


 

News Room



SOURCE: ISTA Pharmaceuticals



March 27, 2012 07:30 ET

ISTA Pharmaceuticals Announces Issuance of U.S. Patent for PROLENSA™

Patent Term Adjustment Extends Intellectual Property Protection for ISTA's Bromfenac-Based Drug Candidates Through September 2025

IRVINE, CA--(Marketwire - Mar 27, 2012) - ISTA Pharmaceuticals, Inc. (NASDAQ: [ISTA](#)) today announced that the United States Patent and Trademark Office has issued Patent No. 8,129,431 with claims covering PROLENSA™ (bromfenac ophthalmic solution), ISTA's once-daily topical nonsteroidal anti-inflammatory product for the treatment of ocular inflammation and pain following cataract surgery. The patent was issued to ISTA's licensor, Senju Pharmaceuticals Co. Ltd., and was granted a patent term adjustment that extends the patent life originally set to expire January 2024 to September 2025.

"The issuance of this patent broadens and further extends the intellectual property position for pipeline products in our bromfenac franchise," said Vicente Anido, Jr., Ph.D., President and Chief Executive Officer of ISTA. "As noted earlier in the year, our bromfenac franchise has multiple barriers to entry, including Hatch-Waxman exclusivity and additional pending patents. This patent should provide protection for not only our new product candidate PROLENSA, but also a potential bromfenac adjunct therapy for age-related macular degeneration (AMD)."

Dr. Anido continued, "The new, optimized formulation used for PROLENSA enhances the penetration of bromfenac into ocular tissues, allowing us to lower the concentration of bromfenac, while maintaining the convenience of once-daily use currently prescribed with BROMDAY. We anticipate filing a New Drug Application (NDA) with the FDA for PROLENSA in the first half of 2012, with a commercial launch following approval planned in early 2013. Because PROLENSA has the advantage of offering a lower concentration of the active ingredient bromfenac with high efficacy and safety, we plan to discontinue BROMDAY sometime after the successful launch of PROLENSA."

ABOUT PROLENSA™

PROLENSA™ (bromfenac ophthalmic solution) is being developed as a once-daily topical nonsteroidal anti-inflammatory compound for the treatment of ocular inflammation and pain following cataract surgery. PROLENSA incorporates a lower concentration of bromfenac than the company's current once-daily NSAID, BROMDAY (bromfenac ophthalmic solution) 0.09% in a new, optimized formulation. From 2005 until 2011, ISTA marketed XIBROM (bromfenac ophthalmic solution)® 0.09% in the U.S. for twice-daily use for the treatment of postoperative inflammation and the reduction of ocular pain in patients who have undergone cataract surgery. In October of 2010, ISTA received FDA approval for once-daily BROMDAY and discontinued shipments of XIBROM in February 2011. ISTA acquired U.S. ophthalmic rights to bromfenac in May 2002 under a license from Senju Pharmaceuticals Co. Ltd. BROMDAY is currently the only once daily treatment option in the \$370 million U.S. ophthalmic nonsteroidal anti-inflammatory market. PROLENSA is an investigational drug and not yet available for commercial use.

ABOUT ISTA PHARMACEUTICALS

ISTA Pharmaceuticals, Inc. is a fast growing and the third largest branded prescription eye care business in the United States, with an expanding focus on allergy therapeutics. ISTA currently markets four products, including treatments for ocular inflammation and pain post-cataract surgery, glaucoma and ocular itching associated with allergic conjunctivitis. The Company's development pipeline contains additional candidates in

various stages of development to treat dry eye, ocular inflammation and pain, and nasal allergies. Headquartered in Irvine, California, ISTA generated revenues of \$160 million in 2011. For additional information about ISTA, please visit the corporate website at www.istavision.com.

BROMDAY™ (bromfenac ophthalmic solution) 0.09%, XIBROM (bromfenac ophthalmic solution)® 0.09% and PROLENSA™ (bromfenac ophthalmic solution) are trademarks of ISTA Pharmaceuticals, Inc.

FORWARD-LOOKING STATEMENTS

Any statements contained in this press release that refer to future events or other non-historical matters are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Reform Act of 1995. Without limiting the foregoing, but by way of example, statements contained in this press release related to the protections provided by patents and statutory provisions, filing and acceptance for review of a new drug application with the U.S. Food and Drug Administration, potential commercial launch in 2013, future discontinuation of BROMDAY, and potential for the use of bromfenac for AMD are forward-looking statements. Except as required by law, ISTA disclaims any intent or obligation to update any forward-looking statements. These forward-looking statements are based on ISTA's expectations as of the date of this press release and are subject to risks and uncertainties that could cause actual results to differ materially. Important factors that could cause actual results to differ from current expectations include, among others, delays and uncertainties related to the FDA or other regulatory agency approval or actions and such other risks and uncertainties as detailed from time to time in ISTA's public filings with the U.S. Securities and Exchange Commission, including but not limited to ISTA's Annual Report on Form 10-K for the year ended December 31, 2011.

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