FDA Approves ZIOPTAN™ (tafluprost ophthalmic solution), Merck’s Once-Daily, Preservative-Free Ophthalmic Medication

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ZIOPTAN is a New and Effective Prostaglandin Analog Option for Lowering Elevated Intraocular Pressure in Patients with Open-Angle Glaucoma or Ocular Hypertension

WHITEHOUSE STATION, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) has approved ZIOPTAN™ (tafluprost ophthalmic solution) 0.0015%, the first preservative-free prostaglandin analog ophthalmic solution. ZIOPTAN (pronounced zye-OP-tan) is approved for reducing elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension. Open-angle glaucoma is the most common form of glaucoma, while ocular hypertension is a condition characterized by an increase in pressure inside the eye.

"Prostaglandin analogs are often used as a first line of treatment to lower intraocular pressure in patients with open-angle glaucoma. The approval of ZIOPTAN will provide a new, effective option to lower IOP," said George L. Spaeth, M.D., Wills Eye Institute, Philadelphia, "I anticipate using ZIOPTAN in many of these patients in my practice."

ZIOPTAN may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, color, thickness, shape and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment.

The FDA approval of ZIOPTAN was based on efficacy and safety results from five controlled clinical studies of up to two years in 905 patients. Both preservative-containing and preservative-free formulations of tafluprost were used in these clinical studies.

ZIOPTAN was shown to have powerful IOP-lowering effects. In clinical studies of up to two years in duration, ZIOPTAN, dosed once-daily in the evening lowered IOP at 3 and 6 months by 6-8 mmHg and 5-8 mmHg respectively, from a baseline pressure of 23-26 mmHg (mmHg = millimeters of mercury, a measurement of fluid pressure in the eye).

"ZIOPTAN is the first preservative-free prostaglandin analog," said David Michelson, M.D., vice president, Neurology and Ophthalmic Therapeutic Area, Merck Research Laboratories. "We are excited to continue Merck's 50-year tradition of bringing forward additional options to help meet the needs of eye care professionals and their patients."

Merck anticipates that ZIOPTAN will be available to customers in March.

Selected Important Safety Information about ZIOPTAN

Warnings and Precautions

ZIOPTAN has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelid) and eyelashes. Pigmentation is expected to increase as long as ZIOPTAN is administered. After discontinuation of ZIOPTAN, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes have been reported to be reversible in some patients. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long term effects of increased pigmentation are not known. Iris color change may not be noticeable for several months to years. While treatment with ZIOPTAN can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

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ZIOPTAN should be used with caution in patients with active intraocular inflammation (e.g., iritis/uveitis) because the inflammation may be exacerbated.
Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin F2α analogs. ZIOPTAN should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Adverse Reactions

In clinical trials of patients receiving either preservative-containing or preservative-free ZIOPTAN, the most common pooled adverse reaction observed was conjunctival hyperemia which was reported in a range of 4 to 20 percent of patients.

Use in Specific Populations

There are no adequate and well-controlled studies in pregnant women. ZIOPTAN should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

It is not known whether ZIOPTAN or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ZIOPTAN is administered to a nursing woman.

Use in pediatric patients is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

Dosing and Administration

The recommended dose of ZIOPTAN is one drop in the conjunctival sac of the affected eye(s) once daily in the evening. The dose should not exceed once daily since it has been shown that more frequent administration of prostaglandin analogs may lessen the IOP lowering effect. ZIOPTAN, which does not contain preservatives, is a sterile solution for single use only and one container is sufficient to treat one or both eyes. Because ZIOPTAN is formulated without preservatives, sterility of opened containers cannot be maintained. Therefore, any unused solution should be discarded immediately after use.

ZIOPTAN may be used concomitantly with other topical ophthalmic drug products to lower IOP. If more than one topical ophthalmic product is being used, each one should be administered at least five minutes apart.

Licensing Agreement Between Merck and Santen

On April 15, 2009, Merck and Santen Pharmaceutical Co., Ltd. entered into a worldwide licensing agreement for tafluprost. Merck has exclusive commercial rights to tafluprost in Western Europe (excluding Germany), North America, South America, Africa, the Middle East, India and Australia. ZIOPTAN is marketed as SAFLUTAN® (tafluprost) in certain markets outside the United States. Santen retains commercial rights to tafluprost in Germany, most countries in Eastern Europe, northern Europe and in countries in the Asia Pacific region, including Japan. Tafluprost is marketed under the trademark of Taptros™ or Talfotan® in certain countries where Santen retains commercial rights. Merck provides promotion support to Santen in Germany. Santen has the option to co-promote tafluprost in the United States.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook and YouTube.

About Santen

Santen Pharmaceutical is a pharmaceutical company based in Osaka, Japan, which specializes in ophthalmic and anti-rheumatic fields. Santen contributes to maintaining people's eyesight and health. Santen applies its efforts mainly in ophthalmology. For details please access: http://www.santen.com.

Merck Forward-Looking Statement

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the United States and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2010 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

Please see Prescribing Information for ZIOPTAN at http://www.merck.com/product/usa/pi_circulars/z/zioptan/zioptan_pi.pdf and Patient Prescribing Information for

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