ISTA Pharmaceuticals Receives FDA Approval for BROMDAY™

- First and Only Once-Daily Eye Drop for the Treatment of Postoperative Inflammation and Reduction of Ocular Pain in Patients Who Have Undergone Cataract Extraction -

IRVINE, Calif., Oct. 16 /PRNewswire-FirstCall/ -- ISTA Pharmaceuticals, Inc. (Nasdaq: ISTA (http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=ISTA)), today announced the U.S. Food and Drug Administration (FDA) has approved the Company's supplemental New Drug Application (sNDA) for BROMDAY™ (bromfenac ophthalmic solution) 0.09% as a once-daily prescription eye drop for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction. ISTA expects to launch BROMDAY (formerly referred to as XiDay) prior to the end of 2010.

"BROMDAY is the only once-daily ophthalmic nonsteroidal anti-inflammatory drug (NSAID) for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction. We believe the convenience of a once-daily eye drop will help with treatment compliance and benefit patients recovering from cataract surgery," stated Vicente Anido, Jr., Ph.D., President and Chief Executive Officer of ISTA. "BROMDAY is an important addition to our growing prescription eye and allergy product portfolio. Within just a few weeks, our expanded sales force will be ready to promote BROMDAY to U.S.-based ophthalmologists, along with BEPREVE®, our recently launched eye drop for the treatment of itching associated with allergic conjunctivitis.

"Since the BROMDAY approval process required additional clinical investigations beyond those conducted for the original approval of XIBROM™ 0.09%, we are seeking a three-year exclusivity period under the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. BROMDAY represents a significant step in extending our successful bromfenac-based product line established when we launched XIBROM, our twice-daily NSAID for use following cataract surgery, in 2005. In addition, we are evaluating a new formulation and lower concentrations of bromfenac called REMURA™ for the potential treatment of dry eye which is now in Phase 3 clinical studies. Beginning in mid-November, we will begin detailing BROMDAY to ophthalmologists; we expect to discontinue the twice-daily XIBROM product in early 2011."

ABOUT BROMDAY

BROMDAY is a once-daily eye drop formulation of a nonsteroidal anti-inflammatory compound for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction. BROMDAY is approved for dosing once-daily beginning one day prior to surgery, on the day of surgery and continuing for the first 14 days after surgery. Since 2005, ISTA has 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. ISTA acquired U.S. ophthalmic rights to bromfenac in May 2002 under a license from Senju Pharmaceuticals Co. Ltd. XIBROM is the 2010 dollar market share leader in the $335 million U.S. ophthalmic nonsteroidal anti-inflammatory market. ISTA reported XIBROM net sales of $81.1 million for the year ended December 31, 2009, and net sales of $41.4 million in the first six months of 2010, up 22% over the first six months of 2009.

INDICATIONS AND USAGE

BROMDAY is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction.

DOSAGE AND ADMINISTRATION

Instill one drop into the affected eye(s) once-daily beginning 1 day prior to surgery, continued on the day of surgery and through the first 14 days post-surgery.

DOSAGE FORMS AND STRENGTHS

Topical ophthalmic solution: bromfenac 0.09%

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

- Sulfite Allergic Reactions
- Slow or Delayed Healing
- Potential for cross-sensitivity
- Increased bleeding of ocular tissues
- Corneal effects including keratitis
- Contact Lens Wear

ADVERSE REACTIONS

The most commonly reported adverse reactions in 2-7% of patients were abnormal sensation in the eye, conjunctival hyperemia and eye irritation (including burning/stinging).

Full prescribing information will be available soon on ISTA Pharmaceuticals' website at http://www.istavision.com (http://www.istavision.com/).

ABOUT ISTA PHARMACEUTICALS

ISTA Pharmaceuticals, Inc. is the fourth largest and fastest growing branded prescription eye care business in the United States, with an expanding focus on allergy therapeutics. ISTA currently markets five products, including treatments for ocular inflammation and pain associated with 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, the Company generated 2009 revenues of $111 million. For additional information about ISTA Pharmaceuticals, please visit the corporate website at www.istavision.com (http://www.istavision.com/).

FORWARD-LOOKING STATEMENTS

Any statements contained in this press release that refer to future events or other non-historical matters are forward-looking statements. Without limiting the foregoing, but by way of example, statements contained in this press release related to the expected launch of BROMDAY in 2010, ISTA's anticipated devotion of resources toward the marketing of BROMDAY and BEPREVE, ISTA's intention to discontinue marketing and selling Xibrom in 2011, the potential exclusivity for BROMDAY under the Drug Price Competition and Patent Term Restoration Act, and the completion of Phase 3 studies for REMURA (bromfenac ophthalmic solution for dry eye), 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, 2009, and its Quarterly Report on Forms 10-Q for the quarters ended March 31 and June 30, 2010.

SOURCE ISTA Pharmaceuticals, Inc.

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