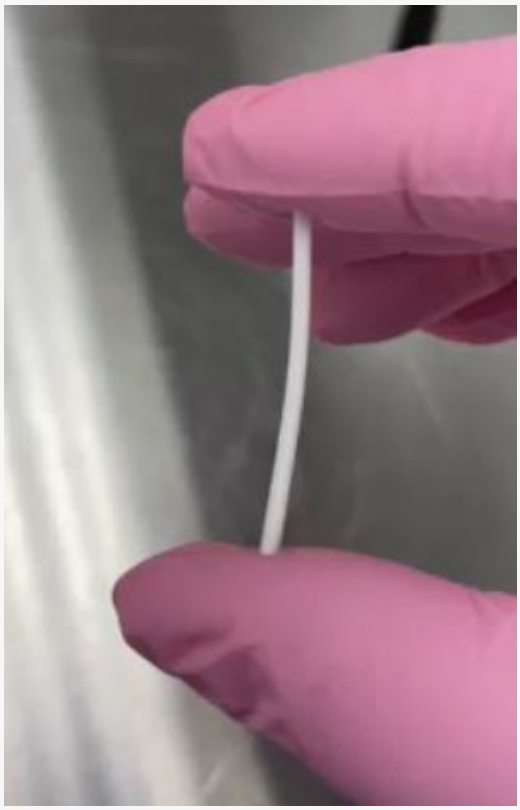
ProMed Pharma announces a preclinical rat study to assess pharmacokinetics of a novel long-acting contraceptive implant

Bioresorbable implant aims to address key unmet needs for family planning at an affordable price in low and middle income (LMIC) settings



Novel bioresorbable contraceptive implant developed at ProMed Pharma

PLYMOUTH, MINNESOTA, UNITED STATES, April 19, 2022 /EINPresswire.com/ -- ProMed Pharma is pleased to announce the initiation of preclinical evaluation of a novel fully resorbable contraceptive implant. The implant, developed in a project funded by the Bill & Melinda Gates Foundation, aims to address key unmet needs for family planning at an affordable price in low and middle income (LMIC) settings.

Commercially available contraceptive implants, while safe and highly effective, require removal by trained health care providers any time the user wants to discontinue the method, including when pregnancy is desired, or when the implant reaches the end of its effectiveness. This requirement imposes a strain on resources in LMIC settings.

The implant being developed by ProMed is specifically designed to address the needs of LMIC settings.

- First, it aims to expand women's contraceptive options by providing 18 months of contraception by long-term release of levonogestrel. This duration fills the gap between that offered by existing injectables and longer-acting methods such as non-erodible implants.
- Second, the implant is fully biodegradable, eliminating the need for women to return to medical clinics for removal at the end of the period of effectiveness.
- Finally, the implant, which comprises a levonogestrel-releasing outer sheath surrounding a drug-free polymer core, is designed to retain sufficient mechanical integrity to allow removal if or when desired. Removability is important to respond to women's needs, such as in cases where pregnancy is desired prior to exhaustion of the contraceptive.

The preclinical evaluation of the implants follows selection of four lead formulations combining levonogestrel with cost-effective, commercially available biopolymers that yield near-linear release without the need of a rate controlling membrane. The preclinical study will evaluate the pharmacokinetics of levonogestrel, establish duration of removability, and track length of biodegradation of the designs. The results will allow further narrowing of formulations for clinical evaluation.

Dr. James Arps, Director of Business Development at ProMed, noted “the implant designs have shown promising mechanical integrity and drug release profiles based on in vitro tests to date and have a form factor which is similar if not superior to other implants on the market.” The study will be carried on for a minimum of 6 months with the option of gathering drug release and polymer degradation data up to 1.5 years.

About ProMed Pharma:

ProMed Pharma specializes in the molding and extrusion of drug-loaded silicones, thermoplastics, and bioresorbable materials, leveraging this expertise to manufacture long-term implants and combination devices under cGMP. Working with both established and early stage companies, we utilize robust manufacturing processes for controlled release of APIs utilizing a variety of materials. From clinical trial materials to commercial products, ProMed supports pharmaceutical and medical device companies developing controlled release formulations including subcutaneous, orthopedic, cardiovacular, and ophthalmic implants, intravaginal rings, and steroid-eluting combination components. The company has facilities in Plymouth and Maple Grove, Minnesota. Please visit www.promedpharmallc.com for more information.

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