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FDA Approves Expanded Indication for Xibrom to Treat Pain Following Cataract Surgery

IRVINE, Calif., January 30, 2006 -- ISTA Pharmaceuticals, Inc. today announced that the U.S. Food & Drug Administration (FDA) has approved ISTA's supplemental New Drug Application (sNDA) for **Xibrom** (bromfenac ophthalmic solution) 0.09%, expanding Xibrom's indications to include the treatment of pain following **cataract surgery**. Xibrom, a topical, twice-daily, non-steroidal anti-inflammatory solution (NSAID), was originally approved by the FDA in March 2005 for the treatment of ocular inflammation following cataract surgery. ISTA launched Xibrom in the U.S. during the second quarter of 2005.

Vicente Anido, Jr., Ph.D., President and Chief Executive Officer of ISTA stated, "Since Xibrom's launch, prescriptions have grown rapidly, and the product has taken a lead position in our portfolio. We are excited to receive this additional approval from the FDA, which we believe will expand the use of our product and greatly facilitate our sales force initiatives reaching the market base of approximately 10,000 ophthalmologists in the U.S."

About Xibrom and the U.S. Ophthalmic Anti-Inflammatory Market

Xibrom (bromfenac ophthalmic solution) 0.09% is a sterile, topical, non-steroidal anti-inflammatory solution for the treatment of ocular inflammation and pain following cataract surgery. Senju Pharmaceuticals Co. Ltd. has marketed this product in Japan since 2000 with over 7.9 million uses since that time. ISTA acquired U.S. marketing rights for Xibrom in May 2002 under a license from Senju.

ISTA completed two pivotal Phase III clinical studies of Xibrom in the United States. In these studies involving 527 patients, a statistically significant proportion of patients treated with Xibrom achieved treatment success, defined as the complete absence of ocular inflammation compared to those patients who received placebo. This effect was evident in the Xibrom group as early as day 3 following initiation of treatment. Furthermore, 75% of patients who experienced pain after cataract surgery were pain-free within two days of being treated with Xibrom twice daily. In addition, 98% of patients experiencing pain after cataract surgery and receiving Xibrom twice daily were pain-free within six days of treatment.

The topical ophthalmic anti-inflammatory market consists of steroids, NSAIDS and combination products. Based upon management estimates of sales and 2004 prescription data from IMS, U.S. sales in 2004 in this market were approximately $400 million, with total prescriptions of 8.6 million.

Source: **ISTA**

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