

**Profit from Innovation** 



# New trial data suggest that SHACT could benefit women undergoing hysteroscopies

STOCKHOLM – March 25, 2014. Today, Pharmanest AB announced positive results from a feasibility study with its local anesthetic agent SHACT in hysteroscopy. The study demonstrated that SHACT did not interfere negatively with the examination in outpatient hysteroscopy and that it was safe and tolerable. Karolinska Development owns 63% of Pharmanest AB.

Pharmanest is developing SHACT to mitigate pain associated with gynecological procedures. SHACT has recently demonstrated convincing Phase II efficacy data as local anesthesia in connection with intrauterine device (IUD) insertion. As part of the strategy to expand to other indications, Pharmanest has now conducted a feasibility study in outpatient hysteroscopy. Hysteroscopies are used to examine the uterine cavity and oviducts and is performed under either local or general anesthesia. Given the focus on decreasing costs, these procedures are increasingly performed in the outpatient setting with local anesthesia. There is no standard of care for analgesia during hysteroscopy procedures, and pain is the primary reason for outpatient hysteroscopy failure.

The primary objective of the study was to obtain information about the feasibility of administering SHACT to patients in conjunction with hysteroscopy. It was a non-comparative open label study at Södersjukhuset in Stockholm, Sweden. Secondary objectives included safety, tolerability and handling properties of SHACT and its instillation device. Ten patients were included in the trial and parameters such as visibility for the examiner, ease of application and time required for use of SHACT were documented. The results indicate that SHACT is not interfering negatively with the examination and that the product can be used in the outpatient setting to ease women's pain and discomfort. No safety or tolerability issues were recorded in the study. The potential pain relief offered by SHACT was not evaluated in this particular study and has therefore to be confirmed in a forthcoming clinical trial.

## Gunilla Lundmark, CEO, Pharmanest:

"The efficacy and tolerability of SHACT in connection with IUD insertion has previously been documented in a Phase II study. We are now happy to report new data indicating that SHACT could also be a future important tool to reduce pain and discomfort during outpatient hysteroscopies. Based on the positive outcome of the feasibility study, Pharmanest is preparing for an efficacy study with the aim to further evaluate the pain relief of SHACT in this indication."

### Dr. Miriam Mints, Ass. Professor at Karolinska Institutet:

"These new data look very promising. Hysteroscopies are often performed as an inpatient procedure, but the benefits with outpatient hysteroscopies are evident. The potential benefits to the patients are less risk of anesthetic complications, shorter hospitalization and recovery time, but fear of pain could be deterrent. SHACT could be a very useful local anesthetic and I am looking forward to follow the future clinical studies."

## Torbjörn Bjerke, CEO, Karolinska Development:

"Pharmanest has recently presented strong data with SHACT in IUD insertion. The purpose of the feasibility study in hysteroscopy was to evaluate if SHACT could be used in one of several additional potential gynecological procedures where efficient pain relief is lacking today, and these data shows exactly that."

Note: Ownership of 63% includes 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. SHACT 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, investors and society 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 33 projects, of which 16 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

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