

Duchesnay USA, Maker of Osphena[®], Applauds Expanded Coverage for Treatments for Dyspareunia due to Menopause under Medicare Part D

Rosemont, PA, October 29, 2018 – Duchesnay USA commends the clarification by the Centers for Medicare and Medicaid Services (CMS) of the statutory intent of "Prescription Drug Benefits" Section 1860D-2(e)(2)(A) of the Social Security Act. In its statement, the CMS confirmed that drugs indicated for the treatment of moderate to severe dyspareunia (painful intercourse) due to menopause are not excluded from Medicare Part D coverage when prescribed in a manner consistent with this labeling.

Dyspareunia is a common postmenopausal condition, with as many as one in three postmenopausal women experiencing pain during intercourse. It is a chronic and progressive medical condition brought about by the decrease in estrogen levels in menopause causing changes in the vaginal tissues. These changes can lead to a medical condition called vulvar and vaginal atrophy (VVA), a component of genitourinary syndrome of menopause (GSM), which can lead to painful sex. Left untreated, dyspareunia due to menopause may worsen.

"This is an important step towards helping postmenopausal women access newer FDA-approved therapies that are both safe and effective," said Graziella Soulban, Senior Director, Medical Affairs at Duchesnay. "We are working with plan sponsors to increase access to additional treatments for women suffering from moderate to severe dyspareunia due to menopause."

"Against the background of significantly better aging men's sexual health coverage, compared to women's, CMS has taken the scientific high road and mandated vastly improved Medicare coverage for aging women's sexual health, beginning in 2019. Hurray!" affirmed Dr. James A. Simon, Clinical Professor of Obstetrics and Gynecology at the George Washington University.

Following this clarification, women suffering from moderate to severe dyspareunia due to menopause will have access to expanded treatment options covered under Medicare Part D. This coverage should include Osphena[®] (ospemifene), an FDA-approved, non-estrogen oral tablet indicated for the treatment of moderate to severe dyspareunia due to menopause.

About Osphena[®] (ospemifene)

Osphena[®] is the only FDA-approved oral pill for the treatment of moderate to severe dyspareunia (painful sex), a symptom of vulvar and vaginal atrophy (VVA), due to menopause. It is not an estrogen, but helps improve specific vaginal tissues* and relieve moderate to severe painful sex due to menopause. In clinical studies, most women reported relief of moderate to severe painful sex due to menopause in as little as 12 weeks after beginning treatment with Osphena[®]. An additional indication for Osphena[®], the treatment of vaginal dryness, is currently under review by the FDA.

For more information, including full **Prescribing Information** and **Boxed Warning**, visit osphena.com.

**Increases superficial cells, decreases parabasal cells and reduces vaginal pH.*

Important Safety Information

WARNING: ENDOMETRIAL CANCER AND CARDIOVASCULAR DISORDERS

Osphena[®] works like estrogen in the lining of the uterus, but can work differently in other parts of the body. Taking estrogen alone or Osphena[®] may increase your chance for getting cancer of the lining of the uterus.

Vaginal bleeding after menopause may be a warning sign of cancer of the lining of the uterus. Your healthcare provider should check any unusual vaginal bleeding to find out the cause, so tell him or her right away if this happens while you are using Osphe[®].

Osphe[®] may increase your chances of having a stroke or blood clots.

You and your healthcare provider should talk regularly about whether you still need treatment with Osphe[®].

Call your healthcare provider right away if you have changes in vision or speech, sudden new severe headaches, and severe pains in your chest or legs with or without shortness of breath, weakness and fatigue. Osphe[®] should not be used if you have unusual vaginal bleeding, have or have had certain types of cancers (including cancer of the breast or uterus), have or have had blood clots, have had a stroke or heart attack, have severe liver problems, are allergic to Osphe[®] or any of its ingredients, or think you may be pregnant. Tell your healthcare provider if you are going to have surgery or will be on bed rest.

Possible side effects of Osphe[®]

Serious but less common side effects can include stroke, blood clots and cancer of the lining of the uterus.

Common side effects may include hot flashes, vaginal discharge, muscle spasms and increased sweating.

Tell your healthcare provider about all of the medicines and supplements you take, as some medicines may affect how Osphe[®] works. Osphe[®] may also affect how other medicines work.

Duchesnay USA encourages you to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

About Duchesnay

Duchesnay is a specialty pharmaceutical company with a long-standing commitment to women's health. The company focuses on filling the void in terms of scientific research and education and on developing pharmacological solutions that are safe and effective for use during pregnancy and breastfeeding. Duchesnay also commercializes a broad portfolio of products to offer safe and effective therapeutic options that meet the health and quality of life needs of women and their family members at various stages of their lives. For more information, visit DuchesnayUSA.com.

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