Current Agreements

Dealdoc

First amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)

Adolor
GSK

Jun 22 2004

First amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)

Companies:	Adolor GSK
Announcement date:	Jun 22 2004
Related contracts:	Termination of licensing, co-development and marketing agreement for Entereg (alvimopan) Third amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) Licensing, co-development and marketing agreement for Entereg (alvimopan) (terminated) Distribution agreement for Entereg (alvimopan) Second amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) Fourth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) Fifth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) First amendment to distribution agreement for Entereg (alvimopan)

- Details
- Financials
- Termsheet
- Press Release
- Filing Data
- Contract

Details

Announcement date:	Jun 22 2004
Start date:	Jun 22 2004
Industry sectors:	Bigpharma Pharmaceutical
Therapy areas:	Hospital care » Surgery Gastrointestinal » Symptoms » Bowel movement
Technology types:	Drug delivery Small molecules
Deal components:	Co-development Co-market Co-promotion Licensing Marketing Promotion
Stages of development:	Phase III
Geographic focus:	Worldwide

Financials

Termsheet

Not available.

Press Release

Not available.

Filing Data

Not available.

Contract

AMENDMENT NO. 1 TO

COLLABORATION AGREEMENT

This Amendment No. 1 (“Amendment No. 1”) to the Collaboration Agreement dated as of April 14, 2002 by and between Adolor Corporation, a Delaware corporation, (“Adolor”) and Glaxo Group Limited, a United Kingdom corporation (“GSK”) (the “Collaboration Agreement”) is entered into as of the 22nd day of June, 2004 by and between Adolor and GSK and shall be effective as of June 24, 2003.

RECITALS

WHEREAS the Parties have been collaborating in the Development of alvimopan pursuant to the terms of the Collaboration Agreement; and

WHEREAS, the Parties have determined to amend Article 3 “Governance of Development and Commercialization of Products” in the manner set forth below.

NOW THEREFORE, intending to be legally bound, the Parties agree as follows:

1. Capitalized terms used in this Amendment No.1 shall have the same meanings as in the Collaboration Agreement, unless otherwise defined herein.

2. Section 1.79 of the Collaboration Agreement defining the term “Joint Development Committee” shall be deleted in its entirety and replaced with the following Section 1.79.

“1.79 “Asset Management Team” shall have the meaning set forth in Section 3.2.1.”

Every place that the term “Joint Development Committee” appears throughout the Collaboration Agreement shall be replaced by the term “Asset Management Team.”

3. Section 1.81 of the Collaboration Agreement defining the term “Joint Marketing Committee” shall be deleted in its entirety and replaced with the following Section 1.81:

“1.81 “Joint U.S. Marketing Team” shall have the meaning set forth in Section 3.3.1.”

Every place that the term “Joint Marketing Committee” appears throughout the Collaboration Agreement shall be replaced by the term “Joint U.S. Marketing Team.”

4. Section 1.82 of the Collaboration Agreement defining the term “Joint Supply Committee” shall be deleted in its entirety and every place that the term “Joint Supply Committee” appears throughout the Collaboration Agreement shall be replaced by the term “Asset Management Team.”

5. Section 3.2.1, of the Collaboration Agreement shall be deleted in its entirety and replaced with the following Section 3.2.1.

“3.2 Asset Management Team

3.2.1 Members; Officers; Subteams . The Parties have established an Asset Management Team (the “Asset Management Team”), to which GSK and Adolor shall designate an equal number of representatives, up to a maximum total of twenty (20) members on such Asset Management Team. Each of GSK and Adolor may replace any or all of its representatives on the Asset Management Team at any time upon written notice to the other Party. Such representatives shall include individuals who have clinical trial and regulatory experience, expertise in pharmaceutical drug Development, Commercialization and manufacturing and supply of drugs. A Party may designate a substitute to temporarily attend and perform the functions of such Party’s designee at any meeting of the Asset Management Team. GSK and Adolor each may, on advance notice to the other Party, invite non-member representatives of such Party to attend meetings of the Asset Management Team. The Asset Management Team shall be chaired on an annual rotating basis by a representative of either Adolor or GSK, as applicable, with Adolor providing the chairperson for the annual term beginning July 1, 2003 through June 30, 2004. The chairperson shall appoint a secretary of the Asset Management Team, who shall be a representative of the other Party and who shall serve for the same annual term as such chairperson. The Asset Management Team shall operate as a joint team for the Development and coordination of the Commercialization of Compound. In carrying out its responsibilities as set forth in Section 3.2.2, the Asset Management Team shall have the authority but not the obligation to establish one or more subteams with representation from each of GSK and Adolor to take on and coordinate activities as identified by the Asset Management Team (each a “Subteam” together, the “Subteams”). By way of example and not limitation, Subteams may be designated for: commercial; supply/chemistry and

manufacturing; clinical and statistical; nonclinical; and regulatory. For each Subteam established, the Asset Management Team shall have the authority to: determine the disciplines that need to be represented from each of GSK and Adolor, delegate activities to

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the Subteam, approve the charter for the Subteam, set up procedural mechanisms for the Subteam to interact with the Asset Management Team, and disband the Subteam. Notwithstanding any such delegation of activities to a Subteam, the Asset Management Team shall be fully responsible for all of the responsibilities set forth in Section 3.2.2, including all activities delegated to the Subteams."

6. Section 3.2.2(f) shall be revised to delete from the first line of that Section the following: "At each meeting of the Joint Development Committee," and to replace that language with the following: "Quarterly the Asset Management Team shall"

7. Section 3.2.2 shall be further amended to delete the current Section 3.2.2(h) and to add the following provisions:

"(h) Coordinate Development and Commercialization of the Collaboration Products in the ROW with the Development and Commercialization of the Collaboration Products in the United States;

(i) Coordinate life cycle management of, and intellectual property protection for, the Collaboration Products in the United States and the ROW;

(j) Manage and oversee the activities in relation to manufacture and supply of API Compound and Collaboration Products for use in Development and Commercialization and establish procedures and protocols for testing API Compound and Collaboration Products to ensure that such API Compound and Collaboration Products comply with the specifications (the "Testing Protocol"). The Parties will utilize such Testing Protocol with respect to API Compound and Collaboration Product that they may receive from Product Suppliers to ensure that such API Compound or Collaboration Product meets specifications;

(k) Recommend and coordinate necessary adjustments to the manufacturing schedule to ensure it is meeting the needs for all Collaboration Products;

(l) Coordinate allocation of API Compound in the event of a shortage between the United States and the ROW, it being understood that, in the event of a shortage, allocation of API Compound shall be as follows: (i) requirements for use in POI Products for Commercialization in the United States shall have first priority; (ii) requirements for use in POI Products for Commercialization in the ROW shall have second priority; (iii) requirements for use in Collaboration Products (other than POI Product) in the United States shall have third priority; (iv) requirements for use in Collaboration Products (other than POI Product) for Commercialization in

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the ROW shall have fourth priority; and (v) requirements for use in all other Products containing API Compound shall have fifth priority. The foregoing priority allocations may be revised by the Asset Management Team based on the relative commercial value of such Collaboration Products;

(m) Review the quality of the manufacture of the Collaboration Products, reviewing as appropriate reports of the manufacturers of API Compound and Collaboration Products and reports as to the quality of any packaging that bears the relevant trademarks or housemarks of the Parties (as owned by or licensed to the relevant Party under Section 2.4) as prescribed by this Agreement;

(n) Recommend and implement optimal inventory levels and safety stock targets;

(o) Set improvement targets and monitor performance against these targets for cost, yield, delivery and other appropriate measures;

(p) Establish guidelines to facilitate improved efficiencies and compliance with current Good Manufacturing Practices by Product Suppliers; and

(q) Have such other responsibilities as may be assigned to the Asset Management Team pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time."

8. Section 3.2.5 shall be amended to add the following sentence as the last sentence of Section 3.2.5 : "Notwithstanding the foregoing any matter relating to supply of API Compound or any Collaboration Product assigned for decision-making to a Party in Article 10 or in the further agreements between the Parties contemplated thereby shall not be subject to referral to the Joint Steering Committee."

9. Section 3.4, including Section 3.4.1, 3.4.2, 3.4.3 and 3.4.4, shall be deleted in its entirety.

10. The term "committee" throughout the Collaboration Agreement shall also be read to refer to the "team" as and if the context requires.

11. Except as specifically set forth above, the Collaboration Agreement remains in full force and effect as originally executed.

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IN WITNESS WHEREOF, the Parties have executed this Amendment No.1 as of this 22nd day of June 2004.

ADOLOR CORPORATION

GLAXO GROUP LIMITED

By:

/s/ Bruce A. Peacock

By:

/s/ Leo Nuttall

Name:

Bruce A. Peacock

Name:

Leo Nuttall

Title:

President and Chief Executive Officer

Title:

Corporate Director