



**SCIELE PHARMA AND PLETHORA SOLUTIONS ANNOUNCE THAT  
PSD502 DEMONSTRATES SUBSTANTIAL BENEFIT IN THE  
TREATMENT OF PREMATURE EJACULATION**

***Results from a European Phase III Study Presented at the AUA Annual Meeting***

- ***Both Patient and Partner Satisfaction Increased Significantly***
  - ***86% of Patients Rated the Treatment as Positive***

ATLANTA (April 28, 2009) – Sciele Pharma, Inc. a Shiongi Company, and Plethora Solutions Holdings PLC (“Plethora” – AME:PLE) today presented highly encouraging results from a European Phase III randomized, double-blind, placebo-controlled study of PSD502 for the treatment of premature ejaculation (PE). In this study, men treated with PSD502 five minutes before intercourse were able to delay ejaculation up to six times longer than those who used a placebo. Additionally, patients and their partners reported significant improvements in overall sexual satisfaction scores when using PSD502. The results were presented today at the American Urological Association Annual Meeting.

“Premature ejaculation is a very distressing condition that can have a devastating impact on the intimate relationship between men and their partners,” said Professor Wallace Dinsmore, Royal Victoria Hospital, Belfast, UK, and lead study investigator. “The data suggest that PSD502 is effective in delaying ejaculation for several minutes, significantly improving the overall sexual experience. Equally important is the fact that in this trial PSD502 was shown to be well tolerated and well accepted by patients.”

The European Phase III study, one of two major international trials, was designed to determine whether PSD502, a metered-dose aerosol formulation of lidocaine and prilocaine, would result in longer intravaginal ejaculatory latency time (IELT) in men who suffer from PE. The study also assessed the safety and tolerability of the therapy.

“Premature ejaculation is experienced by up to 30 percent of the adult male population at some time in their lives, yet there is no FDA-approved prescription product to treat this sexual dysfunction,” said Ira D. Sharlip, M.D., clinical professor of urology, University of California, San Francisco. “The significant improvement in ejaculatory control and overall sexual satisfaction reported by men using PSD502 in this study is very encouraging news for physicians who treat these patients.”

“PSD502 may represent a promising new therapy in the management of premature ejaculation, meeting an unmet medical need in a condition that affects millions of men,” said Ed Schutter, President and Chief Operating Officer of Sciele Pharma. “We look forward to completing the North American Phase III study in the second half of this year, with an anticipated filing with the FDA in the first half of 2010.”

**European Phase III Study:**

The European study was conducted with 300 randomized patients across 32 investigational centers in four countries across Europe. Of these, 268 patients have now been entered into the optional nine-month open-label study.

Final analyses confirmed that PSD502 produced a highly clinically and statistically significant increase from baseline in all three co-primary study endpoints, and also in all secondary endpoints. The IELT for PSD502 was four minutes compared with one minute in placebo ( $p < 0.0001$ ). There was a seven-point difference between PSD502 and placebo in Ejaculatory Control ( $p < 0.0001$ ) and a six-point difference between PSD502 and placebo in Sexual Satisfaction ( $p < 0.0001$ ), where a two-point difference in a 16-point range is considered clinically significant. There was a three-point difference between PSD502 and placebo in the Index of Premature Ejaculation domain for distress ( $p < 0.0001$ ).

Of patients who received PSD502, 91% achieved an IELT of greater than one minute and 75% achieved an IELT of greater than two minutes following treatment. This compared with only 54% and 22% of placebo patients, respectively. Both endpoints were highly clinically and statistically significant ( $p < 0.0001$ ).

There was also a highly statistically significant ( $p < 0.0001$ ) improvement in scores for all four secondary endpoints; that is Control, Distress, Satisfaction and Interpersonal Difficulty in the PSD502 group, compared with placebo. Importantly, both patients and partners benefited from the treatment.

The number of patients in the PSD502 group who rated the quality of their orgasm as good or very good increased from 20% at baseline to 62% after treatment. In comparison, the number of placebo-treated patients with this rating decreased from 21% to 19%.

The study treatment was rated positively by 86% of patients who received PSD502 compared with 34% of placebo patients.

There were no serious adverse events, and only 2.6% of patients reported treatment-related adverse events in the PSD502 group compared with 1% in the placebo. Of these adverse events, only one patient who received PSD502 (0.5%) reported temporary numbness of the penis, which was described as mild. PSD502 was well tolerated and there were no systemic adverse events.

#### **About Premature Ejaculation:**

In 2008, the International Society for Sexual Medicine presented an evidence-based definition of PE as agreed upon by a consensus of the world's leading sexual health experts. They define PE as a male sexual dysfunction characterized by ejaculation which always or nearly always occurs prior to or within about one minute of vaginal penetration; and inability to delay ejaculation on all or nearly all vaginal penetrations; and negative personal consequences, such as distress, bother, frustration and/or the avoidance of sexual intimacy.

#### **About PSD502:**

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 reported to affect between 25% and 30% of men in Europe and the USA. There are currently no approved prescription pharmaceutical treatments for premature ejaculation in the United States.

**About Sciele Pharma, Inc.:**

Sciele Pharma, Inc., a Shionogi Company, is a pharmaceutical company specializing in sales, marketing and development of branded prescription products focused on the therapeutic areas of Cardiovascular, Diabetes, Women's Health and Pediatrics. The Company's Cardiovascular and Diabetes products treat patients with high cholesterol, hypertension, high triglycerides, unstable angina and Type 2 diabetes; its Women's Health products are designed to improve the health and well-being of women and mothers and their babies; and its Pediatrics products treat allergies, asthma, coughs and colds, and attention deficit and hyperactivity disorder (ADHD). Founded in 1992 and headquartered in Atlanta, Georgia, Sciele employs more than 1000 people. The Company's success is based on placing the needs of patients first, improving health and quality of life, and implementing its business platform – an Entrepreneurial Spirit, Innovation, Execution Excellence, Simplicity, and Teamwork.

On October 9, 2008, Shionogi & Co., Ltd. and Sciele Pharma announced the completion of Shionogi's acquisition of Sciele. Sciele is now an indirect wholly owned subsidiary of Shionogi

**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 US national sales operation. 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).

**About Shionogi & Co., Ltd.:**

Shionogi & Co., Ltd. is a major research-driven Japanese pharmaceutical manufacturer. The company's primary businesses are research and development, manufacturing, marketing, and import and export sales of pharmaceuticals and diagnostics. Shionogi follows a basic policy of continually providing the superior medicines essential to people's health. For more details, please visit [www.shionogi.co.jp](http://www.shionogi.co.jp).

**Safe Harbor Statement**

*This press release contains forward-looking statements that are subject to risks and uncertainties that could cause actual results to materially differ from those described. Although we believe that the expectations expressed in these statements are reasonable, we cannot promise that our expectations will turn out to be correct. Our actual results could be materially different from and worse than our expectations.*

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