

Diese Meldung kann unter <http://www.presseportal.de/pm/6631/1512944/flibanserin-demonstrates-efficacy-and-tolerability-in-pivotal-phase-iii-trials-in-pre-menopausal> abgerufen werden.



Flibanserin Demonstrates Efficacy and Tolerability in Pivotal Phase III Trials in Pre-Menopausal Women With Hypoactive Sexual Desire Disorder (HSDD)

16.11.2009 - 14:18 Uhr, Boehringer Ingelheim GmbH

Ingelheim, Germany, November 16 (ots/PRNewswire) - - Results Support Flibanserin as a Potential Treatment for HSDD, an Under-Recognised Women's Sexual Health Condition

- For Medical Media, Outside the US Only

Data from pooled, pivotal Phase III clinical trials demonstrate that flibanserin 100mg taken once daily at bedtime significantly increased the number of Satisfying Sexual Events (SSEs) and sexual desire while significantly decreasing the distress associated with Hypoactive Sexual Desire Disorder (HSDD).[1] Flibanserin is an investigational compound that is being developed by Boehringer Ingelheim for the treatment of pre-menopausal women with HSDD.

To view the Multimedia News Release, please click:
<http://multivu.prnewswire.com/mnr/prne/boehringeringelheim/39236>

HSDD is a medical condition characterised by a decrease in sexual desire associated with marked distress and/or interpersonal difficulties.[2] Women with HSDD often feel a loss of intimacy and closeness that they used to enjoy. The condition can negatively impact a woman's life and her relationship with her partner.[2],[3],[4],[5]

The complete flibanserin pivotal trial programme was presented today at the 12th Congress of the European Society for Sexual Medicine in Lyon, France. It included an analysis of three pivotal Phase III North American trials (DAISY(R), VIOLET(R) and DAHLIA(R)) and the pivotal Phase III European data (ORCHID(R)). In addition results from a pooled analysis of two pivotal Phase III North American trials (DAISY(R) and VIOLET(R)) and a pooled analysis of the North American and European data (DAISY(R), VIOLET(R) and ORCHID(R)) were presented, assessing the safety and efficacy of flibanserin 100mg in pre-menopausal women suffering with HSDD.

"Despite studies demonstrating that HSDD is a common form of female sexual dysfunction, there is currently no approved prescription treatment for pre-menopausal women suffering from the condition" said Professor Rossella Nappi, director of the Gynaecological Endocrinology & Menopause Unit at the Maugeri Foundation, University of Pavia, Italy, and primary investigator of the European pivotal trial. "Flibanserin is a novel, non-hormonal compound, that has been investigated as a treatment for pre-menopausal women with HSDD. Based on the clinical trial results presented at ESSM it has the potential to help many women suffering from their lack of sexual desire."

Pooled North American Phase III Trial Results (DAISY(R) and VIOLET(R))[6]

The pre-specified pooled analysis of 1,378 pre-menopausal women with HSDD shows a statistically significant increase in the frequency of SSEs per month in women taking flibanserin 100mg (from 2.8 at baseline to 4.5), versus placebo (2.7 at baseline increasing to 3.7) over the 24-week study period. Flibanserin also demonstrated statistically significant improvements in sexual desire versus placebo as measured by an electronic diary (the eDiary For HSDD Trials(c)). This finding was further supported by data from the desire domain of the Female Sexual Function Index (FSFI) as an independent secondary measure.

Other key secondary endpoints showed flibanserin significantly improved sexual functioning (as measured by the FSFI total score), distress related to sexual dysfunction (as measured by the Female Sexual Distress Scale-Revised, FSDS-R, score) and distress related to low sexual desire (FSDS-R Item 13 score) versus placebo.

European Phase III Trial Results (ORCHID(R))[7]

The analysis of 634 pre-menopausal women with HSDD showed women taking flibanserin 100mg had statistically significant improvements in their level of sexual desire, as measured by the eDiary. These findings were supported by a trend towards an increase in the FSFI desire domain. In addition there was a statistically significant improvement in the level of distress associated with sexual dysfunction (as measured by the FSDS-R total score) as well as distress related to low sexual desire (FSDS-R Item 13) which is the second key parameter for the diagnosis of HSDD. A numerical increase in the number of SSEs compared to placebo supports the efficacy of flibanserin in pre-menopausal women suffering with HSDD.

North American and European Phase III Trial Results - Pooled Analysis (DAISY(R), VIOLET(R) and ORCHID(R))[1]

A pooled analysis of pivotal data including the European study (ORCHID(R)) and the American Phase III trials (DAISY(R) and VIOLET(R)) reinforces the efficacy of 100mg flibanserin for the treatment of pre-menopausal women with HSDD. Results show a statistically significant improvement versus placebo in the number of SSEs, as well as a statistically significant increase in the level of sexual desire, recorded via the eDiary and the FSFI desire domain scores. Distress associated with sexual dysfunction and specifically low sexual desire was significantly reduced with flibanserin 100mg (as measured by FSDS-R score and FSDS-R Item 13 score).

Safety Analysis[8]

Most adverse drug reactions with flibanserin 100mg were mild to moderate, emerged during the first 14 days of treatment and resolved with continued treatment. The most common adverse events (AEs) reported by more women on flibanserin than on placebo included dizziness, nausea, fatigue, somnolence and insomnia. The findings are consistent across the North American and European trials with about 14% and 16% of women on flibanserin 100mg and 8% and 5% of women on placebo discontinuing treatment due to AEs in the respective trials.

"Findings from the pivotal Phase III trials show that flibanserin 100mg is effective and well-tolerated for the treatment of Hypoactive Sexual Desire Disorder in pre-menopausal women," said Elaine Jolly, Medical Director, Shirley E. Greenberg Women's Health Centre of the Ottawa Hospital and Professor of Obstetrics and Gynecology, University of Ottawa, and one of the Canadian physicians participating in the Phase III trials. "Flibanserin acts as an agonist at the serotonin 5-HT1A receptor and as an antagonist at the 5-HT2A receptor with preferential affinity to selective brain areas. It is believed to act on neurotransmitters within the brain that are thought to play a role in sexual response. By modulating these neurotransmitter systems, flibanserin may help to restore a balance between inhibitory and excitatory factors leading to a healthy sexual response."

Notes to Editors:

This release is from Boehringer Ingelheim Corporate Headquarters in Germany. Please be aware that there may be national differences between countries regarding specific medical information, including licensed uses. Please take account of this when referring to the information provided in this document. This press release is not intended for distribution within the U.S.A.

Please be advised that further background information on the subject of this press release can be accessed via the Boehringer Ingelheim Corporate website following this link:

http://www.boehringer-ingenelheim.com/corporate/news/press_releases/detail.asp?ID=7095

[1] Jolly E, Clayton AH, Thorp J, et al. Efficacy of flibanserin 100 mg qhs as a potential treatment for Hypoactive Sexual Desire Disorder in pre-menopausal women. Abstract accepted to the European Society of Sexual Medicine Congress, November 2009.

[2] Sexual and gender identity disorders. In: American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 4th ed. Washington, DC: American Psychiatric Association; 2000:493-538

[3] Dennerstein L, Koochaki P, Barton I, et al. Hypoactive Sexual Desire Disorder in menopausal women: a survey of Western European women. J Sex Med. 2006;3:212-222

[4] Dennerstein L, Hayes R, Sand M, et al. Attitudes toward and frequency of partner interactions among women reporting decreased sexual desire. J Sex Med. 2009;6:1668-1673

[5] Basson R. Women's sexual dysfunction revised and expanded definitions. CMAJ. 2005;172:1327-1333

[6] Jolly E, Clayton AH, Thorp J, et al. Efficacy of flibanserin 100mg qhs as a potential treatment for Hypoactive Sexual Desire Disorder in North American pre-menopausal women. Abstract accepted to the European Society of Sexual Medicine Congress, November 2009.

[7] Nappi R, Dean J, van Lunsen H, et al. Efficacy of flibanserin as a potential treatment for Hypoactive Sexual Desire Disorder in European pre-menopausal women: Results from the ORCHID trial. Abstract accepted to the European Society of Sexual Medicine Congress, November 2009.

[8] Jolly E, Clayton AH, Thorp J, et al. Safety and tolerability of flibanserin in pre-menopausal women with Hypoactive Sexual Desire Disorder. Abstract accepted to the European Society of Sexual Medicine Congress, November 2009.

Contact:

Contacts: Dr. Heike Specht, Corporate Division Communications, Boehringer Ingelheim GmbH, 55216 Ingelheim/Germany, Mobile: +49(151)15-02-29-30, Fax: +49(6132)77-6601, spechthe@boehringer-ingenelheim.com; Judith von Gordon, Corporate Division Communications, Boehringer Ingelheim GmbH, 55216

Ingelheim/Germany, Mobile: +49(178)2905056,
Judith.vonGordon@boehringer-ingelheim.com

Originaltext:

Boehringer Ingelheim GmbH

Pressemappe:

<http://www.presseportal.de/pm/6631/boehringer-ingelheim-gmbh>

Pressemappe als RSS:

http://presseportal.de/rss/pm_6631.rss2