



**Press release
For immediate release**

Duchesnay Inc. is seeking Health Canada's approval for ospemifene for the treatment of moderate to severe dyspareunia and vaginal dryness, symptoms of vulvar and vaginal atrophy (VVA), a component of genitourinary syndrome of menopause (GSM).

BLAINVILLE, Quebec, June 10, 2019 - Duchesnay Inc. has filed a New Drug Submission (NDS) with Health Canada for a once-daily oral ospemifene tablet, a non-hormonal SERM (selective estrogen receptor modulator) for the treatment of moderate to severe dyspareunia and vaginal dryness, symptoms of vulvar and vaginal atrophy (VVA) due to menopause, a component of genitourinary syndrome of menopause (GSM).

Dyspareunia and vaginal dryness are among the most common bothersome symptoms of VVA due to menopause. Before menopause, estrogen helps maintain the thickness, elasticity and lubrication of vaginal tissues. However, as women age, estrogen levels decrease, leading to significant structural changes in these tissues, resulting in dryness, itching and burning that cause painful sexual intercourse.

"In keeping with Duchesnay's commitment to women's health, we are pleased to be working with Health Canada on this new drug submission to ensure that Osphena® (ospemifene) will be available in Canada," said Michael Gallo, Vice-President of Regulatory and Medical Affairs at Duchesnay Inc.

Duchesnay acquired the exclusive marketing and distribution rights for Osphena® in the United States and Canada from Shionogi Inc., a leading Japanese pharmaceutical company, in 2017, and has since marketed Osphena® in the United States. In keeping with its commitment to women's health at all stages of their lives, Duchesnay looks forward to launching Osphena® in the Canadian market for the well-being of postmenopausal women.

The product's safety and efficacy are still under investigation and marketing authorization has not yet been granted.

References

1. J. Calleja-Agius & M. P. Brincat (2015) The urogenital system and the menopause, *Climacteric*, 18:sup1, 18-22.
2. A Kao, YM Binik, A Kapuscinski, S Khalifé. Dyspareunia in postmenopausal women: A critical review. *Pain Res Manage* 2008;13(3):243-254.
3. Archer DF, Carr BR, Pinkerton JV, Taylor HS, Constantine GD. Effects of ospemifene on the female reproductive and urinary tracts: translation from preclinical models into clinical evidence. *Menopause*. 2015;22(7):786-96.

4. Kingsberg S, Kellogg S, Krychman M. Treating dyspareunia caused by vaginal atrophy: a review of treatment options using vaginal estrogen therapy. *Int J Womens Health*. 2010;1:105-11. Published 2010 Aug 9.
5. Parish SJ, Nappi RE, Krychman ML, et al. Impact of vulvovaginal health on postmenopausal women: a review of surveys on symptoms of vulvovaginal atrophy. *Int J Womens Health*. 2013;5:437-47. Published 2013 Jul 29. doi:10.2147/IJWH.S44579.
6. Gandhi J, Chen A, Dagur G, Suh Y, Smith N, Cali B, Khan SA. Genitourinary syndrome of menopause: an overview of clinical manifestations, pathophysiology, etiology, Evaluation, and management. *Am J Obstet Gynecol*. 2016 Dec;215(6):704-711

-30-

About Duchesnay

Duchesnay is a specialty pharmaceutical company with a long-standing commitment to women's health. Until recently, the company focused 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.

Today, Duchesnay has broadened its 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 different stages of their lives.

For more information about Duchesnay, please visit duchesnay.com

Media inquiries:

Miriam Lauzon, ARP
Vice President, Capital-Image
T 514.739.1188 x224
mlauzon@capital-image.com