

Santen Files for Manufacturing Approval for its Vernal Keratoconjunctivitis Treatment, Ciclosporin Ophthalmic Solution

Osaka, Japan, August 11, 2003 -- Santen Pharmaceutical Co., Ltd. announced that it had applied for a manufacturing approval for its vernal keratoconjunctivitis treatment, ciclosporin ophthalmic solution (generic name), to the Japanese Ministry of Health, Labour and Welfare on August 8. After gaining the manufacturing approval, the drug will be marketed in Japan.

Ciclosporin ophthalmic solution is a preservative-free, unit-dose preparation indicated for the treatment of vernal keratoconjunctivitis (spring catarrh). It is an ophthalmologic application of ciclosporin which was discovered and has been marketed by Novartis Pharma AG, the pharmaceutical division of Novartis AG, worldwide as an immunosuppressant. In Japan, ciclosporin immunosuppressant is marketed by Novartis Pharma K.K. by the brand name Neoral[®]/Sandimmun[®].

Vernal keratoconjunctivitis is a persistent ocular disease with severe allergic conditions, observed mainly within patients under 20 years old. Anti-allergy drugs are usually used in its treatment, however, it is estimated that there are approximately 4,000 vernal keratoconjunctivitis patients in Japan with whom existing anti-allergy drugs are not effective. Ciclosporin ophthalmic solution has a novel mechanism of action that suppresses the generation of cytokine¹ from T cells (the cells that control immune response such as allergy), and will provide an answer for those patients who currently have no effective treatments. Ciclosporin ophthalmic solution was registered as an orphan drug² in Japan in 1999.

In clinical trials, the drug demonstrated significant improvement of giant papillae in palpebral conjunctiva over placebo. Significant improvement was also observed with subjective symptoms such as ocular pain. No side effects, systemic or increase in intraocular pressure, was observed in clinical trials.

Santen believes ciclosporin ophthalmic solution will make an important contribution to the treatment of patients with vernal keratoconjunctivitis with whom existing anti-allergy drugs are not effective. Santen also expects the drug will offer a new treatment option to the patients with severe conditions, leading to their improved quality of life such as decreased side effects of steroids or less need for surgeries including papilla resection.

About Ciclosporin Ophthalmic Solution

Generic name: Ciclosporin ophthalmic solution (Development Code: DE-076)
Brand name: Undetermined
Applied indication: Vernal keratoconjunctivitis (only when anti-allergy drugs are not effective)
Applied dosage: Normally 1 drop/time, 3 times/day

Reference:

About Santen

Santen Pharmaceutical Co., Ltd. (President: Takakazu Morita; headquartered in Osaka, Japan) specializes in the research, development, manufacture and marketing of ophthalmic and anti-rheumatic pharmaceuticals to protect and improve people's eyesight and health. Santen has created innovative pharmaceuticals for all types of ophthalmic disorders and provides information tailored to clinical needs. As a result, Santen leads Japan's market for prescription ophthalmics, which represents nearly 80 percent of the Company sales.

Glossaries

1. Cytokine: Hormone-like proteins secreted by various kinds of cells that control the extent and length of immune response and mediate exchange of information between cells.
2. Orphan drug: A drug with little commercial potential, despite a high degree of medical need, because the number of patients is very small. Orphan drug R&D is eligible for government subsidies in Japan.

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