

For Immediate Release

Duchesnay Inc. Announces Submission of Supplemental New Drug Application (sNDA) for Osphena® (ospemifene) to U.S. FDA Seeking Approval for the Treatment of Vaginal Dryness, a Symptom of Vulvar and Vaginal Atrophy (VVA) Due to Menopause

BLAINVILLE, QC, October 23, 2018 – Duchesnay Inc., a pharmaceutical company specializing in women’s health, announced today that it has submitted a supplemental New Drug Application to the U.S. Food and Drug Administration (FDA) seeking a new indication for Osphena® (ospemifene).

Osphena® received FDA approval for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy (VVA) due to menopause, in February 2013. The company is currently seeking FDA approval to add the indication of moderate to severe vaginal dryness, also a common symptom of vulvar and vaginal atrophy due to menopause.

According to Dr. David Archer, Professor of Obstetrics and Gynecology at Eastern Virginia Medical School, “The changes in the vulva and vagina of postmenopausal women are progressive, reflecting the reduction in ovarian estrogen. The symptoms of dryness, itching and burning reflect the changes in the lining of the vagina and its opening. Globally, 40 to 60% of women surveyed report these symptoms. Over 50% of these women consider their symptoms moderate to severe, with vaginal dryness being the most frequently reported symptom. Osphena® rapidly and successfully reduced this symptom and restored normal changes in the lining of the vagina. Over 49% of women using Osphena® were satisfied with the results. Approval of Osphena® to treat vaginal dryness will improve the quality of life of the older women who are experiencing these symptoms.”

This application is based on new safety and efficacy data acquired through a confirmatory phase 3 randomized, double blind, placebo-controlled multicenter study evaluating the efficacy and safety of ospemifene in patients with moderate to severe vaginal dryness.

“Duchesnay is committed to offering post-menopausal women a new option for the treatment of vaginal dryness, a frequent and most bothersome symptom of VVA, which is a component of the genitourinary syndrome of menopause,” affirmed Michael Gallo, Vice President of Regulatory and Medical Affairs at Duchesnay.

Duchesnay has amassed a significant amount of data regarding ospemifene, including 10 phase 2 and 3 studies. This data has been submitted with the application and is currently under evaluation by the United States Food and Drug Administration. The action date by which FDA must complete its review of the application, as required by the Prescription Drug User Fee Act, is January 26, 2019.

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

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 relieves moderate to severe painful sex due to menopause. A potential additional indication for Osphena®, the treatment of vaginal dryness, is currently under review by the FDA.

**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 OPSHENA[®].

Contraindications

OSPHENA is contraindicated in women with any of the following conditions:

- Undiagnosed abnormal genital bleeding
- Known or suspected estrogen-dependent neoplasia
- Active DVT, pulmonary embolism (PE), or a history of these conditions
- Active arterial thromboembolic disease [for example, stroke and myocardial infarctions (MI)], or a history of these conditions
- Hypersensitivity (for example, angioedema, urticaria, rash, pruritus) to OSPHENA or any ingredients
- Known or suspected pregnancy

Warnings and Precautions

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.

Adverse Reactions

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.

For more information, including full **Prescribing Information** and **Boxed Warning**, visit [osphe[®].com](http://osphe[®].com).

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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