

For Immediate Release

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PLETHORA SOLUTIONS HOLDINGS PLC

Clinical Update

PSD597 for interstitial cystitis: Positive outcome for Phase II study in an area of significant unmet medical need

- **Statistically and clinically significant improvement in symptoms**
- **Treatment effect sustained beyond dosing**
- **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 a positive outcome for a Phase II clinical study of PSD597 for the treatment of interstitial cystitis and painful bladder syndrome (IC/PBS).

IC is a chronic urological disorder that predominantly afflicts young and middle aged women. The condition is characterised by bladder pain, urinary frequency and urgency without an identifiable cause and the intensity of the condition ranges from inconvenience to all pervasive and socially debilitating. In its most severe form, quality of life with IC can be worse than end stage renal disease¹. In a 2006 report², IC prevalence was reported as a global patient population of 16 million with 6.4 million patients in the US alone. Current treatments for IC/PBS are limited in their effectiveness in reducing pain and typically have a short duration of effect.

The Plethora study was a double-blind placebo controlled study with 102 patients recruited from 22 centres in the USA and Canada. The objectives were to show both immediate and sustained relief of the symptoms of interstitial cystitis. A preliminary analysis of the data indicates that patients treated with PSD597 experienced a statistically significant improvement ($p < 0.01$) in their symptoms as measured by the primary endpoint of Global Response Assessment (GRA). GRA is a well recognised parameter used by clinical practitioners treating IC patients and is a standard measure of the patient's response to treatment (including changes in pain, urinary frequency and urgency). These results are further supported by the secondary endpoints, including symptom and problem indices. Importantly, the treatment effect was maintained for several weeks and the drug was safe and well tolerated and devoid of systemic side effects often experienced with oral drug administration. The blinded study was followed by a voluntary, open label study to gather further information on the longer term treatment effect. This open label extension recruited from both the treatment and placebo arms of the blinded study. Significantly, 86% of patients who completed the double-blind placebo controlled study elected to remain in the open label study indicating strong support for this novel treatment. Initial findings from the open label study suggest that the treatment effect was sustained. Full data from the blinded and open label studies will be available later in the year.

1: Held, PJ *et al.* Epidemiology of interstitial cystitis. Hanno, PM. Interstitial Cystitis. 29 – 48. 1990, London, Springer-Verlag

2: Source: Datamonitor Report, "Interstitial Cystitis – Few Treatments, Poor Outcomes", 04.2006

PSD597 is delivered into the bladder using a technique suitable for both out-patient clinics and home administration. The proprietary formulation of the drug 'protects' the drug in the hostile environment of the bladder to ensure that the drug remains in the optimal chemical form for transport across the bladder wall to its site of action.

The Principal Investigator, Professor Curtis Nickel, Dept of Urology, Queen's University, Kingston, Ontario commented:-

"Patients suffering from interstitial cystitis/painful bladder syndrome (IC/PBS) and physicians managing this chronic debilitating condition have become discouraged as one potential beneficial therapy after another has failed to show significant clinical efficacy when subjected to rigorous scientific scrutiny. The results from this well designed, randomised, placebo controlled study evaluating the safety and efficacy of PSD597, which showed very encouraging statistically and clinically significant improvement with PSD597 compared to placebo, may change this pessimism. This study definitely shows that PSD597 is effective for the acute treatment of the pain and voiding symptoms of IC/PBS and will prove to be of significant benefit in treating flares and exacerbations of the condition. Patients and physicians now have a right to be encouraged that a new therapy holds promise for the future."

Dr Mike Wyllie, CSO of Plethora, commented:

"After the success of PSD502 in its Phase II study, the positive data from this successful study provide further validation of the Plethora model where marketed products are reformulated in a novel way and fast-tracked into new therapeutic areas. Not surprisingly, given the size of the commercial opportunity for PSD597, there is considerable interest from pharmaceutical companies in the outcome of this study. Discussions will now be initiated with regulatory authorities to confirm the requirements for the remaining component of the registration programme for this product. We look forward to updating shareholders as this development programme and associated partnering discussions advance."

-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**](http://www.plethorasolutions.co.uk)