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Dilaforette initiates a Phase I/II study with Sevuparin for the treatment of severe malaria

STOCKHOLM – September 23, 2011. Dilaforette, part of the Karolinska Development portfolio, today announced that the first patient has received a dose of Sevuparin in a Phase I/II study. This is the first time that Sevuparin will be tested in malaria patients. The study is conducted in uncomplicated falciparum malaria patients with safety as the primary objective. In the next step efficacy in severe malaria patients will be tested. A total of 98 patients is planned to be included in the trial which will be conducted in Thailand together with the Mahidol Oxford Research Unit (MORU) in Bangkok. MORU is a collaboration between Mahidol University and the University of Oxford sponsored by the Wellcome Trust of Great Britain.

Pirkko Sulila Tamsen, CEO, Dilaforette
"I am delighted to announce that the first malaria patient has been included for treatment with Sevuparin. We have great hopes to turn our malaria research programs into new treatment policies to the benefit of patients suffering from severe malaria. We are pleased to have Prof Arjen Dondorp at MORU as the coordinating principal investigator in our study. Prof Dondorp was the principal investigator for AQUAMAT, the largest ever antimalarial drug trial in severe malaria. AQUAMAT was published in the Lancet 2010 together with Prof Nick White and Prof Nick Day, both world leading experts in the field of malaria research."

Prof Arjen Dondorp, Coordinating Principal Investigator, Department Head and Deputy Director of the MORU
"Although it is still early days I have high expectations of Sevuparin which interferes with the pivotal culprit in malaria pathophysiology, which is blockage of the smallest blood vessels in vital organs. It could help to reduce mortality in cases of severe malaria where potent antimalarial treatment alone is not sufficient."

There are 250 million malaria cases per year resulting in close to one million deaths, mostly children. Despite optimal antimalarial treatment, 10 to 30 percent of the patients with severe malaria die. Sevuparin is a potential new adjuvant treatment of severe malaria that acts by preventing and reversing the infected cells' ability to block blood vessels.

Torbjörn Bjerke, CEO, Karolinska Development
"We believe that Dilaforette has found both an excellent way to fast implementation of the clinical development program as well as access to clinical expertise which will enable this potential lifesaving treatment to reach clinical *proof-of-concept* in malaria patients with a big medical need."

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TO THE EDITORS

About Dilaforette
Dilaforette is a Swedish drug development company developing Sevuparin, a heparin analogue for the treatment of severe malaria. Infection caused by the *Plasmodium falciparum* parasite frequently gives rise to severe malaria in non-immune humans. Infected erythrocytes have a tendency to bind and block the capillaries in many of the vital organs. The main cause of disease severity and pathology is through hampered blood flow and reduced oxygen delivery which results in tissue damage. It is based on the ability of parasite infected erythrocytes to adhere to the vascular endothelium (cytoadherence) and to uninfected erythrocytes (rosetting). Heparin is known to block these processes and has been tried as an adjunctive treatment in severe malaria but was discontinued due to an increase in bleeding complications related to the anticoagulant effects. Sevuparin is a heparin analogue where the anticoagulant activity of the parent molecule has been drastically reduced but the ability to prevent and reverse infected cells' ability to block blood vessels.

About Mahidol - Oxford Tropical Medicine Research Unit (MORU)
The MORU supported by the Wellcome Trust began 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, scrub typhus, melioidosis, leptospirosis and other tropical infections which impose a substantial disease burden on rural populations throughout this populous region. Research from MORU has contributed importantly to the current WHO guidelines on the treatment of severe and uncomplicated malaria, including artesunate for severe malaria and artemisinin combination therapy (ACT) for uncomplicated disease.

About Karolinska Development
Karolinska Development aims to create value for investors, patients, and researchers by developing innovations from world class research 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 these 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. This will result in upfront payments, milestone payments and royalties.

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.

Karolinska Development’s flexible exit strategy enables projects to be exited at whichever stage of development offers the greatest return on investment, usually after Phase II clinical trials have indicated the desired pharmaceutical effect on patients - this being an important value enhancing step.

Today, the portfolio consists of over 35 projects at various stages, from concept development to Phase II clinical trials, twelve projects are in clinical trials. The portfolio is particularly strong in the areas of cancer, dermatology, inflammation, cardiovascular disease, women's health and diseases that affect the central nervous system.
www.karolinskadevelopment.com