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We are pleased to announce Otsuka Pharmaceutical's release of news on November 9, 2010 that they have filed regulatory approval in Japan for rebamipide ophthalmic suspension for dry eye. Acucela and Otsuka are co-developing rebamipide for the treatment of dry eye in the United States. Their announcement is as follows.



Otsuka Pharmaceutical Co., Ltd.

November 9, 2010

**Otsuka Pharmaceutical Files for Regulatory Approval in Japan for Mucosta[®]
Ophthalmic Suspension for Dry Eye**

Tokyo, Japan, November 9, 2010 -- Otsuka Pharmaceutical Co., Ltd. today announced it has applied for regulatory approval in Japan to manufacture and market Mucosta[®] (rebamipide) ophthalmic suspension for treatment of dry eye. Dry eye is a chronic condition of the corneal and conjunctival epithelia resulting from a range of factors, and involves subjective symptoms including ocular discomfort and visual disturbance.

By its novel mechanism of action to promote the production of mucin in the ocular surface (both the cornea and the conjunctiva), Mucosta ophthalmic suspension stabilizes the tear film and has demonstrated effectiveness in dry eye treatment. In a clinical trial conducted in Japan, it was confirmed that in addition to the improvement in corneal-conjunctival damage in patients with dry eye, Mucosta ophthalmic suspension also showed improvements in subjective symptoms.

Dry eye is one of the most common problems treated by ophthalmologists. It is thought that in people with dry eye, the amount of mucin in the tear decreases, resulting in instability in the aqueous layer covering the mucin layer, leading to damages to the corneal and conjunctival

epithelia. Additionally, people with dry eye suffer from unpleasant sensory symptoms such as "dryness, " "gritty/sandy sensation," and "eye pain," as well as subjective symptoms relating to vision, including "difficulty seeing" and "blurred vision." Such symptoms vary considerably in degree but often interfere with dry eye sufferers' daily lives.

Rebamipide, the active ingredient in Mucosta ophthalmic suspension, was discovered by Otsuka Pharmaceutical and first launched as Mucosta Tablets in 1990 in Japan as an anti-gastric ulcer agent. In 1994, a supplemental indication for the treatment of gastric mucosal lesions (erosion, bleeding, reddening, edema) stemming from gastritis (acute gastritis, acute exacerbation of chronic gastritis) was approved. While exploring the potential of this compound, Otsuka Pharmaceutical focused on the mucin-increasing mechanism of Rebamipide, and Mucosta ophthalmic suspension was developed as a novel dry eye treatment that acts on the decreased amount of mucin in the tear, resulting in dry eye.

Based on its corporate philosophy of "Otsuka-people creating new products for better health worldwide," Otsuka Pharmaceutical Co., Ltd. is dedicated to contributing to the health of people around the world.

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