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Futura Medical plc
("Futura" or the "Company")

Futura's Fast-Acting Topical Gel for the Treatment of Erectile Dysfunction Granted Marketing Authorisation by the US FDA for Over the Counter Sale

Futura Medical plc (AIM: FUM) ("Futura" or the "Company"), a pharmaceutical company developing a portfolio of innovative products based on its proprietary, transdermal DermaSys® drug delivery technology currently focused on sexual health, today announces that the US Food and Drug Administration ("FDA") has granted over the counter sale ("OTC") Marketing Authorisation for MED3000, the Company's breakthrough, topical gel formulation for the treatment of erectile dysfunction ("ED") as a De Novo Medical Device.

MED3000 can now be legally marketed in the USA as the first topical treatment for ED available OTC without the need for a prescription. MED3000 is approved as an effective, clinically proven treatment for ED with a 10-minute onset of action. Oral medications ("PDE5i's") such as Cialis and Viagra require a doctor's prescription in the USA and typically are required to be taken at least 30 minutes in advance.

The prevalence of ED disrupts the lives of at least 1 in 5 men globally¹ with around 22 million men suffering ED in the US making the US the largest ED market in the world.

MED3000 has already been approved as the first pan-European clinically proven topical treatment for ED available OTC and is now available in Belgium and the UK. Initial launches commenced under the brand name Eroxon® in March 2023 with further launches planned through 2023 and beyond with commercial agreements in key markets including the European Economic Area, UK, Switzerland, South Korea, Latin America and Middle East.

James Barder, Chief Executive Officer of Futura Medical said "The granting of marketing authorisation by the US FDA as the first clinically proven, topical gel for the treatment of ED in the USA available without a doctor's prescription is a huge milestone for Futura and highlights the incredible progress that the Company continues to make. FDA set a very high standard in evaluating the effectiveness and safety of De Novo Medical Devices. I am delighted that we met this standard with MED3000's submission of 22 clinical, biocompatibility, human factors studies and performance bench tests which were rigorously reviewed and accepted by the FDA. The FDA approval is a major de-risking event for the Company and we look forward to updating shareholders on our US commercialisation plans in due course."

1. EMA, Withdrawal assessment report for Viagra, 2008

The information communicated in this announcement contains inside information for the purposes of Article 7 of the Market Abuse Regulation (EU) No. 596/2014 as amended by the Market Abuse (Amendment) (EU Exit) Regulations 2019.

ENDS

For further information please contact:

Futura Medical plc

James Barder, Chief Executive Officer
Angela Hildreth, Finance Director and COO
Email: investorrelations@futura-medical.com
Tel: +44 (0) 1483 685 670
www.futura-medical.com

Nominated Adviser and Sole Broker:

Liberum

Phil Walker/ Richard Lindley/ Ben Cryer
Tel: +44 (0) 20 3100 2000

For media enquiries please contact:

Optimum Strategic Communications
Hollie Vile/ Jonathan Edwards/ Zoe Bolt
Email: futura-medical@optimumcomms.com
Tel: +44 (0) 203 882 9621

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. 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 novel treatment for erectile dysfunction (ED) through a unique evaporative mode of action. Futura has conducted two Phase 3 studies using MED3000 in ED; FM57 study which enabled Futura to be granted a CE Mark in 2021 and FM71 which enabled Futura to be granted US marketing authorisation. Both studies demonstrated that MED3000 presents an effective clinically proven treatment for ED with a rapid speed of onset and a favourable benefit versus risk profile ideally suited for an 'Over the Counter' classification.

Eroxon® is FDA approved in the US, CE marked in Europe and UKCA marked in the UK as a clinically proven topical treatment for adult men with erectile dysfunction under the brand Eroxon® with a key claim of "Helps you get an erection within 10 minutes". Eroxon® is the agreed brand name in certain regions such as the EU whereas MED3000 continues to be the internal code name used by the Company and also in reference to countries where regulatory approval or commercial distribution agreements have not yet been achieved.

www.eroxon.com

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

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