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UK-based Futura Medical with OCT Clinical to run FM71 study in Eastern Europe, US

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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 four countries: Bulgaria, Poland, Georgia and the US. The companies have already reported the first patient entering the screening in Georgia earlier this week.

MED3000, is a topical gel developed specifically for the treatment of erectile dysfunction (ED). It is a fast-acting topical treatment that 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 per cent 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 US the CRO will start site initiation in these countries. For this project, the OCT Clinical team will engage a total of 18 research sites in Bulgaria, Poland, Georgia and the US.

This is a multi-centre, 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 24 weeks. 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, CEO, 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

US, the biggest market for ED, as well as other regions."