# UK-based Futura Medical partners with OCT Clinical to run its FM71 study in Eastern Europe and the USA

ST. PETERSBURG, RUSSIA, September 21, 2021 /EINPresswire.com/ -- Futura Medical, a pharmaceutical company developing a portfolio of innovative products based on its proprietary, transdermal DermaSys® drug delivery technology and currently focused on sexual health and pain, has partnered with OCT Clinical to run its FM71 clinical study for MED3000 in erectile dysfunction in 4 countries: Bulgaria, Poland, Georgia and the USA. The companies have already reported the first patient entering the screening in Georgia earlier this week.

> We are pleased to once again work with the professional OCT Clinical team as we continue to generate important scientific evidence related to our MED3000 gel."
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> *James Barder, Chief Executive Officer, Futura Medical*

MED3000, is a topical gel developed specifically for the treatment of erectile dysfunction ("ED"). It is a fast-acting topical treatment which has the potential to be a highly differentiated product by addressing significant unmet needs in the ED market including speed of onset, safety and tolerability.

The OCT Clinical team has already obtained study approval in Georgia where site initiation has been started: 50% of sites have been opened and the first patients have been screened.

As soon as the clinical trial application (CTA) approvals are obtained from the regulatory authorities in Bulgaria, Poland and the USA the CRO will start site initiation in these countries. For this project, the OCT Clinical team will engage the total of 18 research sites in Bulgaria, Poland, Georgia and the USA.

This is a multi-center, randomised, open-label, home use, parallel group, clinical investigation of topically-applied MED3000 gel and oral tadalafil (5 mg) tablets for the treatment of erectile dysfunction (ED) over a 24-week period. This clinical investigation is intended to assess the efficacy and safety of MED3000 gel in 100 male patients clinically diagnosed with a mix of mild, moderate and severe ED. The enrollment target will include 20 African American patients (from the US) and 80 patients from Eastern Europe, who will undergo a seven-month study.

James Barder, Chief Executive Officer of Futura Medical commented: “We are pleased to once again work with the professional OCT Clinical team as we continue to generate important scientific evidence related to our MED3000 gel. We are excited to see such a robust start to the study and are looking forward to making our treatment available to patients with erectile dysfunction in the USA, the biggest market for ED, as well as other regions."


OCT Clinical, one of the leading CROs in Eastern Europe, announced it has been contracted by the UK-based Futura Medical to run a confirmatory clinical trial, supporting US regulatory filing, of a topical gel for male erectile dysfunction.

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About Futura Medical plc
Futura Medical plc (AIM: FUM), is a pharmaceutical company developing a portfolio of innovative products based on its proprietary, transdermal DermaSys® technology. Each DermaSys® formulation is separately patented and specifically tailored for the selected indication and application, as well as being optimised for clinical efficacy, safety, administration and patient convenience. The products are developed for the prescription and consumer healthcare markets as appropriate. Current therapeutic areas are sexual health, including erectile dysfunction, and pain relief. Development and commercialisation strategies are designed to maximise product differentiation and value creation whilst minimising risk.

MED3000 is Futura's topical gel formulation that is a breakthrough treatment for erectile dysfunction (ED) through a unique evaporative mode of action. Futura has conducted a Phase 3 study using MED3000 in ED, referred to as "FM57". This was a 1,000 patient, dose-ranging, multi-centre, randomised, double blind, placebo-controlled, home use, parallel group study delivering highly statistically significant results compared to pre-treatment baseline, consistently meeting

all co-primary endpoints of IIEF, SEP2 and SEP3 (internationally accepted clinical trial endpoints in ED) with over 60% of patients experiencing a clinically meaningful improvement in their ED. MED3000 also begins to work immediately in some patients, with 60% of patients seeing onset of their erection within 10 minutes of application. MED3000 is CE marked in Europe and the UK as a clinically proven topical treatment for adult men with erectile dysfunction.

Futura is based in Guildford, Surrey, and its shares trade on the AIM market of the London Stock Exchange. www.futuramedical.com

About OCT Clinical
OCT Clinical is the leading CRO in Russia, with operations in Central and Eastern Europe and the CIS region. With a team of over 200 professionals, the company provides a full range of high-quality clinical research services for phase I-IV and BE studies. With strong local expertise and focus on quality, OCT ensures seamless clinical trial conduct and drug registration on time and within budget. OCT's experienced team delivers both standalone services such as medical writing, consultancy, project management/monitoring, data management/biostatistics and turnkey service for clinical development. Since 2005, OCT Clinical Trials has worked on over 300 full-service and functional service projects in more than 20 therapeutic areas. OCT Clinical, a CRO operating in 12 countries, was selected as a principal CRO, responsible for the full range of activities for the vaccine trial in Russia, including regulatory and logistic support, project management, subject enrollment, site monitoring. Learn more at www.OCT-ClinicalTrials.com

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