

# PRESS RELEASE FOR IMMEDIATE RELEASE

#### **Ergomed Announces Co-Development Agreement with Asarina AB**

London, UK and Stockholm, Sweden – 1 November 2016: Ergomed plc (LSE: ERGO) ('Ergomed' or 'the Company'), a clinical trial services and drug development company, today announces that it has entered into a co-development agreement with Asarina Pharma AB ('Asarina') for the Phase IIb clinical development of Sepranolone (UC1010) as a targeted treatment for patients with premenstrual dysphoric disorder ("PMDD").

Under the terms of the agreement, Ergomed has been appointed as the clinical development organisation contracted to conduct Asarina's multicentre, multinational, randomised Phase IIb clinical trial. The study is planned to start in 2017. Ergomed will co-invest into the trial in return for an equity stake in Asarina.

PMDD is the most severe form of Premenstrual Syndrome, characterized by cyclic symptoms such as depression, anxiety, irritability, mood lability and loss of emotional control consistently occurring during the latter part of the menstrual cycle with high impact on personal and professional life. Approximately 5% of all women will experience this disorder during their fertile years from the onset of menstruation till menopause.

Asarina's product candidate, Sepranolone, is a proprietary, first-in-class, endogenous, small molecule, that acts as a GABA-A modulating steroid antagonist (GAMSA). Sepranolone is the first product developed exclusively for PMDD. The effect of Sepranolone has been demonstrated in animal models of the disorder as well as in a validated human pharmaco-dynamic model used to evaluate target engagement of drugs that influence GABA mechanisms in the brain.

Asarina has completed an exploratory, double-blind, randomized, placebo-controlled, clinical phase I/II study involving 120 women with PMDD to evaluate the safety, efficacy and pharmacokinetics of Sepranolone. This study demonstrated that, in addition to an acceptable safety profile and good tolerability, Sepranolone induced a statistically significant improvement in PMDD symptoms compared to placebo. Importantly the drug also normalized work and family life for these women.

Commenting on the announcement, Dr Miroslav Reljanovic, CEO of Ergomed plc, said:

"We are delighted to be the co-development partner for Asarina as it embarks upon its Phase IIb clinical trial programme for Sepranolone which has the potential to be a first-in-class therapy for this serious disease. This further expands the number of pipeline opportunities where we share in the potential upside as a drug is successfully developed through leveraging our expertise and experience in providing clinical trial services to support such development."

Peter Nordkild, CEO of Asarina, added:

"We are pleased to announce our partnership with Ergomed to conduct our Phase IIb study for Sepranolone. Premenstrual dysphoric disorder is very debilitating for women who suffer from this disorder. We believe Ergomed is an excellent partner to help us advance this innovative therapy through the clinic and look forward to working with the team."

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## **About Ergomed**

Ergomed plc is a profitable UK-based business providing drug development services to the pharmaceutical industry and has a growing portfolio of co-development partnerships. It operates in over 50 countries.

Ergomed provides clinical development, trial management and pharmacovigilance services to over 100 clients ranging from top 10 pharmaceutical companies to small and mid-sized drug development companies. Ergomed successfully manages clinical development from Phase I through to late phase programmes.

Ergomed has a wide therapeutic focus, with a particular expertise in oncology, neurology and immunology and the development of orphan drugs. Ergomed believes its 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 which share the risks and rewards of drug development. Ergomed leverages its expertise and services in return for carried interest in the drugs under development. Lastly, Ergomed recently acquired a pipeline of proprietary development products for haemostasis in surgical settings. For further information, visit: http://ergomedplc.com.

#### **About Asarina**

Asarina Pharma is developing novel and targeted products to treat women with severe symptoms associated with the menstrual cycle such as premenstrual dysphoric disorder (PMDD), allowing these women to remain in control of their own life.