

For Immediate Release

Duchesnay Inc. Receives Approval of Supplemental New Drug Application (sNDA) to Add Moderate to Severe Vaginal Dryness, a Symptom of Vulvar and Vaginal Atrophy (VVA) Due to Menopause, to the Indication of Osphe[®] (ospemifene)

BLAINVILLE, QC, January 29, 2019 – Duchesnay Inc., a pharmaceutical company specializing in women’s health, announced today that the FDA has approved its supplemental New Drug Application (sNDA) seeking to add moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA), due to menopause, to the indication of Osphe[®] (ospemifene).

The sNDA was 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. Osphe[®] is non-hormonal and helps improve specific vaginal tissues by increasing superficial cells, decreasing parabasal cells and reducing vaginal pH.

Prior to this approval, Osphe[®] was indicated only for the treatment of moderate to severe dyspareunia (painful intercourse), also a symptom of VVA, due to menopause.

“Many menopausal women are not aware that vaginal dryness is one of the two most common and most bothersome symptoms (MBS) of vulvovaginal atrophy due to menopause. FDA’s approval of this additional indication affirms Osphe[®]’s safety and effectiveness for treating moderate to severe vaginal dryness, broadening its benefits to a larger number of menopausal women,” affirmed Dr. James A. Simon, Clinical Professor of Obstetrics and Gynecology at George Washington University.

Before menopause, estrogen helps maintain the thickness, elasticity and lubrication of vaginal tissues. However, as women age, estrogen levels drop, causing changes in these tissues, which can lead to dryness, itching, burning and painful intercourse.

“With the addition of moderate to severe vaginal dryness to Osphe[®]’s indication, Duchesnay USA can now help postmenopausal women suffering from this symptom of VVA”, explained Dean Hopkins, General Manager of Duchesnay USA. “With this new indication, Osphe[®] now provides an oral option for women who prefer a non-hormonal treatment alternative.”

Please see below for Important Safety Information, including **Boxed Warning** regarding **endometrial cancer and cardiovascular disorders**, and full **Prescribing Information** at osphe.com.

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IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING AND INDICATION

Indication: What is Osphe[®]?

Osphe[®] is a prescription oral pill that treats: ● moderate to severe painful intercourse, ● moderate to severe vaginal dryness, symptoms of changes in and around your vagina, due to menopause.

Most Important Information you should know about Osphe[®]

Osphe[®] works like estrogen in the lining of the uterus (endometrium), but can work differently in other parts of the body. Taking estrogen alone or Osphe[®] 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 unusual vaginal bleeding, changes in vision or speech, sudden new severe headaches, and pains in your chest or legs with or without shortness of breath, weakness and fatigue.

Who should not take OSPHENA?

Osphena® 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, had a stroke or heart attack, have severe liver problems, are allergic to Osphena® 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

Serious but less common side effects can include:

- stroke
- blood clots
- cancer of the lining of the uterus

Less serious, but common side effects include:

- hot flushes or flashes
- headache
- heavy vaginal bleeding (vaginal hemorrhage)
- vaginal discharge
- excessive sweating (hyperhidrosis)
- night sweats
- muscle spasms

Tell your healthcare provider about all of the medicines and supplements you take, as some medicines may affect how Osphena® works. Osphena® 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.

Please read accompanying [Patient Information for Osphena® \(ospemifene\) tablets](#), including **Boxed Warning** in the [U.S. Full Prescribing Information](#).

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.

Contact:

Amy Feldman
Senior Director
Lazar Partners
212-867-1779
afeldman@lazarpartners.com