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Shionogi 'painful intercourse' drug gets FDA nod

27 February 2013 | Regulatory | By BioSpectrum Bureau

Singapore: Shionogi, US, received US FDA approval for Osphena (ospemifene) tablets for the treatment of moderate to severe dyspareunia (painful intercourse), a symptom of vulvar and vaginal atrophy (VVA), due to menopause.

Osphena, as an estrogen agonist/antagonist with tissue selective effects, is the first and only oral treatment alternative to vaginal or oral steroidal estrogens for women with dyspareunia due to menopause. Its biological actions are mediated through binding to estrogen receptors, which results in activation of estrogenic pathways in some tissues (agonism) and blockade of estrogenic pathways in others (antagonism).

The efficacy and safety of Osphenawas demonstrated in three clinical trials. Osphena demonstrated significant improvements in dyspareunia (painful intercourse) as well as on the physical changes of the vagina associated with menopause. These improvements include increased superficial cells and decreased parabasal cells and vaginal pH.

"While more than half of all women in the US will experience symptoms of VVA at some time in their postmenopausal life, the vast majority of women with VVA are not being treated with a prescription medication because women and their healthcare professionals are not proactively discussing the condition, and its associated symptoms," said Mr David J Portman, B/GYN and director, Columbus Center for Women's Health Research, US.

"The FDA approval of Osphena represents an important advancement in the treatment of dyspareunia, providing an alternative treatment option for the millions of women living with this condition," said Dr John Keller, president and chief executive officer, Shionogi. "We look forward to building our product portfolio in women's health by advancing important therapies, such as Osphena."