

Dealdoc

Licensing, development, marketing and option agreement for oral small molecule analgesic, GRT 6005 (terminated)

Grunenthal Forest Laboratories Ireland

Dec 06 2010

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Companies:

Forest Laboratories Ireland

Announcement date: Dec 06 2010
Amendment date: Nov 27 2014

Deal value, US\$m: n/d

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Details

Announcement date: Dec 06 2010
Amendment date: Nov 27 2014
Termination date: Nov 27 2014
Industry sectors: Bigpharma

Compound name: Pharmaceutical Cebranopadol (GRT6005)

Exclusivity: Exclusive
Asset type: Compound

Therapy areas:

Central Nervous System » Pain

Central Nervous System » Pain

Central Nervous System » Pain » Neuralgia

Technology types: Small molecules

Co-development Co-promotion

Deal components: Licensing

Option
Termination
Phase I

Stages of development: Phase II

Europe

Geographic focus: North America » Canada

North America » United States

Financials

Deal value, US\$m: n/d

Upfront, US\$m: n/d : upfront payments

Milestones, US\$m: n/d : development and commercial milestone payments

Royalty rates, %: n/d : royalty payments on net sales

More details:

Development costs will be shared between the parties according to an

undisclosed formula

Termsheet

27 November 2014

Grünenthal announced the termination of the license agreement with Actavis for the development and commercialization of Cebranopadol, a novel analgesic for the treatment of chronic pain.

Forest Laboratories Ireland and Grünenthal had entered into a license agreement on Cebranopadol in December 2010.

This agreement included the co-development and commercialization of Cebranopadol (GRT6005), with exclusive rights for Actavis in the United States and Canada, while Grünenthal held the rights in Europe and the rest of the world.

Grünenthal continues the development program as planned.

The termination of the license agreement does not have any impact on the enrollment status of patients who are currently participating in the ongoing clinical trials in Europe and the US.

6 December 2010

Gruenenthal GmbH and Forest Laboratories Ireland have entered into a license agreement for the co-development and commercialization of a novel oral small molecule analgesic, GRT 6005, and its follow-on compound GRT 6006.

Both compounds were discovered and developed by Gruenenthal and represent novel

GRT 6005 has successfully completed initial proof-of-concept studies in nociceptive and neuropathic pain with further Phase 2 studies planned prior to initiation of Phase 3.

The license agreement provides that Forest pay Gruenenthal an undisclosed upfront license payment in addition to development and commercialization milestones and royalties on net sales.

Forest will have exclusive rights in the United States and Canada with an option to co-promote in Europe.

Gruenenthal will have an option to co-promote in the United States and Canada.

Development costs will be shared between the parties according to an undisclosed formula.

Press Release

27 November 2014

Grünenthal Announces Termination of License Agreement with Actavis for the Development of Cebranopadol as of October 1, 2014

Grünenthal continues the clinical program as planned

Aachen, Germany, November 27, 2014. Grünenthal announced the termination of the license agreement with Actavis for the development and commercialization of Cebranopadol, a novel analgesic for the treatment of chronic pain.

Actavis' subsidiary Forest Laboratories Ireland Limited and Grünenthal GmbH had entered into a license agreement on Cebranopadol in December 2010. This agreement included the co-development and commercialization of Cebranopadol (GRT6005), with exclusive rights for Actavis in the United States and Canada, while Grünenthal held the rights in Europe and the rest of the world.

Grünenthal continues the development program as planned. The termination of the license agreement does not have any impact on the enrollment status of patients who are currently participating in the ongoing clinical trials in Europe and the US.

"We will work with Actavis to fully transition the development activities under the license agreement", said Klaus-Dieter Langner, PhD, Grünenthal Chief Scientific Officer. "We will continue the development of Cebranopadol to define the best direction for this innovative compound."

About Cebranopadol Cebranopadol is a novel small molecule analgesic which was discovered by Grünenthal GmbH, Germany. Cebranopadol represents a novel first-in-class molecule with unique pharmacological and pharmacokinetic profiles1. Cebranopadol is currently in phase IIb clinical development in USA and Europe for the treatment of chronic pain with currently about 2.000 patients treated.

About Grünenthal The Grünenthal Group is an independent, family-owned, international research-based pharmaceutical company headquartered in Aachen, Germany. Building on its unique position in pain treatment, its objective is to become the most patient-centric company in the field of pain and thus to be a leader in therapy innovation. Grünenthal is one of the last five remaining research-oriented pharmaceutical companies with headquarters in Germany which sustainably invests in research and development. Research and development costs amounted to about 27 percent of revenues in 2013. Grünenthal's research and development strategy concentrates on selected fields of therapy and state-of-the-art technologies. We are intensely focused on discovering new ways to treat pain better and more effectively, with fewer side-effects than current therapies. Altogether, the Grünenthal Group has affiliates in 25 countries worldwide. Grünenthal products are sold in

more than 155 countries and approx. 5,500 employees are working for the Grünenthal Group worldwide. In 2013, Grünenthal achieved revenues of €901 mn. More information: www.grunenthal.com

6 December 2010

Forest Laboratories and Gruenenthal Enter Into Licensing Agreement for the Development and Commercialization of Novel Analgesic Compound

AACHEN, Germany & NEW YORK--(BUSINESS WIRE)--The Gruenenthal Group and Forest Laboratories, Inc. (NYSE: FRX), today announced that Gruenenthal GmbH and Forest Laboratories Ireland Limited, a wholly owned subsidiary of Forest Laboratories, Inc. have entered into a license agreement for the co-development and commercialization of a novel oral small molecule analgesic, GRT 6005, and its follow-on compound GRT 6006. Both compounds were discovered and developed by Gruenenthal and represent novel first in class molecules with unique pharmacological and pharmacokinetic profiles that may enhance their effect in certain pain conditions. The unique mode of action of these compounds builds on the ORL-1 receptor and, supported by the established mu opioid receptor, is particularly suitable for the treatment of moderate to severe chronic pain. GRT 6005 has successfully completed initial proof-of-concept studies in nociceptive and neuropathic pain with further Phase 2 studies planned prior to initiation of Phase 3.

The license agreement provides that Forest pay Gruenenthal an undisclosed upfront license payment in addition to development and commercialization milestones and royalties on net sales. Under the agreement, Forest will have exclusive rights in the United States and Canada with an option to co-promote in Europe. Gruenenthal will have an option to co-promote in the United States and Canada. Development costs will be shared between the parties according to an undisclosed formula.

Harald F. Stock, CEO of the Gruenenthal Group said, "We look forward to this cooperation with a strong and well-reputed partner. We provide the pain market with high-end compounds and thus are an attractive partner for companies like Forest. This cooperation once more confirms Gruenenthal's innovative power as preferred partner in pain management."

Howard Solomon, Chairman and Chief Executive Officer of Forest, said, "We are pleased to have entered into this collaboration with Gruenenthal, a leading company in the field of pain management. The unique profile of the licensed molecules may provide needed alternative analgesic options for patients. We look forward to working with Gruenenthal to make this novel class of products available to the millions of patients suffering from moderate to severe pain."

About GRT 6005 and GRT 6006

GRT 6005 and 6006 are novel first in class compounds with potent agonist activity on ORL-1 (opioid receptor like -1) and the well established mu opioid receptor. Preliminary evidence suggests that targeting ORL-1 receptors may have synergistic effects with mu receptors hence enhancing the therapeutic profile of the compounds in the treatment of pain. The unique pharmacological and pharmacokinetic profile of these compounds is particularly suited for the management of moderate to severe chronic pain, including neuropathic pain. The compounds are covered by a composition of matter patent that will expire in November 2023. Additional patent term extension is expected.

About The Gruenenthal Group

The Gruenenthal Group is an independent, family-owned international research based pharmaceutical company headquartered in Aachen, Germany. Building on its unique position in pain, its objective is to become the most patient-centric company to be a leader in therapy innovation. Altogether, the Gruenenthal Group has affiliates in 35 countries worldwide. Gruenenthal products are sold in more than 100 countries and approx. 4,900 employees are working for the Gruenenthal Group globally. In 2009, Grünenthal reached revenues of about 881 Mio €.

More information: www.grunenthal.com.

Current press material is available in the press section at www.grunenthal.com.

About Forest Laboratories

Forest Laboratories' (NYSE: FRX) longstanding global partnerships and track record developing and marketing pharmaceutical products in the United States have yielded its well-established central nervous system and cardiovascular franchises and innovations in anti-infective medicine. The Company's pipeline, the most robust in its history, includes product candidates in all stages of development across a wide range of therapeutic areas. The Company is headquartered in New York, NY. To learn more, visit www.FRX.com.

Except for the historical information contained herein, this release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and the risk factors listed from time to time in Forest Laboratories' Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and any subsequent SEC filings.

Filing Data

Not available.

Contract

Not available.