

## Santen Launches PAPILOCK Mini Ophthalmic Solution 0.1%

January 23, 2006, Osaka, Japan—Santen Pharmaceutical Co., Ltd. (President: Takakazu Morita) announced that it has launched its new vernal keratoconjunctivitis (1) treatment PAPILOCK Mini ophthalmic solution 0.1% (generic name: ciclosporin).

PAPILOCK Mini ophthalmic solution 0.1% is a water-based ophthalmologic application of ciclosporin. Ciclosporin was discovered and has been marketed worldwide as an immunosuppressant by Novartis Pharma AG, the pharmaceutical division of Novartis AG headquartered in Switzerland. 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.

- Features:
- A novel mechanism of action that suppresses the generation of cytokine<sup>(2)</sup> from T cells which control immune responses such as allergies
  - Registered as an orphan drug<sup>(3)</sup> in Japan
  - Significant improvement of giant papillae on tarsal conjunctiva<sup>(4)</sup>, the predominant symptom of vernal keratoconjunctivitis
  - Preservative-free, unit-dose preparation

### **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
Package:	A box contains 0.4mL × 90 vials ( 30 vials / aluminum bag × 3)
Price:	212.60 JPY for 0.1% 0.4mL

Date of approval: October 11, 2005

Date of NHI price listing: December 9, 2005

Date of launch: January 23, 2006

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 on 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.

Guidance:

Take measures to avoid any omissions in the registration process for the post-marketing observational study. In addition, review the results periodically and provide information to medical professionals.

Treatment using this drug during the post-marketing observational study term shall be limited to ophthalmologists.

### **Glossary**

- (1) Vernal keratoconjunctivitis: A persistent ocular disease with severe allergic conditions, observed mainly in patients under 20 years old. Anti-allergy drugs are usually used in its treatment. However, it is estimated that the existing anti-allergy drugs are not effective for approximately half of the vernal keratoconjunctivitis patients in Japan.
- (2) Cytokine: Hormone-like protein secreted by various kinds of cells that control the extent and length of immune responses and mediate the exchange of information between cells.
- (3) Orphan drug: A drug for which there is a high degree of medical need among patients numbering less than fifty thousand (in Japan) and which is considered to have exceptional value in use if it receives manufacturing and marketing approval. Orphan drug R&D is eligible for government subsidies in Japan.
- (4) Giant papillae on tarsal conjunctiva: One of the typical symptoms of vernal keratokonjunctivitis, characterized by stonewall-like bumps (papillae) that appear on the inside of the eyelid (tarsal conjunctiva). Giant papillae are those larger than 1mm.

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