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FDA grants three years of marketing exclusivity to ISTA's BROMDAY

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ISTA Pharmaceuticals, Inc. (Nasdaq: ISTA), today announced the U.S. Food and Drug Administration (FDA) has granted the Company three years of marketing exclusivity for BROMDAY™ (bromfenac ophthalmic solution) 0.09%, as provided under the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. BROMDAY (formerly referred to as XiDay), the first and only once-daily prescription eye drop for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction, was approved by the FDA in October of 2010. Under the Hatch-Waxman Act, the FDA may not approve an Abbreviated New Drug Application for a generic version of BROMDAY until October of 2013.

ISTA also announced it recently shipped the first orders of BROMDAY to wholesalers and expects BROMDAY to be available in pharmacies beginning the week of November 22, 2010. The ISTA sales force has begun detailing BROMDAY to ophthalmologists, and the company expects to discontinue the twice-daily XIBROM product in early 2011.

Source:

ISTA Pharmaceuticals, Inc.

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