EX-99.2 3 dex992.htm PRESS RELEASE, DATED MARCH 28, 2005.

Exhibit 99.2

Press Release Source: ISTA Pharmaceuticals, Inc.

ISTA Pharmaceuticals Receives FDA Approval for Xibrom(TM) for the Treatment of Ocular Inflammation Following Cataract Surgery
Monday March 28, 7:30 am ET

- Xibrom will be ISTA's Third Product Launched in the U.S. Market -

IRVINE, Calif., March 28 /PRNewswire-FirstCall/ — ISTA Pharmaceuticals, Inc. (Nasdaq: ISTA - News) today announced that the U.S. Food & Drug Administration (FDA) has approved the New Drug Application (NDA) for Xibrom(TM) (bromfenac ophthalmic solution) 0.09% for the treatment of ocular inflammation following cataract surgery. ISTA expects to launch Xibrom(TM), a topical, twice-daily, non-steroidal anti-inflammatory solution (NSAID), during the second quarter of 2005, after securing commercial quantities of the product from its manufacturer and completing the further expansion of its sales force.

Eric Donnenfeld, M.D., Associate Professor of Ophthalmology, New York University Medical Center, New York and an investigator in the Xibrom Phase III clinical trials, commented, "Xibrom is the first twice-daily ophthalmic NSAID to be approved in the United States. All other ophthalmic NSAIDS are dosed four times daily. Xibrom represents an advance for ophthalmic care because of the improved patient compliance and its early onset of action, and I am pleased that patients will have this new treatment option."

Vicente Anido, Jr., Ph.D., President and Chief Executive Officer of ISTA stated, "We are excited to receive FDA approval of our third commercial product and anticipate launching Xibrom during the second quarter of 2005. We recently completed the interim expansion of our sales force which is now promoting Istalol(TM) and Vitrase®. With the Xibrom approval, we plan on hiring additional sales representatives in order to reach approximately 10,000 ophthalmologists in the U.S."

There will be a conference call today with ISTA management at 10:30 a.m. EDT to discuss the approval of Xibrom in further detail. If you would like to participate in the call, please dial (800) 665-0430 from the United States or Canada or (913) 981-5591 from outside North America. A playback of this call will be available today for 24 hours and may be accessed by dialing (888) 203-1112 from the United States or Canada or (719) 457-0820 from outside North America. The rebroadcast access code is 3204174. In addition, this conference call will be webcast live and subsequently archived on ISTA's website at http://www.istavision.com.

ABOUT XIBROM AND THE U.S. OPHTHALMIC ANTI-INFLAMMATORY MARKET

Xibrom (bromfenac ophthalmic solution) 0.09% is a sterile, topical, non-steroidal anti-inflammatory compound for the treatment of ocular inflammation following cataract surgery. Senju Pharmaceuticals Co. Ltd. has marketed this product in Japan since 2000. 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. ISTA filed its NDA for Xibrom with the FDA in May 2004.

According to company estimates and data compiled by IMS Health, the U.S. ophthalmic anti-inflammatory market, consisting of steroids, NSAIDS and other related products, is approximately $250 million per year.

ABOUT ISTA

ISTA is a specialty pharmaceutical company focused on the development and commercialization of unique and uniquely improved ophthalmic products. ISTA's products and product candidates seek to address serious diseases and conditions of the eye such as dry eye, vitreous hemorrhage, diabetic retinopathy, hyphema, glaucoma and inflammation. Building on this pipeline, ISTA's goal is to continue its growth as a specialty pharmaceutical company by acquiring complementary products, either already marketed or in late-stage development. For additional information regarding ISTA, please visit ISTA Pharmaceuticals' Website at http://www.istavision.com.

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 regarding the timing of our expected commercial launch of Xibrom, our receipt of Xibrom launch quantities, or our sales force expansion plans are forward-looking statements. ISTA disclaims any intent or obligation to update any forward-looking statements. Such 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: risks and uncertainties related to the timing, scope and outcome of FDA and other governmental agency actions and decisions; uncertainties and risks regarding market acceptance of Xibrom, including but not limited to the impact of competitive products and pricing; uncertainties and risks related to ISTA's ability to continue to sufficiently develop and expand its sales, marketing and distribution capabilities and properly manage its growth; uncertainties and risks related to the availability on a timely basis of third party sourced products (including Xibrom) on commercially reasonable terms; uncertainties and risks related to the scope, validity and enforceability of patents related to ISTA's products and technologies and the impact of patents and other intellectual property rights held by third parties; and such 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, 2004.