

For Immediate Release

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PLETHORA SOLUTIONS HOLDINGS PLC

Clinical Update

Positive Phase II clinical data for PSD503 in the treatment of stress urinary incontinence

- **44% improvement in primary efficacy endpoint of pad weight vs placebo**
- **Drug safe and well tolerated with no evidence of blood pressure elevation**

Plethora Solutions Holdings PLC ("Plethora", AIM : PLE), the specialist developer of products for the treatment and management of urological disorders, is pleased to announce that preliminary analysis of Phase II data has confirmed a positive clinical effect and safety of PSD503 as a front-line therapy for stress urinary incontinence (SUI).

SUI is the most common form of urinary incontinence in women. It is characterised by urine leakage when pressure is increased in the abdominal cavity during coughing, sneezing, laughing, exercising or even sitting. Epidemiological studies indicate that SUI afflicts over half of all female incontinence sufferers and is the most frequently reported type of incontinence in women under 50. This equates to a potential treatment population of 23 million women in North America, France, Germany, Italy, Spain and the UK who suffer from mild to moderate SUI. The condition can have a significant negative impact on quality of life and there is, as yet, no drug with global approval for the treatment of the condition.

PSD503 is a metered dose, topical gel formulation of phenylephrine, which is a member of a class of drugs called alpha-adrenergic agonists which have a long history of clinical use as both systemic and topical agents for appetite suppression and nasal decongestants. There has also been previously reported evidence that alpha agonists can reduce the symptoms of SUI. However, they have also been associated with side effects including agitation, tremor, respiratory difficulty and particularly hypertension and cardiac arrhythmias that would preclude their use as oral agents for the long term treatment of SUI. PSD503 has been developed specifically as a locally administered formulation of an alpha agonist which would achieve target organ selectivity and provide effective symptom improvement in the absence of obtrusive side effects.

This preliminary analysis, in 12 patients, of the double-blind, crossover placebo controlled study shows that PSD503 produced a 44% overall reduction in leakage (as measured from pad weight), whereas placebo was largely without effect (11% increase in pad weight). Improvement with PSD503, beyond that of placebo, was reported in 50% of the women with stress incontinence which represents a good responder rate for a urological condition such as incontinence or benign prostatic hyperplasia (BPH). In addition, the cardiovascular side effect profiles of placebo and PSD503 are indistinguishable, with no evidence of blood pressure elevation in any subject. Consistent with this finding, only very low systemic plasma

concentrations of phenylephrine are found. These data are consistent with an earlier Plethora open label study conducted at the Institute of Urology in London, which demonstrated that, at this dose, PSD503 can have an effect on urethral resistance and overall urodynamic parameters. The purpose of this Phase II study was to further quantify the magnitude of the improvement achieved with PSD503 and these results add support to the commercial potential of this development product.

Dr Steven Powell, CEO of Plethora, commented:

"These data further confirm the potential for PSD503 to meet a poorly met medical need in the treatment of stress urinary incontinence. They also add substantially to the package of data required for successful out-licensing. Potential licensing partners have expressed an interest in this programme already and, with this data, we look forward to advancing these discussions.

"After the successes in Phase II with PSD502 and PSD597, these results for PSD503 further validate the Plethora model in which marketed products are reformulated in a novel way to minimise systemic exposure and fast-tracked into new therapeutic areas."

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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. Plethora has a US subsidiary, Timm Medical Technologies Inc, which markets products for the treatment of erectile dysfunction (ED) to urology clinics through a national US specialty sales team. The Company is headquartered in the UK and is listed on the London Stock Exchange (AIM:LSE). Further information is available at www.plethorasolutions.co.uk.