Amakem Initiates Phase 2a Proof of Concept Study with the Rho Kinase (ROCK) Inhibitor AMA0076 in Patients with Glaucoma and Ocular Hypertension under a US IND

Diepenbeek (Belgium), 27 September, 2012 - Amakem NV, a kinase platform company focusing on ophthalmology, today announces that it has initiated a Phase 2a proof of concept study of its novel Rho Kinase (ROCK) inhibitor, AMA0076, in patients with glaucoma and ocular hypertension. The start of the study follows Amakem's receipt of Investigational New Drug Application (IND) approval from the United States Food and Drug Administration (FDA). AMA0076 is a highly potent ROCK inhibitor and is based on Amakem's 'Localized Drug Action' platform, which generates novel kinase inhibitors that minimize the risk of systemic as well as local side effects such as hyperemia.

The study is a multicenter, randomized, double-masked, placebo-controlled dose-escalation study with AMA0076 applied topically, as eye drops. First patients have initiated treatment in this 80 patient clinical trial with six participating centers in the United States (ClinicalTrials.gov identifier NCT01693315).

The primary efficacy endpoint will be reduction in intraocular pressure (IOP), which is a major factor in the pathology of glaucoma, after two and four weeks of dosing. A number of secondary efficacy endpoints will be used to further analyze the impact of AMA0076 on IOP. The Company expects to report top line results in 2013.

AMA0076 is aimed at providing better patient outcomes than other ROCK inhibitor based treatments currently in development because its improved side effect profile enables higher dosing, leading to better efficacy. Pre-clinical studies have shown that AMA0076 highly effectively lowers IOP in relevant models, with a magnitude of IOP reduction exceeding that of the current leading glaucoma treatment latanoprost. Importantly, AMA0076 has been shown to avoid hyperemia, also known as 'red eye', which is seen as a major dose limiting side effect for other ROCK inhibitors in development.

Dr Jack Elands, CEO of Amakem, said: "Today's announcement is a major milestone for Amakem. With our first product entering the clinic we expect to validate our Localized Drug Action platform. Conceived and developed by the company's founder and CSO, Dr Dirk Leysen, this platform allows the development of novel drugs in ophthalmology and other indications, by harnessing the power of kinase inhibition while managing potential side effects. It is very satisfying to have progressed AMA0076 within 20 months from discovery into its first clinical trial and to the point where we believe we will further demonstrate the potential of our platform to create valuable new therapeutics."

Dr Steve Pakola, Chief Medical Officer of Amakem, said: "Glaucoma affects many millions of people and remains a significant cause of vision loss and blindness. Existing treatments are not effective for all patients and while the potential of ROCK inhibitors to reduce IOP has been recognized, their development has been held back by their side effect profile, particularly hyperemia which is distressing for patients and reduces compliance. We look forward to confirming in the clinic the highly promising results we have seen so far with AMA0076 and to advancing what we believe has the potential to be a valuable new treatment option for glaucoma patients."

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About Amakem

Amakem 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 novel kinase inhibitors that minimize systemic exposure with the aim of reducing side effects. Amakem's lead candidate, AMA0076, is for glaucoma and the Company is working to apply the Localized Drug Action approach to a range of other eye diseases. AMA0076 is currently undergoing Phase 2a proof of concept trials.

Founded in 2010, Amakem has raised more than €21m in funding and is backed by leading life sciences investors including Forbion, 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 the Ophthalmology Research Center of the University Leuven Hospital.

About Localized Drug Action

Amakem's 'Localized Drug Action' platform is designed to generate novel kinase inhibitor drugs which are contained locally and thus reduce or eliminate side effects. Kinases are crucial mediators of important disease pathways representing more than 22% of the drugable genome. However, kinases are present throughout the body and so there is a significant risk of toxicity due to on target effects in non-target organs and tissues if there is systemic exposure. This risk is acceptable in oncology indications, but not in others thus substantially reducing the potential of drugs targeting this class.

Amakem's kinase inhibitors are designed to be rapidly inactivated outside the target organ. In indications that can be treated by topical administration, it is therefore possible to contain the drug locally as it becomes inactive before it can reach other organs or tissues if it leaks out of the target organ.

Localized Drug Action is based on the inactivation of kinase inhibitors outside the target organ, e.g. in the bloodstream by specifically targeted enzymes. Each of Amakem's kinase inhibitors brings together kinase specificity and enzymatic conversion specificity. When the drug candidate leaves the target organ it is converted to a functionally inactive metabolite. This inactive metabolite is then eliminated from the body.