

Santen Receives Manufacturing and Marketing Approval for its Vernal Keratoconjunctivitis Treatment, PAPILOCK Mini Ophthalmic Solution 0.1%

October 12, 2005, Osaka, Japan -- Santen Pharmaceutical Co., Ltd. (President: Takakazu Morita) announced that it had received a manufacturing and marketing approval for its new vernal keratoconjunctivitis⁽¹⁾ treatment PAPILOCK Mini ophthalmic solution 0.1% (generic name: ciclosporin) from the Ministry of Health, Labour and Welfare on October 11.

PAPILOCK Mini ophthalmic solution 0.1% is a water-based ophthalmologic application of ciclosporin. Ciclosporin was discovered and has been marketed by Novartis Pharma AG, the pharmaceutical division of Novartis AG headquartered in Switzerland, worldwide as an immunosuppressant. In Japan, ciclosporin immunosuppressant is marketed by Novartis Pharma K.K. under the brand name Neoral®/Sandimmun®.

Santen believes PAPILOCK Mini ophthalmic solution 0.1% 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 new drug will offer a new treatment option to patients with severe conditions, leading to their improved quality of life such as decreased side effects of steroids or less need for surgery, including papilla resection.

About PAPILOCK Mini ophthalmic solution 0.1%

- Brand name: PAPILOCK Mini ophthalmic solution 0.1%
- Generic name: Ciclosporin
- Indication: Vernal keratoconjunctivitis (in patients whose symptoms cannot be adequately controlled by anti-allergy drugs)
- Dosage: Normally 1 drop/time, 3 times/day
- Features:
- A novel mechanism of action that suppresses the generation of cytokine⁽²⁾ from T cells which control immune responses such as allergies
 - Registered as an orphan drug⁽³⁾ in Japan
 - Significant improvement of giant papillae on tarsal conjunctiva⁽⁴⁾, the predominant symptom of vernal keratoconjunctivitis
 - Preservative-free, unit-dose preparation

Condition for approval:

Because the number of clinical trial cases is very small, the ministry approval of PAPILOCK is subject to a post-marketing observational study for every patient administered with this drug until data of a certain number of patients are collected. Santen will gather safety and efficacy data as well as conduct the necessary actions for the proper use of the new drug.

Glossary

- (1) Vernal keratoconjunctivitis: 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.
- (2) Cytokine: Hormone-like protein secreted by various kinds of cells that control the extent and length of immune response and mediate exchange of information between cells.
- (3) 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.
- (4) Giant papillae on tarsal conjunctiva: One of the typical symptoms of vernal keratoconjunctivitis, characterized by stonewall-like bumps (papillae) that appear on the inner side of the eyelid (tarsal conjunctiva). Giant papillae are those sized larger than 1mm.

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