

For Immediate Release

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Clinical Update – PSD502 for Premature Ejaculation

PSD502 advances into final stage of development

Plethora Solutions Holdings PLC ("Plethora", AIM : PLE), the specialist developer of products for the treatment and management of urological disorders, has initiated the Phase III programme for PSD502 in the USA for the treatment of premature ejaculation, marking the final stage of the clinical development for this product.

PSD502 is a proprietary formulation of two marketed drugs, lidocaine and prilocaine, dispensed by a metered dose aerosol developed for the treatment of premature ejaculation, a disorder affecting up to 30% of men in Europe and the USA and for which there is no approved treatment. The product is applied locally when needed (often referred to as "on demand" therapy) and is effective within five minutes. Other key advantages of the product are a good safety profile, minimal partner transfer, eliminating the need to use a condom for protection from the product and the potential for the dose to be self-titrated or adjusted under physician direction. The product was shown to increase ejaculation latency time substantially when compared with placebo in a multi-centre Phase II study. This data has been published recently in *BJU International* (Dinsmore W et al 2007, *BJU Int* 99: 369-35).

In May 2007 Plethora licensed PSD502 to Sciele Pharma, Inc. for the premature ejaculation indication in the US while retaining co-promotion rights to the US urologist market.

Study Details:

The company intends to run the two pivotal studies in parallel, one in the USA and one in Europe. Each will be a multi-centre, randomised, double blind, placebo-controlled efficacy study recruiting a total of 540 patients across both studies. Patients will be treated for a 12 week period with an optional 5 month open label phase. The primary endpoints will be Intra-vaginal Ejaculation Latency Time (IVELT), sexual satisfaction and ejaculatory control. Secondary endpoints will include Sexual Quality of Life and partner satisfaction. The study design and powering, agreed with both US and EU regulatory authorities, will employ validated patient reported outcomes (PROs). The two studies will recruit patients in 36 centres in Europe and 38 in the USA and Canada, including almost all North American opinion leaders. It has also been agreed with the regulators that 1-year open label extensions to the studies are not required and this will reduce time to study closure considerably.

Steven Powell, Plethora CEO, commented:

"We are pleased to be advancing PSD502 into the final stage of clinical development for the treatment of premature ejaculation. If patient recruitment proceeds as planned, we would expect to see headline data towards the end of 2008 which will be a major milestone in the life of both this product and Plethora".

Patrick Fourteau, President and CEO of Sciele Pharma commented:

"We are pleased with the excellent progress Plethora has made with the development of PSD502, initiating the Phase III pivotal trials within our previously announced timelines. PSD502 for premature ejaculation addresses an unmet medical need that affects a significant number of adult males in all age groups."

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About Plethora:

Plethora is focused on the development and marketing of products for the treatment of urological disorders. The Company has products in clinical development for the treatment of overactive bladder, stress urinary incontinence, interstitial cystitis, gynaecological pain, erectile dysfunction and premature ejaculation. In January 2006, Plethora acquired Minneapolis (Mn) based Timm Medical Technologies Inc which markets products for the treatment of erectile dysfunction (ED) to urology clinics through a US-based specialty sales team. The Company is headquartered in the UK and is listed on the London Stock Exchange (AIM:PLE) Further information is available at **www.plethorasolutions.co.uk**