

For Immediate Release

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PLETHORA SOLUTIONS HOLDINGS PLC

Clinical Update

Full analysis of Phase II clinical results confirm PSD597 is an effective, safe and rapidly acting treatment for patients suffering from interstitial cystitis/painful bladder syndrome

- **Significant improvement in both Primary and Secondary efficacy endpoints**
- **Both immediate and sustained clinical benefit confirmed**
- **Drug safe and well tolerated**

Plethora Solutions Holdings PLC ("Plethora", AIM : PLE), the specialist developer of products for the treatment and management of urological disorders, is pleased to announce further results and analysis of a Phase II clinical study of PSD597 in the treatment of interstitial cystitis and painful bladder syndrome (IC/PBS). The full analysis confirms and extends the initial positive outcomes announced on 6 September 2007.

IC is a chronic urological disorder that afflicts young and middle aged women especially. The condition is characterised by bladder pain, urinary frequency and urgency. Symptoms may be severe, to the point that pain and associated complaints come to dominate the sufferer's life. In a 2006 report¹ a global patient population of 16 million with IC was reported with a prevalence of 6.4 million patients in the USA alone. Current treatments for IC/PBS are of limited effectiveness and any improvement is typically of short duration.

Trial Protocol

The Plethora study was a randomized, double-blind, placebo controlled trial into which 102 patients were recruited in 22 centres in the USA and Canada. Bladder pain was required for patient enrolment, but the entry criteria were otherwise widely drawn so that a broad and representative group of patients might enter. The immediate and prolonged effects of a course of PSD597 treatment were investigated.

Results – clear and substantial improvements in GRA, the primary endpoint

Patients who received PSD597 showed clear and substantial improvements in the primary endpoint measure, Global Response Assessment (GRA), a patient-rated scale of improvement in bladder symptoms which is now an international standard in IC/PBS trials. At Day 8, 15 patients (30%) in the 'intent-to-treat' population reported moderate or marked improvement after PSD597 treatment compared with only 5 patients (10%) randomized to placebo ($p=0.012$); improvements in the two groups at Day 15 were 24% and 12% respectively ($p=0.102$). Analysing the response across all GRA categories, the difference with PSD597 treatment at Day

15 was highly significantly different from placebo (p=0.005). These positive results were replicated across all secondary endpoints with improvements reported in bladder pain, urinary frequency and urgency, whether assessed as individual symptoms or combined into widely-accepted symptom and problem indices. The O'Leary-Sant Interstitial Cystitis Symptom Index and Interstitial Cystitis Problem Index each improved following treatment with PSD597 (p=0.041, p<0.001 at Day 8, respectively, comparing PSD597 and placebo treatment groups; p=0.12, p=0.038 comparing the two treatments at Day 15). PSD597 was well tolerated, appeared safe, and was devoid of systemic side effects often experienced with oral drugs.

Voluntary Open Label Study – 86% of patients elected to receive second treatment

The drug effect was confirmed in an extension to the study. In this voluntary part of the trial, patients who completed the double-blind placebo controlled phase were offered the choice of open label treatment with PSD597 for 5 days from Day 15. Notably, 86% of patients elected to receive a second treatment. This provides direct evidence of treatment acceptability and the lack of alternative treatment options. Treatment was again well tolerated and safe. At Day 22, 63% of those patients who had received PSD597 in the double-blind study phase reported moderate or marked improvement in Global Response Assessment after the second treatment; of the patients who previously were randomized to placebo, 44% now responded to active treatment. By Day 29, GRA response rates were still maintained at 56% and 39% in the two groups. The results complement those seen in the initial double-blind study phase and, together, they suggest that the benefits of PSD597 are sustained for a considerable period after treatment and, secondly, confirm that clinical benefit can be increased with repeated PSD597.

Dr. Mike Wyllie, CSO of Plethora, commented:

"These full results confirm and extend previous findings and show that PSD597 offers a simple, effective treatment for patients suffering from interstitial cystitis. These longer term studies confirm that the product produces rapid and effective relief of symptoms and that the effect is maintained over several weeks. Dialogue will now be initiated with regulatory authorities to define the phase III programme required for registration in parallel with discussions with potential licensing partners."

-Ends-

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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