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Plethora Solutions Holdings plc

Final Analysis from a Positive Phase II Clinical Study of PSD502 for the treatment of Premature Ejaculation (PE)

Plethora Solutions Holdings plc ("Plethora" or the "Company") is pleased to announce final data from the Phase II studies of its treatment for premature ejaculation, PSD502.

This report contains additional data, including secondary clinical endpoints, and follows the announcement of initial findings from the study made on 1 December 2005

Key points of the final PSD502 data are:

- **Clinically and statistically significant increase in ejaculation latency time**
- **PSD502 superior to placebo with respect to improvements in all secondary endpoints**
- **Well tolerated and devoid of systemic side effects**

In addition to the previously reported highly significant differences between PSD502 and placebo with respect to increases in intravaginal ejaculation latency time (IELT) (Table 1), PSD502 was also found to be superior to placebo on all secondary endpoints measured.

Over half of patients responded favourably to PSD502 with only approximately a third responding to placebo (Table 2). As would be expected from the overall response, a considerably greater number of patients also showed both a three minute and four minute increase on PSD502 when compared to placebo.

The changes observed in all other clinically validated endpoints were entirely consistent with clinically significant differences in IELT increase produced by PSD502 compared to placebo. PSD502 was superior to placebo with respect to ejaculatory control and sexual quality of life for patients and their partners, (Tables 3 and 4 respectively). In addition, eighty-one percent of patients felt that the PSD502 spray was easy to use.

Using comparable endpoints to those used in large scale studies of oral treatments for PE, it can be concluded that PSD502 has now been shown unequivocally to produce clinical benefit and to be superior to placebo.

The study also showed a benign side effect profile (Table 5) as would be expected due to the established, long term safety of the components.

Dr Steven Powell, Chief Executive of Plethora, commented:

"The final data from this Phase II study has demonstrated that PSD502 has great potential as a treatment for this common and distressing condition. The findings from the study confirm not only its viability as a treatment for premature ejaculation but also the strong safety profile of PSD502. The subjective perceptions of benefit found in this study increase our confidence that men and their partners will find PSD502 to be an acceptable means of treating PE. Discussions continue with potential partners to take PSD502 through the next stage of its clinical development and I look forward to updating shareholders on progress."

Table 1. Summary of the raw means for Intravaginal Ejaculation Latency Time (IELT)

Variable	Visit	PSD502 Mean (*s.e.*)	Placebo Mean (*s.e.*)
IELT (minutes)	Baseline	1.0 (0.27)	0.9 (0.15)
	End of study	4.9 (1.13)	1.6 (0.33)

The change from baseline in IELT adjusted for centre and baseline was clinically and statistically significantly higher in the PSD502 treated group compared to the placebo treated group ($p<0.01$).

Table 2: Percentage of Patients who achieved IELTs on ≥ 2 occasions during the treatment period above a predefined level

Response level	Treatment	
≥2 IELT times of at least:	**PSD502**	**Placebo**
2 minutes	55%	35%
3 minutes	40%	13%
4 minutes	25%	13%

Table 3: Summary of the raw means for Index of Ejaculatory Control

Variable	Visit	PSD502 Mean (*s.e.*)	Placebo Mean (*s.e.*)
Index of ejaculatory control (0-24)*	Baseline	2.6 (0.67)	2.7 (0.55)
	End of study	9.6 (1.41)	5.6 (0.91)

*Low responses reflect a poor outcome and high scores reflect a good outcome.

Table 4: Summary of the Mean Change from baselines for Sexual QoL adjusted for baseline and centre

Variable	Mean:	PSD502	Placebo
Sexual quality of life (patients)	Change from baseline, adjusted for centre and baseline	**7.9**	**5.4**
	95% confidence interval	2.7 to 13.1	0.5 to 10.3
Sexual quality of life (partners)	Change from baseline, adjusted for centre and baseline	**3.47**	**1.71**
	95% confidence interval	–1.0 to 8.0	–2.4 to 5.8

Table 5: Treatment Related Adverse Events with an incidence of >5%

	Entered	Reported any adverse events	
		Patients *	Partners
PSD502	26	3	0
Placebo	28	0	0

*All local numbness mild (2 patients) and moderate (1 patient)
No adverse event led to discontinuation from study

For further information contact:

Plethora Solutions **Tel : 0207 269 8630**
Steven Powell

Collins Stewart **Tel : 0207 523 8350**
Tim Mickley

Buchanan Communications **Tel : 0207 466 5000**
Isabel Podda

About Plethora:

Plethora is a UK-based specialty pharmaceutical company focused on the development of products for the treatment of urological disease. The company has products in clinical development for the treatment of overactive bladder, benign prostatic hyperplasia, stress urinary incontinence, interstitial cystitis and premature ejaculation. The company is headquartered in the UK and recently listed on the London Stock Exchange (AIM:PLE).