BAUSCH Health

Valeant Pharmaceuticals Acquires U.S. Rights to Targretin® from Eisai Inc.

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WOODCLIFF LAKE, NJ. and MONTREAL, Quebec, Feb. 21, 2013 /PRNewswire/ -- Eisai Inc., the U.S. pharmaceutical subsidiary of Eisai Co., Ltd., and Valeant Pharmaceuticals International, Inc. (NYSE: VRX)(TSX: VRX) announced today that Valeant has acquired U.S. rights for Targretin® (bexarotene) capsules and Targretin® (bexarotene) gel 1% from Eisai for $65 million upfront, plus potential contingent payments based on certain milestones.

(Photo:
http://photos.prnewswire.com/prnh/20130221/LA63958
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As part of the transaction, which takes effect immediately, Eisai has transferred the New Drug Application (NDA) for Targretin to Valeant, with Valeant assuming responsibilities for all regulatory obligations associated with the product in the United States. Eisai will retain its rights to Targretin outside of the United States and continue to meet the needs of its distribution partners outside of the United States.

Targretin Capsules

Indication
Targretin (bexarotene) capsules are used to treat the skin problems arising from a disease called cutaneous T-cell lymphoma, or CTCL when at least one systemic therapy has not worked. Your doctor must supervise the use of Targretin capsules.

Important Safety Information
Do not take Targretin® capsules if you are pregnant or if you plan to become pregnant.

- **Targretin® capsules may harm your fetus (unborn baby). You should contact your doctor immediately if you believe or suspect you are pregnant while you are taking Targretin® capsules and until one month after you stop taking Targretin® capsules.**
- **If you are capable of becoming pregnant, you must have a pregnancy test within one week before you start Targretin® capsule therapy and monthly while you are taking, confirming you are not pregnant.**
- **You must use effective contraception (birth control) continuously starting one month before beginning treatment with Targretin® capsules until one month after you stop taking Targretin® capsules. It is strongly recommended that two reliable forms of contraception be used together. At least one of these two forms of contraception should include condoms, diaphragms, cervical caps, IUDs, or spermicides.**
- **If you are male and your partner is pregnant or capable of becoming pregnant, you should discuss with your doctor the precautions you should take.**

Do not take Targretin capsules if you are allergic to this medicine or retinoid medications (for example: Accutane® [isotretinoin], Soriatane® [acitretin], Tegison [etretinate], Vesinoid® [tretinoin])‡.

Targretin capsules can greatly increase blood levels of lipids (triglycerides and cholesterol) and these levels must be monitored and, if elevated, treated.

Targretin capsules can cause an underactive thyroid and periodic blood tests will be needed to detect this. Medication to control the condition may be necessary.

Before you start to take this medicine, tell your doctor if you are pregnant, have or previously had an inflamed pancreas, are breastfeeding, are taking gemfibrozil (Lopid®)* a medicine to reduce high triglyceride cholesterol levels in the blood, or are taking tamoxifen (Nolvadex®)†.

Your skin may become more sensitive to sunlight while taking this medicine. Minimize exposure to sunlight and do not use a sunlamp.

The most common side effects with Targretin capsules are increase in blood lipids, headache, weakness, underactive thyroid, decreased white blood cells and diarrhea.

Please also see full prescribing information including boxed warning and patient instructions for use.

Targretin Gel

Indication
Targretin gel is used to treat the skin problems arising from a disease called cutaneous T-cell lymphoma, or CTCL (stage I) when other therapies have not worked or were not tolerated. Your doctor must instruct you on the proper use of Targretin gel.

Important Safety Information
Do not use Targretin gel if you are pregnant or if you plan to become pregnant. Targretin gel may harm your fetus (unborn baby). You should contact your doctor immediately if you believe or suspect you are pregnant while you are using Targretin gel and until one month after you stop using Targretin gel. Do not use Targretin gel if you are breast feeding.

Do not use Targretin gel if you are allergic to this medicine or retinoid medications (for example: Accutane ® [isotretinoin], Soriatane® [acitretin], Tegison [etretinate], Vesinoid® [tretinoin]).

Because vitamin A in large doses may cause some side effects which are similar to those seen in patients applying Targretin gel, do not take more than the recommended daily dietary allowance of vitamin A (4000 to 5000 International Units). If you are not sure, ask your doctor or pharmacist.

Do not apply Targretin gel to the healthy skin around the lesion and avoid application of the gel on or near mucosal surfaces of the body such as eyes, nostrils, mouth, lips, vagina, tip of the penis, rectum, or anus.

Your skin may become more sensitive to sunlight while using this medicine. Minimize exposure to sunlight and do not use a sunlamp.

Do not use insect repellents or other products containing DEET while using Targretin gel.

Store Targretin gel at room temperature. Keep away from heat or flame.

The most common side effects include redness, itching, burning, irritation and scaling at the area of application.

Please also see full prescribing information including boxed warning and patient instructions for use.

Eisai Inc.
Eisai Inc. was established in 1995 and began marketing its first product in the United States in 1997. Since that time, Eisai Inc. has rapidly grown to become a fully integrated pharmaceutical business. Eisai's key areas of commercial focus are neurology and oncology. The company serves as the U.S. pharmaceutical operation of Eisai Co., Ltd., a research-based *human health care* (*hhc*) company that discovers, develops and markets products throughout the world.

Eisai has a global product creation organization that includes U.S.-based R&D facilities in Massachusetts, New Jersey, North Carolina and Pennsylvania, as well as manufacturing facilities in Maryland and North Carolina. The company's areas of R&D focus include neuroscience; oncology; vascular, inflammatory and immunological reaction; and antibody-based programs. For more information about Eisai, please visit
www.eisai.com/US
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Eisai Co., Ltd.
Eisai Co., Ltd. is a research-based *human health care* (*hhc*) company that discovers, develops and markets products throughout the world. Through a global network of research facilities, manufacturing sites and marketing subsidiaries, Eisai actively participates in all aspects of the worldwide healthcare system.

Valeant Pharmaceuticals International, Inc.
Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, neurology, and branded generics. More information about Valeant Pharmaceuticals International, Inc. can be found at
www.valeant.com
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