ISTA Pharmaceuticals Initiates Phase 3 Clinical Program for REMURA™ in Dry Eye Disease

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IRVINE, Calif., Sept. 16 /PRNewswire/ -- ISTA Pharmaceuticals, Inc. (Nasdaq: ISTA [1]), today announced that it has initiated a Phase 3 clinical program of ISTA's proprietary formulation of REMURA™ (bromfenac ophthalmic solution for dry eye) for alleviating the signs and symptoms of dry eye disease. The Phase 3 efficacy studies are being conducted under a Special Protocol Assessment (SPA) agreed upon with the U.S. Food and Drug Administration (FDA).

"We are pleased by the initiation of our pivotal REMURA dry eye efficacy program. Further, reaching agreement with the FDA on the SPA for REMURA efficacy studies provides additional clarity regarding the path to approval, which will help us to bring a safe and effective treatment to patients suffering from dry eye," stated Vicente Anido, Jr., Ph.D., President and Chief Executive Officer of ISTA. "Dry eye is a large and growing market, with 2010 worldwide prescription sales expected to be about $600 million. Dry eye also is an underserved market, as patients suffering from chronic dry eye syndrome have few quality therapy options. We are very excited by the potential of REMURA as a new treatment modality for dry eye patients."

At this time, ISTA plans to assess the safety and efficacy of REMURA in alleviating the signs and symptoms of dry eye disease by conducting four randomized, double-masked, placebo-controlled Phase 3 studies. The recently initiated Phase 3 studies will evaluate the efficacy and safety of bromfenac in two simultaneous studies operating under a common protocol in approximately 1000 patients with mild or moderate dry eye disease. The multi-center trials will be conducted at more than 30 sites in the U.S. Two concentrations of bromfenac (both lower than the currently marketed Xibrom (bromfenac ophthalmic solution)® 0.09%), will be dosed in addition to placebo. Patients will be ra
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