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March 22

First and only melt-in-the-mouth erectile dysfunction (ED) treatment launches in the UK today

Newbury, Berkshire, 22nd March 2011 – Levitra® (vardenafil) 10mg orodispersible tablet rapidly dissolves on the tongue in seconds without the need for water¹, has a minty flavour and comes in a discreet pack with new anti-counterfeiting measures.

Today marks the launch of the first ED treatment available as an orodispersible tablet. In contrast to other drugs of the same class, the new formulation has been designed specifically to be discreet and convenient, has a minty flavour and dissolves on the tongue within seconds². It is packaged in a new, thin black pocket-sized box which is unlike traditional pharmaceutical packaging and also incorporates numerous anti-counterfeiting measures. Currently, an estimated 2.3 million UK men suffer from ED, yet only 1 in 10 receive treatment³ and according to market research commissioned by Bayer, 4 in 10 men regard presently available therapies as inconvenient⁴.

“Bayer is committed to men’s health and is continuously striving to develop new and innovative treatment options for people living with erectile dysfunction, which is becoming more prevalent in the UK but is still undertreated,” said Marc van Unen, Business Unit Head General Medicine. “Levitra orodispersible was developed to help remove the known barriers associated with erectile dysfunction medication by providing men with a more convenient and discreet treatment option which may also help to lessen the embarrassment surrounding the condition. It is hoped that ultimately, the advantages of the new product and its discreet packaging, which includes 120 anti-counterfeiting measures, will reduce the growing numbers of patients purchasing counterfeit pills online and lead to improved patient satisfaction and treatment outcomes in ED overall.”

According to the 2009 European Association of Urology Guidelines, the patient has an important role in treatment decisions for ED.⁵ Prior to the launch of the new formulation, Bayer commissioned market research on 300 patients and 240 physicians to explore levels of satisfaction with current ED medication.⁴ It found that patients’ interest in trying the new formulation was high, due to its convenience and product characteristics (e.g. dissolves in the mouth in seconds, there’s no need to take it with water and it’s discreet).⁴ In addition, 9 out of 10 physicians had a positive overall impression of it, particularly with regards to its taste, efficacy and convenience.⁴

The new formulation was approved by the European Commission in September 2010 and is the first and only ED medication to be available in this convenient orodispersible formulation, yet it comes with the proven safety and efficacy and similar pharmacokinetic profile to that of the Levitra film-coated tablet.⁶

Dr Geoff Hackett, Consultant in Sexual Medicine, Good Hope Hospital, Sutton Coldfield said; “Despite the fact that a range of PDE-5 inhibitors exist, uptake has always been relatively low so the majority of ED sufferers go untreated or risk obtaining unregulated medication online.” He continued: “I hope that the availability of the new formulation will encourage men who are having erection problems to discuss the condition with a healthcare professional, and re-assure those diagnosed patients that are dissatisfied with their current treatment, that other alternatives exist.”

The overall efficacy and safety of Levitra orodispersible tablet has been demonstrated in two large independent clinical trials.^{6,7,8} For this registration, it was tested in the Phase III multinational trials POTENT I and II (Pivotal phase III trial to investigate the efficacy and safety of an Orodispersible Tablet vardenafil versus placebo in the treatment of men with Erectile dysfunction: a fixed-dose, double-blind, randomised multicentre Trial).^{7,8}

These pivotal studies compared the efficacy and safety of the new formulation with placebo after 12 weeks of treatment in a general population of men with ED. These two international twin studies were conducted with identical study design, enrolling a total of 882 men above the age of 18 years who had ED for more than 6 months. For both POTENT I and POTENT II studies, the new formulation was statistically significantly superior to placebo for all primary and secondary efficacy measures (all p<0.0001).^{7,8}

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Note to Editors

About Levitra® Orodispersible Tablet

The product packaging incorporates 120 different anti-counterfeiting measures, including:

- The word 'LEVITRA' is embossed (tangible) on the surface of the pack and
- The word 'LEVITRA' and the flame symbol are repeated on a number of diagonal lines

incorporated into the structure of the foil.

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