

Clanotech receives orphan drug designation in the U.S.

STOCKHOLM – March 27, 2015. Clanotech AB announced today that its candidate drug CLT-28643 has received orphan drug designation by the U.S. Food and Drug Administration (FDA) for prevention of scarring after glaucoma surgery.

The European Medicines Agency (EMA) has previously granted an orphan drug designation pertaining to the EU. The orphan drug designations will significantly shorten future market approval processes and reinforce market exclusivity for a launched product in the U.S. and EU.

“This positive decision from the FDA underpins the great need for products that can improve the outcome of glaucoma surgery. Clanotech is now preparing for a phase I/II trial with CLT-28643”, said Patrizia Caldirola, CEO, Clanotech.

Clanotech’s lead compound, an $\alpha 5\beta 1$ -integrin antagonist, has anti-angiogenic, anti-fibrotic and anti-inflammatory properties. Based on promising preclinical data in animal models for glaucoma, CLT-28643 has the potential to regulate wound healing processes following glaucoma surgery.

Glaucoma patients refractory to medications that lower the intraocular pressure undergo surgical intervention that creates a flap in the eye to drain liquid and more effectively lower the pressure in the eye. Correct healing of the flap is critical for the long term success of the procedure. A cytotoxic antimetabolite is used today to prevent closure of the flap, however, the treatment is associated with significant side effects. Clanotech’s mission is to improve the outcome of glaucoma surgery by the development of CLT-28643 and thereby replace non-specific cytotoxic treatment with a target specific therapy that has an improved safety profile.

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TO THE EDITORS

About Clanotech AB

Clanotech is a Swedish biotech company active in ophthalmology. Clanotech development strategy spans from niche indications with orphan drug opportunities such as developing safe and target specific anti-scarring treatment in glaucoma surgery techniques to therapeutic areas with high commercial potential as wet Age Related Macular Degeneration. Clanotech’s lead candidate is an inhibitor of the $\alpha 5\beta 1$ -integrin receptor which is present in fibroblast and on vascular endothelial cells. $\alpha 5\beta 1$ -integrin is strongly up-regulated in fibroblast when switching to the fibrotic state and in scars after glaucoma surgery.