel at its sole cost. Regardless of which Party is the Defending Party (or if both Parties are a Defending Party), the Defending Party shall seek and reasonably consider the other Party's comments before determining the strategy for such matter. Without limiting the foregoing, the Defending Party shall keep the other Party advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide the other Party copies of and an opportunity to review and comment on any such communications, filings and submissions. [*] The Defending Party shall not settle or consent to the entry of any judgment in any enforcement action hereunder without the other Party's prior written consent, not to be unreasonably withheld or delayed. Each Party shall keep the other reasonably informed of all claims and actions governed by this Section 10.4 (Defense and Settlement of Third Party Claims).

10.5. Enforcement.

10.5.1. *In Territory.* Each Party shall promptly notify the other Party in writing if it reasonably believes that any [*] are infringed or misappropriated by a Third Party in the Territory.

10.5.1.1. *Collaborator [*] Enforcement.* [*]

10.5.1.2. *Amgen [*] Enforcement.* [*]

10.5.2. *Outside Territory.* [*]

10.6. Allocation of Recoveries. All Recoveries shall first be applied to reimbursement of the unreimbursed legal fees and expenses reasonably incurred by the Parties in the action from which such Recovery was received on a pro rata basis. Any Recoveries that are left over after such reimbursement shall be allocated between the Parties [*] percent ([*]%) to Collaborator and [*] percent ([*]%) to Amgen. Amgen shall have the sole right to retain any and all recoveries with respect to the enforcement of any Amgen intellectual property or proprietary right, Licensed Collaborator Patents, Licensed Collaborator Know-How or Joint Patents outside the Territory. After any termination or expiration of this Agreement, Amgen shall have the right to retain one hundred percent (100%) of any Recoveries left over after reimbursement of costs.

10.7. Patent Term Extensions. Each Party shall provide reasonable assistance to the other Party (Amgen to Collaborator with respect to Licensed Amgen Patents and Collaborator to Amgen with respect to Licensed Collaborator Patents) in connection with obtaining SPCs to Licensed Amgen Patents and Licensed Collaborator Patents consistent with the rights of the other Party to control such matters as specified in Section 10.3 (Prosecution and Maintenance). To the extent reasonably and legally required in order to obtain any such SPC in a particular country, each Party shall make available to the

other a copy of the necessary documentation to enable such other Party to use the same for the purpose of obtaining the SPC in such country.

- 10.8. Employee Agreements. Prior to beginning work relating to any aspect of the subject matter of this Agreement and/or being given access to Licensed Amgen Know-How or Licensed Collaborator Know-How or Confidential Information of the other Party, each employee, consultant or agent of Collaborator or Amgen, respectively, shall have signed or shall be bound to a non-disclosure and invention assignment agreement pursuant to which each such person shall agree to comply with all of the obligations of Collaborator or Amgen, as appropriate, substantially including: (i) promptly reporting any Information, as appropriate; (ii) assigning to Collaborator or Amgen, as appropriate, all of his or her right, title and interest in and to any such Information; (iii) cooperating in the preparation, filing, prosecution, maintenance, enforcement and defense of any intellectual property rights; (iv) performing all acts and signing, executing, acknowledging and delivering any and all papers, documents and instruments required for effecting the obligations and purposes of this Agreement; and (v) abiding by the obligations of confidentiality and non-use set forth in this Agreement. It is understood and agreed that any such non-disclosure and invention assignment agreement need not be specific to this Agreement, and that the operation of a collective employment policy sufficient to achieve the intent of the foregoing shall be sufficient to satisfy such obligation. Each Party shall be responsible for any compensation and any other payments due to its own inventors of any patent right.
- 10.9. Patent Marking. Dmab marketed and sold by Collaborator hereunder shall be marked with appropriate patent numbers or indicia of Licensed Amgen Patents, to the extent permitted by Law in the Territory. Dmab marketed and sold by Amgen hereunder in the Territory shall be marked with appropriate patent numbers or indicia of Licensed Collaborator Patents, to the extent permitted by Law in the Territory.

11. CONFIDENTIALITY AND PUBLICATIONS

- 11.1. Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [*] ([*]) years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential and proprietary information and materials furnished to it by the other Party pursuant to this Agreement (collectively, "*Confidential Information*"). Collaborator shall have no right to and shall not utilize any Confidential Information of Amgen for activities outside the Territory (including, with respect to the research, development or commercialization of any Competing Product outside the Territory). For clarity, Confidential Information of a Party shall include, without limitation, all information and materials disclosed by such Party or its designee that (i) is marked as "Confidential," "Proprietary" or with similar designation at the time of disclosure or (ii) by its nature can reasonably be expected to be considered Confidential Information by the recipient. Information disclosed orally shall not be required to be identified as such to be considered Confidential Information. Notwithstanding the foregoing, Confidential Information shall not include any information to the extent that it can be established by written documentation by the receiving Party that such information:
- 11.1.1. was already known to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure;

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- 11.1.2. was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
- 11.1.3. became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
- 11.1.4. was independently developed by the receiving Party as demonstrated by documented evidence prepared contemporaneously with such independent development; or
- 11.1.5. was disclosed to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.
- 11.2. Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) under appropriate confidentiality provisions substantially equivalent to those in this Agreement: (a) in connection with the performance of its obligations or as reasonably necessary or useful in the exercise of its rights under this Agreement, including the right to grant licenses or sublicenses as permitted hereunder, and (b) to the extent such disclosure is reasonably necessary or useful in conducting development under this Agreement; (ii) to the extent such disclosure is to a Governmental Authority as reasonably necessary in filing or prosecuting patent, copyright and trademark applications in accordance with this Agreement, prosecuting or defending litigation related to this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement, filing Regulatory Filings, obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for Dmab, or otherwise required by Law, provided, however, that if a Party is required by Law or the rules of any securities exchange or automated quotation system to make any such disclosure of the other Party's Confidential Information it shall, except where impracticable for necessary disclosures (for example, in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and, in the case of each of the foregoing, shall use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; (iii) to advisors (including lawyers and accountants) on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement; or (iv) to the extent mutually agreed to by the Parties.
- 11.3. Terms and Conditions Confidential. Neither Party shall disclose the terms and conditions of this Agreement except as may be required by Law. Notwithstanding the foregoing, with respect to complying with the disclosure requirements of any

Governmental Authority in connection with any required filing of this Agreement, the Parties shall consult with one another concerning which terms of this Agreement shall be requested to be redacted in any public disclosure of the Agreement, and in any event each Party shall seek reasonable confidential treatment for any public disclosure by any such Governmental Authority. Notwithstanding the foregoing, the Parties shall agree upon and release a mutual press release to announce the execution of this Agreement in the form attached hereto as the Press Release Schedule for use in responding to inquiries about the Agreement; thereafter, Collaborator and Amgen may each disclose to Third Parties the information contained in such press release without the need for further approval by the other. Each Party shall additionally have the right to issue additional press releases with the prior written agreement of the other Party or as required to comply with any Law or by the rules of any stock exchange or automated quotation system (in the case of such required disclosure, by providing five (5) business days' notice to the other Party and reasonably considering comments provided by such other Party within three (3) business days after such notice).

11.4. Prior Agreement. This Agreement supersedes the Confidential Disclosure Agreement between the Parties dated [*], as amended, including any written requests thereunder, (the "*Prior Agreement*") with respect to information disclosed thereunder relating to Dmab and the research and development related thereto. All confidential information exchanged between the Parties under the Prior Agreement shall be deemed Confidential Information of the disclosing Party and shall be subject to the terms of this Agreement.

11.5. Publications.

11.5.1. *[*] Right*. Collaborator shall have the [*] right to publish with respect to Dmab in Collaborator Indications in publications based in the Territory and to make scientific presentations on Dmab in Collaborator Indications within the Territory. Amgen shall have the [*] right to publish in publications based in the Territory and to make scientific presentations on Dmab in the Territory, in each case only with respect to Dmab in Amgen Additional Indications. Amgen shall have the [*] right to publish in publications based outside the Territory and to make scientific presentations on Dmab outside the Territory, in each case in all indications. Any proposed publication by Collaborator outside the Territory and any proposed publication by Amgen outside Amgen Additional Indications within the Territory (each such publication a "[*] *Publication*") shall be made only to the extent approved by each of the Parties pursuant to Sections 11.5.2 (Other Publications) and 11.5.3 (Oversight and Review).

11.5.2. *Other Publications*. The Parties shall regularly consult and confer with respect to a global publication strategy for Dmab, with the understanding that Collaborator shall be solely responsible for shaping and determining the publication strategy with respect to the Territory, and Amgen solely responsible for shaping and determining the publication strategy outside the Territory, but [*]

11.5.3. *Oversight and Review*. Except as required by Law or court order, any publication or presentation concerning the activities to be conducted in the Territory hereunder, including studies or clinical trials carried out by a Party

under this Agreement, shall be subject to the oversight, guidelines and approval of the Development Committee. Unless otherwise mutually agreed upon by the Parties, the Party desiring to publish or present any publication or presentation concerning the activities to be conducted in the Territory hereunder (the "*Publishing Party*") (A) shall transmit to the other Party (the "*Reviewing Party*") for review and comment a copy of the proposed publication or presentation, at least thirty (30) days prior to the submission of the proposed publication or presentation to a Third Party; (B) shall postpone the publication or presentation for up to an additional sixty (60) days upon request by the Reviewing Party in order to allow the consideration of appropriate patent applications or other protection to be filed on information contained in the publication or presentation; (C) upon request of the Reviewing Party, shall remove all Confidential Information of the Reviewing Party from the information intended to be published or presented; and (D) shall consider all reasonable comments made by the Reviewing Party to the proposed publication or presentation. [*]

- 11.6. Attorney-Client Privilege. Neither Party is waiving, nor shall be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties: (a) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (b) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that after the Effective Date both the receiving Party and the disclosing Party shall have the right to assert such protections and privileges.

12. REPRESENTATIONS, WARRANTIES AND COVENANTS

- 12.1. Mutual Representations, Warranties and Covenants. Each of the Parties hereby represents, warrants and covenants to the other Party as follows:

- 12.1.1. It is duly organized and validly existing under the Laws of its jurisdiction of incorporation and it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;
- 12.1.2. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, by which it is bound, nor to its knowledge as of the Effective Date violate any Law. The person or

persons executing this Agreement on such Party's behalf have been duly authorized to do so by all requisite corporate action;

12.1.3. To its knowledge, as of the Effective Date no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority, under Law, is or shall be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed concurrently herewith, or (except for MHLW or other regulatory approvals, licenses, clearances and the like necessary for the research, development, manufacture, sales or marketing of pharmaceutical products and except for any required filing with the United States Securities and Exchange Commission) for the performance by it of its obligations under this Agreement;

12.1.4. Each Party represents and warrants that it has not been debarred or the subject of debarment proceedings by any Governmental Authority. Neither Party shall knowingly use in connection with the research, development, manufacture or commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been debarred or the subject of debarment proceedings by any regulatory agency;

12.1.5. Each Party covenants to carry out its activities hereunder in compliance with Law;

12.1.6. Each Party covenants to not misappropriate any trade secret(s) of a Third Party in connection with the performance of its activities hereunder;

12.1.7. Each Party represents and warrants that it has not granted as of the Effective Date, and during the Term shall not grant, any right to any Third Party relating to any Licensed Amgen Patent, Licensed Amgen Trademark or Licensed Amgen Know-How (with respect to Amgen) or any Licensed Collaborator Patent, Licensed Collaborator Trademark or Licensed Collaborator Know-How (with respect to Collaborator) that conflicts with the rights granted to the other Party hereunder;

12.1.8. [*]

12.2. Amgen Additional Representations and Warranties. In addition to Section 12.1 (Mutual Representations, Warranties and Covenants), Amgen hereby represents and warrants to Collaborator that Amgen has in place policies and procedures designed to ensure that Amgen Development Data is generated in compliance with Law.

12.3. Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 12 (Representations, Warranties and Covenants), COLLABORATOR AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE COLLABORATION, THE LICENSED AMGEN PATENTS, LICENSED AMGEN TRADEMARKS, LICENSED AMGEN KNOW-HOW, THE LICENSED COLLABORATOR PATENTS, LICENSED COLLABORATOR TRADEMARKS, LICENSED COLLABORATOR KNOW-HOW, THIS AGREEMENT, OR ANY OTHER SUBJECT MATTER RELATING TO THIS

AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.

13. LIMITATIONS OF LIABILITY; INSURANCE

- 13.1. Limitations of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE), EVEN IF SUCH PARTY WAS ADVISED OR OTHERWISE AWARE OF THE LIKELIHOOD OF SUCH DAMAGES. The limitations set forth in this Section 13.1 (Limitations of Liability) shall not apply with respect to (i) either Party's indemnification obligations under Article 14 (Indemnification), (ii) breach of Section 4.4 (Development in Combination or Outside Territory), 11.1 (Confidentiality; Exceptions), 11.2 (Authorized Disclosure), or (iii) gross negligence or intentional misconduct of a Party.
- 13.2. Insurance. During the Term and for six (6) years thereafter each Party shall obtain and maintain comprehensive general liability insurance covering its obligations and activities hereunder, including products liability insurance and coverage for clinical trials, with reputable and financially secure insurance carriers in a form and at levels as customary for a company of its size in the pharmaceutical industry in the Territory (or reasonable self-insurance sufficient to provide materially the same level and type of protection).

14. INDEMNIFICATION

- 14.1. Indemnity. Subject to the remainder of this Article 14 (Indemnification), Collaborator shall defend, indemnify, and hold harmless Amgen, its Affiliates, and their respective directors, officers, employees and agents (collectively, "*Amgen Indemnitees*"), at Collaborator's cost and expense, from and against any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and attorneys' fees incurred by any Amgen Indemnitees until such time as Collaborator has acknowledged and assumed its indemnification obligation hereunder with respect to a claim) paid to a Third Party (collectively, "*Losses*") arising out of any claim, action, lawsuit, or other proceeding (collectively, "*Claims*") brought against any Amgen Indemnitee by a Third Party to the extent such Losses result from (i) the negligence or willful misconduct of Collaborator, or its Affiliates or agents, (ii) a breach by Collaborator of this Agreement, (iii) a violation of Law by Collaborator, or its Affiliates or agents, or (iv) Collaborator's, its Affiliate's or its licensee's (other than Amgen, its Affiliates or its licensees) development or commercialization of Dmab but excluding such Losses to the extent they arise from (w), (x), (y) or (z) below. Subject to the remainder of this Article 14 (Indemnification), Amgen shall defend, indemnify, and hold harmless Collaborator, its Affiliates, and their respective directors, officers, employees and agents (collectively, "*Collaborator Indemnitees*"), at Amgen's cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys' fees incurred by any

Collaborator Indemnitees until such time as Amgen has acknowledged and assumed its indemnification obligation hereunder with respect to a claim) arising out of any Claim brought against any Collaborator Indemnitee by a Third Party to the extent such Losses result from (w) the negligence or willful misconduct of Amgen, or its Affiliates or agents, (x) a breach by Amgen of this Agreement, (y) a violation of Law by Amgen, or its Affiliates or agents, or (z) Amgen's, its Affiliate's or its licensee's (other than Collaborator, its Affiliates or its licensees) development or commercialization of Dmab, but excluding such Losses to the extent they arise from (i), (ii), (iii) or (iv) above.

- 14.2. Claim for Indemnification. Whenever any Claim or Loss shall arise for which a Collaborator Indemnitee or an Amgen Indemnitee (the "*Indemnified Party*") may seek indemnification under this Article 14 (Indemnification), the Indemnified Party shall promptly notify the other Party (the "*Indemnifying Party*") of the Claim or Loss and, when known, the facts constituting the basis for the Claim; provided, however, that the failure by an Indemnified Party to give such notice or to otherwise meet its obligations under this Section 14.2 (Claim for Indemnification) shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. The Indemnifying Party shall have exclusive control of the defense and settlement of all Claims for which it is responsible for indemnification and shall promptly assume defense thereof at its own expense. The Indemnified Party shall not settle or compromise any Claim by a Third Party for which it is entitled to indemnification without the prior written consent of the Indemnifying Party, unless the Indemnifying Party is in breach of its obligation to defend hereunder. In no event shall the Indemnifying Party settle any Claim without the prior written consent of the other Party if such settlement does not include a complete release from liability on such Claim or if such settlement would involve undertaking an obligation other than the payment of money, would bind or impair the other Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of the other Party is invalid or unenforceable. The Indemnified Party shall reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense and shall make available to the Indemnifying Party reasonably requested information under the control of the Indemnified Party, which information shall be subject to Article 11 (Confidentiality and Publications).

15. TERM AND TERMINATION

- 15.1. Term. This Agreement shall come into effect as of the Effective Date and shall remain in effect until the expiration or termination of the Term, at which point it shall terminate, unless sooner terminated in accordance with this Article 15 (Term and Termination). In the event either Party wishes to continue to collaborate on commercialization of Dmab in the Territory after the Term, such Party shall deliver a notice to the other Party at least eighteen (18) months prior to the expiration of the Term and the Parties shall discuss in good faith a potential extension to this Agreement.

15.2. Termination. The Parties shall have the right to terminate this Agreement as follows:

- 15.2.1. *Termination for Breach*. If either Party believes that the other Party or its Affiliate is in material breach of this Agreement, then such Party may deliver notice of such material breach (specifying the nature of the breach in reasonable detail) to the other Party. In such written notice, the noticing Party shall identify the actions or conduct that such Party would consider to be an acceptable cure of such material breach (if curable). If the breaching Party (or its Affiliate) fails to cure such material breach within ninety (90) days after the receipt of such notice, then the other Party shall be permitted to terminate this Agreement by written notice given within ninety (90) days of the end of such ninety (90) day cure period and effective upon delivery.
- 15.2.2. *Termination for Challenge*. Amgen shall have the right to terminate this Agreement by written notice to Collaborator should Collaborator, its Affiliate or its or their sublicensee bring or join any challenge to the validity or enforceability of any Licensed Amgen Patent or Licensed Amgen Trademark.
- 15.2.3. *Termination for Change of Control*. Collaborator shall give Amgen written notice within five (5) days of the public announcement or disclosure of any proposed Change of Control of Collaborator. In the event of the occurrence of any Change of Control of Collaborator, Amgen shall have the right to terminate this Agreement upon [*] written notice.
- 15.2.4. [*]. From and after the [*], in the event that [*].
- 15.2.5. *Termination for* [*]. Should Collaborator elect [*] in its notice given pursuant to [*], this Agreement shall terminate twelve (12) months from its provision of such notice (or such shorter period as Amgen may specify following receipt of such notice).
- 15.2.6. [*]. In the event that Amgen and Collaborator are unable to agree to [*] that Amgen has notified Collaborator is [*]:
- 15.2.6.1. *Conditions*. [*] shall be [*] ([*]) year period following the Effective Date, and only until such time as [*] (i) [*]; and (ii) [*];
- 15.2.6.2. *Good-Faith Discussion*. Prior to [*] pursuant to this Section 15.2.6 ([*]), Collaborator and Amgen shall negotiate in good faith for a period of no less than thirty (30) days to determine [*]
- 15.2.6.3. *Notice; Effectiveness*. Termination pursuant to this Section 15.2.6 ([*]) shall be made by three (3) months written notice, given no later than five (5) years following the Effective Date and no later than thirty (30) days following the thirty (30) day negotiation period entered into pursuant to Section 15.2.6.2 (Good-Faith Discussion). Such notice shall be automatically effective as of the end of such three (3) month notice period unless [*] or that Collaborator shall [*] pursuant to [*], in which case such termination notice shall be of no force and effect.

15.3. Effect of Termination. Expiration or termination of this Agreement shall have the following effects:

- 15.3.1. *General*. In the event of any termination or expiration of this Agreement: (i) any liabilities previously accrued shall survive; (ii) Collaborator shall return to Amgen or destroy (and certify such destruction to Amgen) all Amgen Confidential Information; (iii) Collaborator shall, to the extent permitted by Law and requested by Amgen, assign any contracts related to Dmab in the Territory to Amgen or its designee (including by requesting and using good-faith efforts to obtain any required consents); (iv) Collaborator shall assign the Licensed Collaborator Trademarks to Amgen pursuant to Section 3.7.2 (Grant to Amgen); (v) Collaborator and Amgen shall continue to make payments pursuant to Section 8.3 (Royalty Payments) with respect to sales made prior to the effective date of such expiration or termination (the “*Termination Date*”) or, if later, prior to completion of the transition by Collaborator pursuant to Section 15.5 (Transition Period); (vi) the Parties shall transition responsibility for commercialization and development of Dmab to Amgen in accordance with Section 15.5 (Transition Period); (vii) the Parties shall cooperate to promptly transition sole responsibility for the prosecution, maintenance and enforcement in the Territory of Licensed Amgen Patents, Licensed Collaborator Patents and Joint Patents to Amgen; (viii) Amgen shall have the right to reacquire some or all of the inventory of Dmab, as requested by Amgen, in possession of Collaborator and its Affiliates and shall reimburse Collaborator the price paid by it for such inventory; and (ix) the Parties shall cooperate to promptly transfer ownership of all Regulatory Filings and Regulatory Approvals, and responsibility for regulatory communication held by Collaborator in the Territory to Amgen. In the event that the Parties are not permitted to transfer Regulatory Filings or Regulatory Approvals under clause (ix) above pursuant to Law, the Parties shall cooperate to establish a right of access and reference to such filings and approvals for Amgen, and Collaborator shall maintain such filings and approvals, and take any actions reasonably requested by Amgen with respect thereto, and thereafter Collaborator shall transfer ownership of all such Regulatory Filings and Regulatory Approvals to Amgen or its designee as and when it becomes permissible to do so. Amgen shall reimburse Collaborator its reasonable, out-of-pocket costs incurred as necessary for such maintenance and to perform such requested actions. Any termination or expiration of this Agreement shall be without prejudice to any other right or remedy to which a Party may be entitled. Upon termination or expiration of this Agreement, all regulatory filings, approvals and other proprietary information relating to Dmab shall be considered Amgen Confidential Information.
- 15.3.2. *Intellectual Property Licenses*. The provisions of [*] shall survive any expiration or termination of this Agreement, natural or otherwise[*]. The foregoing is without prejudice to the provisions of Section 8.2.3 (Maintenance Payments) and 8.2.4 (Payments Survive).
- 15.3.3. *Development Cost Share*. In the event of termination by [*] under Sections [*], or by [*] under [*] obligation to [*] pursuant to [*] with respect to [*] shall survive. In the event of termination by [*] under [*], [*] shall continue to [*] pursuant to [*] only with respect to [*] attributable to [*].

15.3.4.[*]. In the event of termination of this Agreement (not including any [*] or [*]:

15.3.4.1.the following [*] within thirty (30) days after[*], only to the extent [*] the Termination Date. For the avoidance of doubt, no such [*] shall be [*] with respect to any of the [*] which [*] the Termination Date. For the purposes of determining whether such [*] the Termination Date, filing for Regulatory Approval or First Commercial Sale by Collaborator shall be considered filing or sale by Amgen's licensee. For the avoidance of doubt, [*] pursuant to this Section 15.3.4.1.

[*] [*] [*] [*]
 [*] [*]

15.3.4.2.only in the event of termination by Collaborator pursuant to Section 15.2.6 ([*]) then, within ninety (90) days of such termination, Amgen shall [*] in such event, taking into account all relevant factors, including, if and to the extent relevant, any or all of the following: (i)[*]. Such [*] shall reflect [*] in Japan assuming [*]. Upon [*] (Notice; Effectiveness), the Parties shall promptly meet to [*]. Should the Parties [*], then either party shall have the right to[*] of this Agreement or effectuation of the provisions of Sections 15.3 (Effect of Termination) through 15.5 (Transition Period).

15.3.5.[*]. In the event of a termination of this Agreement by Amgen pursuant to Section [*], then Amgen shall [*] taking into account all relevant factors, including, if and to the extent relevant, any or all of the following [*]. The Parties agree that [*] in accordance with [*]. For the avoidance of doubt, should the[*]. In addition, with respect to any [*]. The [*] are intended to apply to [*] and in no event shall [*] and similar provisions of this Agreement shall be applied to [*]. Upon Amgen's notice of termination pursuant to Section [*], the Parties shall [*]. Amgen shall disclose to Collaborator any [*] to the extent necessary for [*]. It is [*]. The use of [*] of this Agreement or effectuation of the provisions of Sections 15.3 (Effect of Termination) through 15.5 (Transition Period).

15.4. Additional Surviving Provisions. In addition and without prejudice to the provisions of Section 15.3 (Effect of Termination), in the event of any expiration or termination of this Agreement the following provisions shall survive: [*]; Section [*]; Section 8.2 (License Payments by Amgen); Section 8.6 (Reports) (with respect to sales made during the Transition Period); Section 8.8.3 (Reports) (for the duration of Collaborator's payment obligations); Section 8.10 (Payment Method); Section 8.12 (Audits); Section 8.18 (Third Party Royalties); Section 9.1 (Settlement); Section 10.2.2 (Cooperation); Section 10.3.2 (Outside Territory); Section 10.4 (Defense and Settlement of Third Party Claims); Section 10.5.2 (Outside Territory); Section 10.6 (Allocation of Recoveries) (with respect to any action initiated prior to such expiration or termination); Section 10.7 (Patent Term Extensions); Section 10.9 (Patent Marking) (with respect to sales

made during the Transition Period); Section 11.1 (Confidentiality; Exceptions); Section 11.6 (Attorney-Client Privilege); Section 12.3 (Disclaimer of Warranties); Article 13 (Limitations of Liability; Insurance); Article 14 (Indemnification); this Article 15 (Term and Termination); and Article 16 (Miscellaneous). For the avoidance of doubt, Collaborator's [*].

- 15.5. Transition Period. During the twelve (12) months prior to [*], or for a twelve (12) month period following provision of notice of termination by [*] (the "*Transition Period*"), the Parties shall [*]. Collaborator shall take all actions [*] to facilitate [*], and the Parties shall [*] as reasonably necessary to [*] in the Territory. The Parties shall each be responsible for [*], provided that, in the event of [*], Amgen shall [*], and in the event of expiration in accordance with [*]. During any such [*], Amgen shall be responsible for [*], except to the extent the relevant [*] but [*] of [*], and Collaborator shall be responsible for [*] otherwise [*].
- 15.6. [*]. In the event that either Party [*] pursuant to Section [*] or Section [*] ([*]), then such Party shall have the right to have [*] (and, consequently, [*] pursuant to the relevant section) exclusively [*] in accordance with Section [*] or Section [*], as relevant. Such [*] shall be [*]. The [*] both parties. The [*] shall be [*]. The [*] shall be [*]. [*] shall be [*] shall only [*] in accordance with Section [*] or Section [*], and shall [*] either party. Each Party shall [*].

16. MISCELLANEOUS

- 16.1. Affiliates. Amgen shall have the right to exercise its rights and perform its obligations hereunder through its Affiliates, provided Amgen shall be responsible for such Affiliates' performance hereunder.
- 16.2. Assignment. Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred (whether by operation of Law, general succession or otherwise) by Collaborator without the prior written consent of Amgen. Amgen may assign this Agreement, and its rights and obligations hereunder without prior written consent to any Affiliate or, with prior notice, in connection with the transfer or sale of all or substantially all of the business of Amgen to which this Agreement relates. Any assignment not in accordance with this Agreement shall be void. Subject to the foregoing, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.
- 16.3. Choice of Law. This Agreement shall be governed by, and enforced and construed in accordance with, the laws of the State of California without regard to its conflicts of law provisions.
- 16.4. Construction. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall". The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted,

and that no rule of strict construction shall be applied in the interpretation hereof. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Laws herein shall be construed as referring to such Laws as from time to time enacted, repealed or amended, (iii) any reference herein to any person shall be construed to include the person's permitted successors and assigns, (iv) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (v) all references herein to Articles, Sections, Schedules or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, Schedules or Exhibits of this Agreement. This Agreement has been executed in English, and the English version of this Agreement shall control.

- 16.5. Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument. Signature pages of this Agreement may be exchanged by facsimile or other electronic means without affecting the validity thereof.
- 16.6. Currency. With respect to Net Sales invoiced or expenses incurred in a currency other than U.S. Dollars, such Net Sales invoiced or expenses incurred shall be converted into the U.S. Dollar equivalent using a rate of exchange which corresponds to the rate used by Collaborator or Amgen, for the respective reporting period, related to recording such Net Sales or expenses in its books and records that are maintained in accordance with GAAP. Any royalty amount shall be calculated based upon the U.S. Dollar equivalent calculated in accordance with the foregoing.
- 16.7. Entire Agreement. This Agreement, including the attached Appendices, Schedules and Exhibits constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same.
- 16.8. Force Majeure. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, earthquakes, labor strikes, acts of war, terrorism or civil unrest ("*Force Majeure*"); provided, however, that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect) and further provided that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with reasonable dispatch whenever such causes are removed.
- 16.9. Further Assurances. Each Party agrees to do and perform all such further acts and things and shall execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may reasonably request in order to carry out

the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

16.10. Headings. Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.

16.11. Jurisdiction and Venue. Each Party hereby irrevocably submits to the exclusive jurisdiction of the courts of the State of California (“*State Court*”) and the courts of the United States of America located in the State of California (“*Federal Court*”), for the purposes of any suit, action or other proceeding arising out of or relating to this Agreement or out of any transaction contemplated hereby. Each Party agrees that service of any process, summons, notice or document by personal delivery, by registered mail, or by a recognized international express delivery service to such Party’s respective address set forth in Section 16.13 (Notices) (as such address may be changed by notice delivered pursuant to such section) shall be effective service of process for any action, suit or proceeding in the applicable Federal Court or State Court with respect to any matters to which it has submitted to jurisdiction in this Section 16.11 (Jurisdiction and Venue). Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the applicable Federal Court or State Court, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Any action brought arising out of or relating to this Agreement or out of any transaction contemplated hereby shall be conducted in English. Notwithstanding the foregoing, either Party shall have the right to seek exigent, injunctive or temporary relief in any court of competent jurisdiction.

16.12. No Set-Off. No Party shall have the right to deduct from amounts otherwise payable hereunder any amounts payable to such Party (or its Affiliates) from the other Party (or its Affiliates).

16.13. Notices. Any notice required or permitted to be given by this Agreement shall be in writing, in English, and shall be delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by registered or certified mail addressed as set forth below unless changed by notice so given:

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

With a copy to: Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
Attention: Vice President, Licensing
Telephone: (805) 447-1000
Facsimile: [*]

If to Collaborator: Daiichi Sankyo Company, Limited
 3-5-1 Nihonbashi-honcho, Chuo-ku,
 Tokyo 103-8426, Japan
 Attention: General Manager, Licensing
 Telephone: [*]
 Telecopy: [*]

With a copy to: Daiichi Sankyo Company, Limited
 3-5-1 Nihonbashi-honcho, Chuo-ku,
 Tokyo 103-8426, Japan
 Attention: General Manager, Legal Affairs
 Telephone: [*]
 Telecopy: [*]

Any such notice shall be deemed given on the date delivered. A Party may add, delete (so long as at least one person is remaining), or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 16.13 (Notices).

- 16.14. Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute Collaborator and Amgen as partners, agents or joint venturers. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.
- 16.15. Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall negotiate in good faith 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.
- 16.16. Third Party Beneficiaries. Except as expressly provided with respect to Indemnitees in Article 14 (Indemnification), there are no third party beneficiaries intended hereunder and no Third Party shall have any right or obligation hereunder.
- 16.17. Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any other occasion. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by all Parties hereto.
- 16.18. Reimportation. Collaborator shall undertake all steps necessary to prevent any Dmab provided to Collaborator hereunder for use or sale inside the Territory from being distributed or sold outside the Territory, except where Amgen and Collaborator agree that the exporting person or entity is in possession of all regulatory authorizations and intellectual property licenses necessary for such export, import and sale. Collaborator

shall notify Amgen if it becomes aware of the exportation of Dmab from the Territory and discuss with Amgen the same.

(Signature page follows)

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

DAIICHI SANKYO COMPANY, LIMITED**AMGEN INC.**By: /s/ Takashi Shoda

Name: Takashi Shoda

Title: Representative Director, President
and Chief Executive OfficerBy: /s/ Kevin W. Sharer

Name: Kevin W. Sharer

[SEAL] Title: Chairman of the Board,
Chief Executive Officer & President

Schedule
[*]

Schedule
Form of Press Release



News Release

**AMGEN AND DAIICHI SANKYO ANNOUNCE
AGREEMENT FOR DENOSUMAB IN JAPAN**

**Amgen Grants Daiichi Sankyo Exclusive Rights to Develop and
Commercialize Denosumab in Japan**

FOR IMMEDIATE RELEASE

THOUSAND OAKS, Calif. (July 11, 2007) and TOKYO (July 12, 2007) – Amgen (NASDAQ:AMGN) and Daiichi Sankyo Company, Limited (TSE:4568) today announced a collaboration and license agreement for the development and commercialization of denosumab in Japan. Denosumab is a fully human monoclonal antibody that targets RANK Ligand (an essential mediator of cells that break down bone) and is being investigated for its potential to treat and prevent a broad range of bone loss conditions including osteoporosis and bone metastases.

Under the terms of the agreement, Amgen has granted Daiichi Sankyo exclusive rights to develop and commercialize denosumab in Japan in post-menopausal osteoporosis and oncology with the potential for additional indications. As part of the agreement, Amgen will receive exclusive worldwide rights to certain Daiichi Sankyo intellectual property to the extent applicable to denosumab.

The financial terms include an upfront payment to Amgen of \$20 million. In addition, Daiichi Sankyo will assume all development costs for denosumab in Japan and will pay approximately \$150 million of expected worldwide development costs for denosumab through 2009. In consideration of its intellectual property, Daiichi Sankyo is also eligible to receive milestone payments dependent on the approval of denosumab in the European Union or Japan, in two indications. In connection with its activities under the collaboration and license agreement, Daiichi Sankyo will pay royalties on annual net sales of denosumab in Japan in amounts commensurate with a major late stage product for the Japan market.

“Daiichi Sankyo is an ideal partner for denosumab,” said Kevin Sharer, Chairman and CEO of Amgen. “Daiichi Sankyo is uniquely positioned to bring this potential therapy to patients with a wide spectrum of bone-related diseases in Japan.”

“Daiichi Sankyo is thrilled to partner with a world leader in biotechnology to gain access to this important antibody product,” said Takashi Shoda, President and CEO of Daiichi Sankyo. “We believe that denosumab has the potential to be a first-in-class, leading product in Japan for multiple indications within Daiichi Sankyo’s therapeutic areas of focus. Denosumab’s potential applicability in oncology makes it an important part of the foundation for our growing oncology business.” Daiichi Sankyo has a full range of commercial capabilities, including in the primary care and hospital settings, a track record of successful large, first-in-class product launches and the financial strength to ensure appropriate investment in the product.

About Denosumab

Denosumab is a fully human monoclonal antibody that targets RANK Ligand and is being investigated for its potential to prevent and treat a broad range of bone loss conditions including osteoporosis, bone metastases, treatment-induced bone loss, multiple myeloma and bone erosions in rheumatoid arthritis. Denosumab is the first late-stage investigational therapy that specifically inhibits RANK Ligand, an essential mediator of the cells that break down bone.

About Amgen

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science’s promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people’s lives.

To learn more about our pioneering science and our vital medicines, visit www.amgen.com.

About Daiichi Sankyo Company, Limited

DAIICHI SANKYO COMPANY, LIMITED was established in September 2005 as the joint holding company for the DAIICHI SANKYO Group by means of a stock transfer. Business integration has proceeded steadily since then, and the integration process was completed in April 2007 with the merger of Sankyo Co. Ltd. and Daiichi Pharmaceutical Co., Ltd. into DAIICHI SANKYO. DAIICHI SANKYO is a global pharmaceutical innovator, continuously generating innovative drugs and services and maximizing its corporate value. For further details, please refer to the company Web site at www.daiichisankyo.com

Forward-Looking Statement: Amgen

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in our Form 10-K for the year ended Dec. 31, 2006, and in our periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. The Company's results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments (domestic or foreign) involving current and future products, sales growth of recently launched products, competition from other products (domestic or foreign), difficulties or delays in manufacturing our products. In addition, sales of our products are affected by reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and health care cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers.

CONTACT: Amgen, Thousand Oaks
Anne McNickle 805-447- 5890 (w) 323-868-5827 (mobile) (Media)
Arvind Sood, 805-447-1060 (Investors)

CONTACT: Daiichi Sankyo, Tokyo

Masaya Tamae, +81-3-6225-1126 (office)

Schedule
[*]

Schedule
Supply Agreement Term Sheet

| | |
|-------------------------------|---|
| Defined Terms | Capitalized terms used but not defined in this term sheet shall have the meanings assigned to them in the Collaboration Agreement. |
| Supply of Drug Product | <p>Amgen will sell, and Collaborator will buy, Collaborator's requirements of Dmab (except for clinical supply, which is handled under the Collaboration Agreement). Supply for post-marketing studies would be dealt with in the Supply Agreement, not the Collaboration Agreement; provided that, supply for post-marketing studies which are required for obtaining a Regulatory Approval by MHLW and for which Collaborator is required by Law to provide Dmab [*] would be dealt with in the Collaboration Agreement. Supply of Dmab would be provided in [*] ("<i>Drug Product</i>").</p> <p>Collaborator would be free to order any presentation [*] of Drug Product from those presentations initially used by Amgen outside the Territory or later adopted by Amgen for use outside the Territory. Supply Agreement will contemplate [*] in order to commercialize Dmab in the Territory. The Parties shall meet to discuss the need for and determine how to address such [*] with the minimum potential disruption to Amgen's manufacturing operations and its commercialization and development of Dmab outside the Territory, and Collaborator would bear all incremental costs associated with the [*].</p> |
| Pricing | Pricing for Drug Product would consist of two components: [*]. |
| Forecasts | The Supply Agreement will set forth a forecast procedure for Dmab to be provided thereunder. The forecast procedure will contemplate Collaborator's needs for reasonable flexibility in forecasting and Amgen's needs for sufficient information and certainty to reasonably enable it to timely supply Collaborator. |
| Orders | Orders will be placed at least 90 days in advance. Amgen will fill conforming orders, and will provide Drug Product [*] Incoterms 2000. Amgen will ensure all such Drug Product complies with the relevant specifications. The Supply Agreement shall specify the remaining shelf-life upon delivery of Drug Product. |
| Shortage; Allocation | In the event of any shortage of Drug Product, Amgen would allocate product such that [*]. |
| Approvals and Licenses | Amgen will be responsible for obtaining and maintaining all necessary approvals, licenses and documentation related to the export of Drug Product. Collaborator shall be responsible for obtaining and maintaining |

all necessary approvals, licenses and documentation related to the import of Drug Product in the Territory, except that Amgen shall be responsible for obtaining and maintaining all necessary approvals and documentation related to the master file and the accreditation of foreign manufacturers in the Territory. Each Party shall provide copies thereof to the other as requested at least 60 days prior to the first scheduled delivery of Drug Product.

Testing and Non-compliance

Collaborator will have [*] days to test product for conformance with the specifications. In the event of any disagreement as to compliance with the specifications upon delivery, such matter will be determined by an independent third party. In the event of any such non-compliance, Collaborator's sole remedy will be the replacement of the non-conforming Drug Product by Amgen.

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Regulatory Responsibility

Amgen will have sole regulatory responsibility for all manufacturing matters, in accordance with Section 4.15.2 of the Collaboration Agreement, and will cooperate with Collaborator with respect thereto in accordance with Section 4.15.3 thereof.

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If it is determined that the manufacture of Drug Product should be [*] to Collaborator for the Collaborator Indications in the Territory (which information will be confidential and [*]). Collaborator and Amgen shall each be responsible for [*]. Collaborator shall still be required to pay Amgen [*]

Contract Manufacturer

Amgen will have the right to utilize one or more third-party contract manufacturers in the manufacture of Dmab and Drug Product, and Amgen shall provide written notice to Collaborator prior to the use of such third-party to produce Drug Product to be provided to Collaborator. Use of such third-party contract manufacturers shall not excuse Amgen's performance under the Supply Agreement and Amgen will be responsible for any breach of the Supply Agreement (subject to the relevant force majeure provisions, provided that failure of a contract manufacturer (other than for reasons which would, independently, constitute a force majeure) shall not constitute a force majeure).

Confidentiality

Confidentiality provisions would be included commensurate with those contained in the Collaboration Agreement. In addition, any information obtained in any inspections would be Amgen's confidential information, and shared within Collaborator only on a strict need-to-know basis.

Quality Agreement

Promptly following the execution of the Supply Agreement, the quality assurance departments of Amgen and Collaborator will develop and agree upon a quality agreement governing the quality and specifications of Drug

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| | Product to be supplied under the Supply Agreement including with respect to product quality and product complaints with respect to Dmab. The quality agreement will be documented in writing, and routinely updated. |
| Representations and Warranties | Each of the Parties will make standard representations and warranties regarding corporate power to enter into the agreement, binding nature of agreement and the like. Amgen will warrant that, upon delivery, the Drug Product will comply with the specifications. Collaborator will warrant that the Drug Product purchased will be used only for Collaborator Indications in the Territory, and that it will only order Drug Product as it reasonably anticipates it will need for such purpose. Collaborator will warrant that it will use reasonable commercial efforts to provide accurate forecasts. Amgen will warrant that it will ensure compliance with applicable U.S. export control laws, Collaborator will warrant that it will ensure compliance with applicable importation laws within the Territory (and U.S. export control laws, if applicable) and each Party will warrant to the other that it will ensure product integrity during any storage and transportation for which it is responsible. All other warranties by the parties will be disclaimed (including those of merchantability, fitness for a particular purpose, and non-infringement). |
| Insurance and Indemnity | Commensurate with Collaboration Agreement. |
| Term and Termination | <p>Commensurate with Collaboration Agreement. In addition, the Supply Agreement will automatically terminate on termination of the Collaboration Agreement. Amgen would retain the right to terminate upon [*] notice in the event [*]</p> <p>Amgen would have no obligation to supply Drug Product to Collaborator if and for so long as Collaborator is in breach of its obligations under the Supply Agreement or Collaboration Agreement.</p> |
| Miscellaneous | Commensurate with the Collaboration Agreement. The United Nations Convention for the International Sale of Goods will be disclaimed. |