

Santen Submits New Drug Application To FDA Levofloxacin 1.5% Ophthalmic Solution NDA Is Third U.S. NDA in Recent Years

May 6, 2003, Osaka, Japan -- Santen Pharmaceutical Co., Ltd. (President and CEO: Takakazu Morita; Headquarters: Osaka, Japan), announced today that Santen has filed with the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) for its new ocular anti-infective product. The NDA was submitted to the FDA by Santen Incorporated, Santen's Napa, California-based subsidiary.

Levofloxacin is a potent, broad-spectrum antibiotic. Levofloxacin's higher solubility, at neutral pH, allows the active drug to be formulated at a higher concentration (1.5%) than other fluoroquinolones on the market. In 2000 the company received approval for QUIXIN[®] (levofloxacin ophthalmic solution) 0.5%. Prior to Santen's formulating a higher 0.5% concentration, older generation fluoroquinolones were generally formulated at a lower 0.3% concentration. Santen was the first company to bring a higher concentration ophthalmic fluoroquinolone to market.

"Levofloxacin 1.5% is our third New Drug Application in the U.S. Santen is proud of this accomplishment by its team based in Napa, CA. We are in a unique position to offer the latest advance in fluoroquinolone treatment to the U.S. ophthalmic community. Levofloxacin 1.5% will provide physicians and patients with a powerful new option," said Santen Incorporated President and CEO Adrienne Graves, Ph.D.

A pharmaceutical company founded in Osaka in 1890, Santen specializes in treatments for eye and rheumatic diseases, offering both prescription and OTC products. Among prescription ophthalmic pharmaceuticals, Santen holds the top share within the Japanese market and is one of the leading ophthalmic companies worldwide, offering a full selection of medications for a variety of eye disorders. Santen has subsidiaries in the U.S., Europe and Asia, including its California-based unit, Santen Incorporated, and is actively pursuing technological and marketing alliances with a number of pharmaceutical companies and research institutes.

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