

Dilaforette – Phase II study with sevuparin for the treatment of severe malaria initiated

STOCKHOLM – January 30, 2013. Dilaforette, a Karolinska Development portfolio company, today announces that the company has approval from the regulatory authority in India to start a Phase II study with sevuparin in patients with moderate to severe malaria.

Dilaforette and its collaborator, The Mahidol Oxford Tropical Medicine Research Unit (MORU), plan to enroll 50 patients in India, where severe malaria remains an important problem. The primary objective of the study is to evaluate safety along with several efficacy parameters. The study design has been discussed at a pre-IND meeting with the US Food and Drug Administration (FDA). The first study site is open for enrollment and the first patients are expected in connection with the coming rain season. A separate clinical trial in uncomplicated *falciparum malaria* is already on-going in Thailand since 2011.

"The initiation of the Phase II trial at the ISPAT General Hospital in Rourkela in India constitutes a major step in the development of sevuparin for severe malaria. We are proud of the continued support we are receiving from world leading expertise in the field of malaria", says Pirkko Sulila Tamsen, CEO, Dilaforette.

"I have continued high expectations on sevuparin which interferes with a pivotal culprit in malaria pathophysiology; blockage of the smallest blood vessels in vital organs. It can potentially help to reduce mortality in cases of severe malaria where antimalarial treatment alone is not sufficient", says Prof Arjen Dondorp, Coordinating Principal Investigator, Department Head and Deputy Director of the MORU.

There are about 10 million severe *falciparum malaria* cases every year resulting in close to one million deaths, mostly children, despite optimal antimalarial treatment. Sevuparin is a potential new adjunctive treatment of severe malaria that acts by preventing and reversing the infected cells' ability to block blood vessels.

"We have high hopes that sevuparin will make a difference in the treatment of severe malaria. We also appreciate that Dilaforette has access to world leading clinical expertise", says Torbjörn Bjerke, CEO, Karolinska Development.

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TO THE EDITORS

About Dilaforette

Dilaforette is a Swedish drug development company developing sevuparin, a heparin derivative with low anticoagulant activity for the treatment of severe malaria and vaso-occlusive crisis in Sickle Cell Disease.

In severe malaria, microvascular obstruction is caused by sequestration of parasitized red blood cells and adhesive forces between infected/uninfected red cells. This constitutes the central feature in the pathogenesis and is a direct cause of acidosis, coma and death.

Sickle Cell Disease is a genetic life shortening disorder where one main feature is the vaso-occlusive crisis caused by sickle cell shaped red blood cells that obstruct blood flow in capillaries, resulting in ischemia and severe pain. For more information, please visit www.dilaforette.se.

About Mahidol - Oxford Tropical Medicine Research Unit (MORU)

The MORU, supported by the Wellcome Trust, was founded in 1979 as a research collaboration between the Faculty of Tropical Medicine, Mahidol University and the University of Oxford. The main research interests are the epidemiology, diagnosis, pathophysiology and treatment of malaria and other tropical infections.

About Karolinska Development

Karolinska Development aims to create value for patients, researchers, and investors by developing innovations from world class science into products that can be sold or out-licensed with high returns. The business model is to: SELECT the most commercially attractive medical innovations; DEVELOP innovations to the stage where the greatest return on investment can be achieved; and COMMERCIALIZE the innovations through the sale of companies or out-licensing of products. An exclusive deal flow agreement with Karolinska Institutet Innovations AB, along with other cooperation agreements with leading Nordic universities, delivers a continuous flow of innovations. Today, the portfolio consists of 34 projects, of which 15 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

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