

Conceptus Announces Enrollment of First Patient in European Clinical Trial for Next Generation Essure

GlobeNewswire

MOUNTAIN VIEW, Calif., Feb. 5, 2013 (GLOBE NEWSWIRE) -- **Conceptus, Inc. (Nasdaq:CPTS [1])**, developer of the Essure[®] procedure, the leading surgery-free permanent birth control method, announced today that it has initiated enrollment in its European clinical study designed to support the company's CE Mark application for its next generation Essure device.

The European clinical trial will enroll up to 60 patients in multiple sites in Europe, and will assess effectiveness for pregnancy prevention at both the 3-months and 1-year endpoints. Dr. Sebastiaan Veersema, the trial's principal investigator, at St. Antonius Hospital in Nieuwegein, Netherlands, performed the first procedure in the clinical study on January 31, 2013.

The key benefit of the next generation Essure design is immediate, permanent contraception without a three-month waiting period or 90-day confirmation test. To achieve immediate contraception, a proprietary hydrogel component is incorporated into the distal end of what is otherwise very similar to the current Essure insert, and which is intended to immediately occlude the fallopian tube once the device is placed.

"We are pleased to participate in the world's first clinical trial evaluating safety and effectiveness of the next generation Essure that can be immediately relied upon for contraception. This product could revolutionize female permanent birth control. We are highly encouraged by the successful placement of the first patient enrolled with Conceptus' innovative contraceptive technology," stated Dr. Veersema.

"We are enthusiastic to have initiated enrollment in Europe with our next generation Essure device ahead of our timing expectations. With immediate confirmation and very little additional training requirements, we believe this groundbreaking technology will dramatically strengthen our competitive positioning against surgical tubal ligation," said D. Keith Grossman, President and Chief Executive Officer of Conceptus.

About the Essure[®] Procedure

The Essure procedure, FDA approved since 2002, is the only surgery-free and hormone-free permanent birth control method that can be performed in the comfort of a physician's office in less than 10 minutes (average hysteroscopic time) without the risks associated with general anesthesia or tubal ligation. Soft, flexible inserts are placed in a woman's fallopian tubes through the cervix without incisions. Over the next three months, the body forms a natural barrier around and through the

Conceptus Announces Enrollment of First Patient in European Clinical Trial

Published on Medical Design Technology (<http://www.mdtmag.com>)

inserts to prevent sperm from reaching the egg. Three months after the Essure procedure, an Essure Confirmation Test is given to confirm that the inserts are in place and that the fallopian tubes are blocked, verifying that the patient can rely on Essure for permanent birth control.

The Essure procedure is 99.83% effective based on five years of follow up with zero pregnancies reported in clinical trials, making it the most effective permanent birth control available. Essure's 10-year commercial data tracks closely with its five-year clinical results, and Essure has been proven and trusted by physicians since 2002. The Essure procedure is covered in the U.S. by most public and private insurance plans and approximately 730,000 women worldwide have undergone the procedure.

About Conceptus[®], Inc.

Conceptus, Inc. is the leader in the development of innovative device-based solutions in permanent birth control. The Company manufactures and markets the Essure procedure. The Essure procedure is available in the United States, Europe, Australia, New Zealand, Canada, Mexico, Central and South America and the Middle East.

Please visit [2]www.essure.com [3] for more information on the Essure procedure. Patients may call the Essure Information Center at 1-877-ESSURE-1 with questions or to find a physician in their area.

Source URL (retrieved on 02/01/2015 - 4:02am):

<http://www.mdtmag.com/news/2013/02/conceptus-announces-enrollment-first-patient-european-clinical-trial-next-generation-essure>

Links:

[1] <http://globenewswire.com/News/Listing?symbol=CPTS&exchange=2>

[2] <http://www.essure.com/>

[3] http://globenewswire.com/Tracker?data=EPwwcUkGuobdAdCQlcFc40iMMEjBMLvPy3108W8JiRcvaUXJApG_n4XdCi2IiLV3