

April 20, 2012

News Release

Senju Pharmaceutical Co., Ltd.

To be released on May 11, 2012:  
“AIPHAGAN® Ophthalmic Solution 0.1%”  
for the treatment of Glaucoma / Ocular Hypertension

Senju Pharmaceutical Co., Ltd. (Head office: Chuo-ku, Osaka, President: Yukoh Yoshida) will newly release AIPHAGAN® Ophthalmic Solution 0.1% (INN: Brimonidine tartrate) on May 11.

We developed this drug in Japan after Kyorin Pharmaceutical Co., Ltd. (Head office: Chiyoda-ku, Tokyo, President: Keiji Hirai) sublicensed it to us in 2004.

Brimonidine tartrate is a novel intraocular pressure (IOP) lowering drug developed by Allergan Inc. (U.S.A.) that shows high selectivity for  $\alpha_2$ -adrenergic receptor; while regulating aqueous humor production, it promotes aqueous humor outflow via uveoscleral pathway, exhibiting IOP lowering effect. In 1996, this brimonidine tartrate ophthalmic solution was approved for the indication for "open-angle glaucoma or ocular hypertension" in the United States, and it is approved in 84 countries and areas including the U.S. and is widely used in clinical sites (as of September 2011).

In clinical studies conducted in Japan, "AIPHAGAN® Ophthalmic Solution 0.1%" approved this time exhibited long-term stable IOP lowering effect for primary open-angle glaucoma (broad definition) as a single drug or in combination with other therapeutic drugs for glaucoma.

Glaucoma is "a disease that is characterized by ocular functional structural abnormality where optic nerve neuropathy can be normally improved or controlled by sufficient IOP reduction, with characteristic changes in optic nerve and visual field." Therefore, IOP reduction is the only evidence-based treatment method; as the lost visual field cannot be recovered, it is viewed important to continue to control IOP for entire lifetime. Thus, in selecting drugs, what is desired is an ophthalmic solution that has sufficient IOP-lowering effect and is highly sustainable and safe.

Senju Pharmaceutical expects to contribute to the enhancement of ophthalmological medical care and the QOL of patients by providing "AIPHAGAN® Ophthalmic Solution 0.1%" as one of the alternatives for the treatment of glaucoma and ocular hypertension.

## Overview of AIPHAGAN<sup>®</sup> Ophthalmic Solution 0.1%

Product name:	"AIPHAGAN <sup>®</sup> Ophthalmic Solution 0.1%" (Brimonidine tartrate)
Therapeutic category:	Therapeutic agent for glaucoma, ocular hypertension
Indication:	When the other glaucoma therapeutic agents are not effective enough or cannot be used in the following diseases: Glaucoma, ocular hypertension
Dosage and administration	Instillation of one drop twice daily normally
Date of approval:	January 18, 2012
Date of NIH drug listing:	April 17, 2012
Drug Price:	AIPHAGAN <sup>®</sup> Ophthalmic Solution 0.01%: 438.20 Yen for 1 mL