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PHARMANEST

Pharmanest meets all efficacy and safety end points in Phase II study of SHACT

STOCKHOLM – August 1, 2013. Pharmanest AB announced today positive results from a Phase II-study investigating the efficacy and tolerability of SHACT. The data show that SHACT is effective in reducing pain in connection with intrauterine device insertion. Karolinska Development owns 63% of Pharmanest*.

Every year, millions of women around the world experience pain and discomfort during IUD insertion (intrauterine contraception). There are few treatment options with proven efficacy and safety available to these women. SHACT is a product based on an innovative formulation of lidocaine, a well-known anesthetic, and a proprietary application device developed to simplify topical application in the cervix and uterus.

Gunilla Lundmark, CEO of Pharmanest:
”The clinical evidence suggests that SHACT represents a major breakthrough for women that experience pain and discomfort during IUD insertion. Pain management in connection with IUD insertion represents a significant commercial opportunity alone, but as SHACT is specifically designed for topical administration we also see significant potential for other clinical uses.”

The Phase II-study with SHACT was a randomized, double-blind trial involving 218 women between 18 and 45 years of age. Data from the study shows that women that received SHACT during IUD insertion experienced a more than 30% reduction in pain, measured on a visual analogue scale (VAS), compared to patients who received placebo. This effect was statistically significant ($p < 0.0001$). Patients who received SHACT also experienced less discomfort ($p < 0.05$) than women who received placebo. Women who received SHACT reported similar adverse events, in terms of type and frequency, as women who received placebo treatment. The most common adverse event was nausea in both treatment groups. No serious adverse events were reported.

Torbjörn Bjerke, CEO of Karolinska Development :
"Pharmanest has made an extraordinary achievement, going from first human dose to clinical proof of concept in just fifteen months. With these positive data it is clear that SHACT has the potential to become the first safe and effective pain relief product for millions of women who use IUD."

The study, conducted in Sweden at the Karolinska University Hospital in Solna and two other sites, met all primary and secondary objectives and provides a clinical foundation for the regulatory submission of SHACT in the European Union (EU) and other countries around the world.

Pharmanest also reported data from a Phase I study investigating the pharmacokinetic properties of SHACT. The study showed that the majority of women had measurable levels of lidocaine after 5 minutes suggesting a rapid onset of action. No toxicity concerns were observed during the study.

*Including indirect ownership through KCIF Co-Investment Fund KB.

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TO THE EDITORS

About Pharmanest AB

Pharmanest is a Stockholm-based pharmaceutical company specializing in developing products for local anesthesia in gynecology and obstetrics. For more information, please visit www.pharmanest.se.

About SHACT

SHACT is a proprietary 4 % lidocaine formulation developed by Pharmanest, and patent applications are pending worldwide. This is applied topically in the cervix and uterus with a device developed by Pharmanest. SHACT is thermogelling and becomes a gel at body temperature, which minimizes the leakage from the site of application. SHACT has a rapid onset of action and is easy to apply for healthcare professionals.

About Karolinska Development AB

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 universities, delivers a continuous flow of innovations. Today, the portfolio consists of 38 projects, of which 16 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

Karolinska Development is listed on NASDAQ OMX. Karolinska Development may be required to disclose the information provided herein pursuant to the Securities Markets Act.