

Santen Receives Manufacturing Approval for Ophthagreen for Intravenous Injection 25 mg, Fluorescein Fundus Angiography Contrast Medium

April 11, 2002 --- Santen Pharmaceutical Co., Ltd. (headquartered at Osaka City; president: Takakazu Morita) received approval for the manufacture of the fluorescein fundus angiography contrast medium “Ophthagreen for Intravenous Injection 25 mg” (nonproprietary name: indocyanine green) on April 11.

Ophthagreen for Intravenous Injection 25 mg is a fluorescein fundus angiography contrast medium developed for the ophthalmological application of indocyanine green, a pigment manufactured and marketed by Daiichi Pharmaceutical Co., Ltd. as a liver function and circulatory function test reagent. This product is the only test reagent that enables the diagnosis of retinochoroidal^{(*)1} disease under retinal pigment epithelium or hemorrhagic lesion, an objective only poorly achieved using conventional contrast medium for fundus angiography.

Ophthagreen for Intravenous Injection 25 mg can be used to diagnose various fundic diseases, including exudative age-related macular degeneration^{(*)2}, which ranks highest among the causes of acquired blindness in the United States and Europe, and the number of whose victims has increased rapidly in Japan.

Ophthagreen for Intravenous Injection 25 mg has the following features:

1. The first contrast medium for fundus angiography having excitation and fluorescence wavelengths in the near infrared band.
2. Enables the diagnosis of retinochoroidal disease under retinal pigment epithelium or hemorrhagic lesion.
3. The incidence of adverse reactions was 1.8% (1/57 subjects) (based on in-house analysis as of time of approval).

[Reference]

1. Retinochoroidal

Pertaining to the retina and choroid in combination. The retina is a thin transparent membrane, corresponding to camera film, located inside the eyeball wall. The choroid, located outside the retina, is rich in vascular vessels and pigments, nourishing the retina.

2. Exudative age-related macular degeneration

A disease caused by age-related changes in the macula, characterized by rapid loss of visual acuity and development of central scotoma (loss of central vision) due to the deterioration of the macula, the part of the retina most closely associated with visual acuity, as a result of abnormal vessel formation (neovascularization) from the choroid.