



Press Release

Modus Therapeutics and Ergomed Initiate Phase II Clinical Trial with Modus' Sevuparin in Sickle-Cell Disease

Stockholm, Sweden and Guildford, UK, – 13 October 2015: Modus Therapeutics AB, a privately held Swedish drug development company focused on innovative treatments for patients with sickle-cell disease (SCD) and Ergomed plc (AIM: ERGO), a profitable UK-based company dedicated to the provision of specialised services to the pharmaceutical industry and the development of new drugs, today announced that the first patient has been enrolled in the Phase II study with sevuparin in patients with SCD.

The Phase II study is a multi-center, double-blind, placebo-controlled study in hospitalized SCD patients experiencing vaso-occlusive crisis (VOC). Both male and female SCD patients will be included and the target will be to have 70 evaluable patients. The patients are randomized and will be treated with i.v. infusion of sevuparin or placebo on top of standard pain medication, which is i.v. infusion of opioids given during the VOC. This Proof-of-Concept study is designed to demonstrate reduced time to resolution of VOC, defined as freedom from parenteral opioid use and readiness for discharge from hospital. Secondary end-points include pharmacokinetics and safety. The study is planned to be performed in four countries in Europe and Middle East. The study is performed under a co-development deal with Ergomed, where Ergomed will co-invest a proportion of its revenues from the clinical and regulatory activities of this trial in return for an equity stake in Modus Therapeutics.

Modus Therapeutics's sevuparin is an innovative, proprietary polysaccharide drug which has the potential to restore blood flow and prevent further microvascular obstructions caused by abnormal blood cells in SCD patients. With its anti-adhesive properties, sevuparin could offer treatment of the underlying cause of VOC in SCD patients, potentially facilitating earlier pain relief, shorter hospital stays, reduced need of opioids and improved quality of life. Resolving the microvascular obstructions with sevuparin may also affect long term outcomes by avoiding additional tissue and organ damage thereby reducing co-morbidities and possibly also mortality.

"We are excited about having initiated this Proof-of-Concept trial for sevuparin and are looking forward to the study results which are expected in the second half of 2016. With sevuparin, Modus Therapeutics aims to introduce an innovative, new treatment option for SCD patients, for the first time addressing the cause and not just the symptoms of vaso-occlusion," **said Christina Herder, CEO of Modus Therapeutics.**

"SCD is a disease with a large, unmet medical need where current treatment focuses on the symptomatic relief of pain rather than treating the underlying cause of VOCs, namely the sickle cell related obstructions of the microvasculature. SCD is associated with a number of acute health problems including VOC, where sevuparin has the potential to significantly improve quality of life for these patients", **said Dr Bart Biemond, Academic Medical Centre, Amsterdam, the Netherlands, Principal Investigator in the study.**

Dr Miroslav Reljanovic, CEO of Ergomed, added: "As our first co-development agreement in orphan drug development, we are very pleased to see the first patient recruited into the trial. The start of the study is an exciting milestone for Ergomed and our collaboration with Modus Therapeutics reaffirms our commitment to developing drugs for rare diseases."

SCD is a disabling and potentially fatal disease with a large unmet medical need in both the developed and developing world. In the US and in Europe, it is estimated that close to 100,000 and 35,000 patients, respectively, are diagnosed with this hereditary disease. There is also an even larger patient pool in the



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Middle East and North Africa (MENA) region. SCD patients undergo on average one VOC per year. This acute complication is caused by sickle blood cells obstructing the blood flow to vital organs leading to ischemia and often severe pain. Long-term, SCD patients are at risk of organ damage and premature death.

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About Modus Therapeutics AB

Modus Therapeutics is a Swedish drug development company developing sevuparin, an innovative, proprietary polysaccharide drug, which has potential to restore blood flow and prevent further microvascular obstruction in both sickle cell disease and malaria patients.

Sevuparin originates from research at the Karolinska Institutet and Uppsala University. The drug development has involved world leading experts in the field of heparin from the Swedish pharmaceutical industry.

The main owner of Modus Therapeutics is KDev Investments AB, part of Karolinska Development AB (Nasdaq Stockholm: KDEV) and Rosetta Capital. Other larger owners are The Foundation for Baltic and European Studies (Östersjöstiftelsen) and Praktikerinvest AB. For more information, please visit www.modustx.com

About Ergomed plc

Founded in 1997, Ergomed plc is a profitable UK-based company, providing drug development services to the pharmaceutical industry and has a growing portfolio of co-development partnerships. It operates in over 40 countries.

Ergomed provides clinical development, trial management and pharmacovigilance services to over 60 clients ranging from top 10 pharmaceutical and generics companies to small and mid-sized drug



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development companies. Ergomed successfully manages clinical development from Phase I through to late phase programmes.

Ergomed has wide therapeutic expertise, with a particular focus in oncology, neurology and immunology and the development of orphan drugs. Ergomed's approach to clinical trials is differentiated from that of other providers by its innovative Study Site Management model and the use of Study Physician Teams, resulting in a close relationship between Ergomed and the physicians involved in clinical trials.

As well as providing high quality clinical development services, Ergomed is building a portfolio of co-development partnerships with pharma and biotech companies. Here Ergomed shares the risks and rewards of drug development, leveraging its expertise and services in return for carried interest in the drugs under development. – a low risk investment model for potential high returns. For further information, visit: <http://ergomedplc.com>.

Global pharmacovigilance and medical information services are provided through its group company PrimeVigilance. www.primevigilance.com

About Sickle-Cell Disease

Sickle-Cell Disease (SCD) is a disabling and potentially fatal disease with a large unmet medical need in both the developed and developing world. SCD patients undergo on average one vaso-occlusive crisis (VOC) per year. This acute complication is caused by sickle blood cells obstructing the blood flow to organs leading to ischemia and often severe pain. Long-term, SCD patients are at risk of organ damage and premature death.

Forward Looking Statements

Certain statements contained within the announcement are forward looking statements and are based on current expectations, estimates and projections about the potential returns of Ergomed plc ("Ergomed") and industry and markets in which Ergomed operates, the Directors' beliefs and assumptions made by the Directors. Words such as "expects", "anticipates", "should", "intends", "plans", "believes", "seeks", "estimates", "projects", "pipeline" and variations of such words and similar expressions are intended to identify such forward looking statements and expectations. These statements are not guarantees of future performance or the ability to identify and consummate investments and involve certain risks, uncertainties, outcomes of negotiations and due diligence and assumptions that are difficult to predict, qualify or quantify. Therefore, actual outcomes and results may differ materially from what is expressed in such forward looking statements or expectations. Among the factors that could cause actual results to differ materially are: the general economic climate, competition, interest rate levels, loss of key personnel, the result of legal and commercial due diligence, the availability of financing on acceptable terms and changes in the legal or regulatory environment.

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