



Amakem Presents Positive Top-Line Clinical Results for AMA0076 for Glaucoma at Ophthalmology Innovation Summit

AMA0076 Demonstrates Clinical Proof of Concept: IOP Lowering Without Significant Hyperemia

Diepenbeek (Belgium), 14 November, 2013 - Amakem Therapeutics, a clinical stage ophthalmology company, today presented top-line clinical results for its lead drug candidate, AMA0076 for the treatment of glaucoma, at the Ophthalmology Innovation Summit (OIS) at the 2013 Annual Meeting of the American Academy of Ophthalmology.

Based on Amakem's 'Localized Drug Action' platform, AMA0076 is a highly potent locally-acting Rho Kinase (ROCK) inhibitor that has been designed to reduce intraocular pressure (IOP) while minimizing side effects such as hyperemia ('red eye') that have been observed with all other ROCK inhibitors so far tested clinically. Hyperemia as observed with all other ROCK inhibitors in development is a particularly problematic side effect leading to patient non-compliance.

Dr. Jack Elands, CEO of Amakem, presented top-line results from two studies, a first-in-human study in patients with glaucoma and ocular hypertension and a Phase 1b formulation study in healthy volunteers.

The first-in-human study was a multicenter, randomized, double-masked, placebo-controlled dose-escalation study with AMA0076 applied topically, as eye drops (ClinicalTrials.gov identifier NCT01693315). At the most effective dose, IOP reduction from baseline (the primary endpoint of the study) was evident across visits, diurnal time points and both eyes while no conjunctival hyperemia related adverse events were observed. At the end of treatment, this dose group achieved a decrease in mean diurnal IOP from baseline of 3.7 mmHg ($p=0.020$ compared to placebo).

Additional work has demonstrated that AMA0076's bioavailability could be further increased and Amakem has conducted a Phase 1b study with several new formulations of AMA0076, all with significantly improved corneal absorption. The optimized formulation led to substantial IOP reduction with no significant hyperemia.

Dr. Elands said: "AMA0076 has demonstrated IOP reduction without significant hyperemia, the first ROCK inhibitor to achieve this goal in the clinic. The data from these two studies therefore provide clinical proof of concept for our lead program as well as for our Localized Drug Action platform. Based on these encouraging results, we have selected an optimized formulation to take into a Phase 2a study in H1 2014. We look forward to building on these early clinical data and advancing what we believe has the potential to be a valuable new treatment option for glaucoma patients."

Dr. Ingeborg Stalmans, Professor, Head of the Glaucoma Unit and Director of Ophthalmology Research Center, University of Leuven, Belgium and a member of Amakem's Clinical Advisory Board, said: "The results seen so far with AMA0076 suggest



that the promise seen in pre-clinical development has been carried into the clinic successfully. To see such low levels of hyperemia accompanying meaningful reductions in IOP is a breakthrough in the development of ROCK inhibitors.”

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About Amakem

Amakem Therapeutics is an ophthalmology company developing new treatments for serious eye conditions. Amakem’s product pipeline is based on its unique Localized Drug Action platform which is designed to generate safe and effective kinase inhibitors that minimize side effects.

Amakem’s lead candidate, AMA0076, is for glaucoma and entered clinical development late last year. The Company is also working to apply the Localized Drug Action approach to a range of other eye diseases.

Founded in 2010, Amakem has raised more than €21m in funding and is backed by leading life sciences investors including Forbion, Omnes Capital (previously Crédit Agricole), Vesalius BioCapital, LRM, PMV/Vinnof and Life Science Research Partners.

Amakem is based in Belgium and located in the life sciences incubator “BioVille” at the University of Hasselt. The Company has a long-standing collaboration with Professor Ingeborg Stalmans at the Ophthalmology Research Center of the University Leuven Hospital, where it sponsors a Chair in Ophthalmology Translational Research.