Pivotal data for the investigational treatment PSD502 for primary premature ejaculation

EurekAlert

SAN FRANCISCO, CA/ATLANTA, GA, June 1, 2010 - Shionogi Pharma, Inc., a U.S.-based group company of Shionogi & Co., Ltd., today presented data summarizing the results of two pivotal studies of the investigational new drug PSD502, a topical metered dose spray being developed for the treatment of primary premature ejaculation (PE). These data were presented at the 2010 American Urological Association (AUA) Annual Meeting in San Francisco.

Evaluating a combined total of 556 (randomized) and 536 (treated) men with primary PE in the United States, Canada and Europe over a three-month period, with more than 23,000 exposures to PSD502 recorded, the data demonstrated that men who were treated with PSD502 five minutes before intercourse by applying PSD502 via a topical metered dose spray had a time to ejaculation 5.5 times longer than those who used a placebo spray with the actual average measurement in minutes for drug and placebo.

A co-primary endpoint also looked at ejaculatory control and satisfaction. Point differences of 6.1 and 5.3 were observed between the PSD502 group and placebo in ejaculatory control and satisfaction domains, respectively ($p<0.0001$ for all).

"Combined results from the PSD502 pivotal studies are very exciting and this is a significant milestone," said Ira D. Sharlip, MD, clinical trial investigator and clinical professor of urology at the University of California, San Francisco.

The exact incidence of PE is not known, as a widely accepted definition of PE has only recently become available. Depending on the definition used, ranges from 5% to more than 30% incidence of PE or ejaculatory control issues have been reported in the literature. For example, according to a large national study, approximately 30% of men suffer from ejaculatory control issues, including climaxing too early, while data from the National Health and Social Life Survey (NHSLS) states the prevalence as 21% in men ages 18 to 59 in the United States.

Pivotal Study Details

Men selected from 70 centers in the United States, Canada and Europe with primary PE and an Intravaginal Ejaculatory Latency Time (IELT) of less than one minute were randomly placed in one of two groups, two-thirds in the PSD502 group and one-third in the placebo group. Participants were instructed to apply PSD502 or placebo to the glans penis five minutes before intercourse. Efficacy was assessed from changes in IELT and in the domains of the Index of Premature Ejaculation (IPE), a patient reported outcome questionnaire, over a period of three months.

The baseline IELT in both study groups was less than 0.6 minutes which increased 5.5 fold and 1.6 fold in the PSD502 and placebo groups, respectively ($p<0.0001$), resulting in a mean IELT of 3.3 minutes in the PSD502 group. There were greater improvements in all domain scores of the IPE in the PSD502 group compared to placebo resulting in 6.1, 5.3 and 2.6 point differences between PSD502 and placebo in ejaculatory control, satisfaction and distress domains respectively ($p<0.0001$ for all).

In the PSD502 group, 6.1% of patients reported treatment-related adverse events versus 0.6% in the placebo group. There was one treatment-related adverse event greater than or equal to 3% (loss of erection; 3.1%). Almost 7 percent (6.7%) of partners reported adverse events compared to 1.7% in the placebo group. The most commonly reported adverse event in partners was vulvovaginal burning sensation (5%).

About Premature Ejaculation (PE)

For years, experts debated about the definition of 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: 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. Currently, there are no prescription therapies approved by the U.S. Food and Drug Administration to treat premature ejaculation.

About PSD502

PSD502 is a proprietary formulation of the two marketed drugs lidocaine and prilocaine dispensed as a topical metered dose spray that is currently under investigation for the treatment of primary premature ejaculation. PSD502 works primarily on non-keratinized skin on the mucosa of the glans penis.

SOURCE [1]

Links:
[1] http://www.eurekalert.org/pub_releases/2010-06/hp-pdf052610.php