News Release

Santen Receives FDA Approval of IQUIX®, New Treatment For Sight-threatening Condition

Levofloxacin 1.5% is Third Santen-Developed Product Approved in Recent Years

March 2, 2004, Osaka, Japan -- Santen Pharmaceutical Co., Ltd. (President and CEO: Takakazu Morita; Headquarters: Osaka, Japan), announced today that the U.S. Food and Drug Administration (FDA) has approved its new ocular anti-infective medication, IQUIX® (levofloxacin ophthalmic solution) 1.5%, indicated for the treatment of bacterial corneal ulcer.* The New Drug Application for IQUIX was submitted to the FDA on April 30, 2003, by Santen Incorporated, Santen's Napa, California-based subsidiary. VISTAKON® Pharmaceuticals, LLC will be the exclusive U.S. distributor for IQUIX.

IQUIX is a sterile topical ophthalmic solution containing 1.5% levofloxacin, a potent fluoroquinolone active against a broad spectrum of Gram-positive and Gram-negative ocular pathogens. Levofloxacin's high solubility, at neutral pH, allows the solution to be formulated with a concentration of active drug (1.5%), three times higher than any other ophthalmic fluoroquinolone on the market.

"IQUIX is our third FDA approval in four years," said Santen Incorporated President and CEO Adrienne Graves, Ph.D. "Santen is proud of this accomplishment by its Napa, California-based research and development team. We are in a unique position to offer the latest advance in fluoroquinolone treatment to the U.S. ophthalmic community. IQUIX will provide physicians and patients with a powerful new option."

A corneal ulcer is a break in the outer corneal layers, often due to a localized infection. Symptoms may include acute eye pain, foreign body sensation, eye discharge and a red eye. If the ulcer becomes deep, a perforation of the cornea may result, requiring aggressive medical or surgical intervention.

"A corneal ulcer is potentially sight threatening due to its residual scarring," explained Richard L. Lindstrom, M.D., Adjunct Professor Emeritus at the University of Minnesota and Founder and Managing Partner of Minnesota Eye Consultants, PA. "IQUIX's high concentration has positive implications for the treatment of ulcers. And it does not contain benzalkonium chloride (BAK) or any other preservative."

* Full spectrum of susceptible organisms can be found in the Package Insert.

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In two randomized, double-masked multi-center controlled clinical trials, IQUIX achieved a clinical cure rate of 73% to 87%. The most frequently reported adverse events in the overall study population were headache and a taste disturbance following instillation, occurring in approximately 8-10% of patients. Adverse events occurring in approximately 1-2% of patients included decreased/blurred vision, diarrhea, dyspepsia, fever, infection, instillation site irritation/discomfort, ocular infection, nausea, ocular pain/discomfort, and throat irritation. Other reported ocular reactions occurring in less than 1% of patients included chemosis, corneal erosion, corneal ulcer, diplopia, floaters, hyperemia, lid edema, and lid erythema.

Under a distribution and supply agreement completed February 16, 2004, VISTAKON® Pharmaceuticals, LLC is the exclusive U.S. distributor for IQUIX and Santen's other three prescription ophthalmic pharmaceutical agents: QUIXIN® (levofloxacin ophthalmic solution) 0.5%, BETIMOL® (timolol ophthalmic solution) 0.25%, 0.5% and ALAMAST® (pemirolast potassium ophthalmic solution) 0.1%. Daiichi Pharmaceutical Co., Ltd. is the licensor of the levofloxacin compound. Mitsubishi Pharma Corporation is the licensor of the pemirolast potassium compound.

Santen continues to have responsibility for manufacturing, clinical and regulatory activities associated with all four of the products it has developed. The company has medications for the treatment of dry eye and glaucoma and other products currently in clinical development.

Santen Pharmaceutical Co., Ltd., founded in Osaka, Japan in 1890, specializes in the research, development, production and marketing of ophthalmic and anti-rheumatic pharmaceuticals and surgical devices. Among prescription ophthalmic pharmaceuticals, Santen holds the top share within the Japanese market and is one of the leading ophthalmic companies worldwide. Santen has subsidiaries in the U.S., Europe and Asia, including its wholly-owned Napa, California-based Santen Inc.

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