



The European Medicines Agency accepts marketing authorisation application for Intrarosa™ for the treatment of vulvar and vaginal atrophy in postmenopausal women

Quebec City, Nov. 9th, 2017 – Endoceutics Inc., a private Quebec City based biopharma company, today announced that the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Intrarosa™, intended for the treatment of vulvar and vaginal atrophy in postmenopausal women.

Intrarosa™ will be available as a 6.5 mg pessary. The active substance of Intrarosa™ is prasterone, also known as dehydroepiandrosterone (DHEA), a precursor steroid which is converted into oestrogens and androgens. The medicine increases the number of superficial and intermediate cells and decreases the number of parabasal cells in the vaginal mucosa via an oestrogen-mediated mechanism. In addition, it decreases the vaginal pH towards the normal range, thus facilitating the growth of the normal bacterial flora.

The benefit with Intrarosa™ is its ability to improve dyspareunia. The most common side effect is vaginal discharge.

The full indication is: "Intrarosa™ is indicated for the treatment of vulvar and vaginal atrophy in postmenopausal women having moderate to severe symptoms".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.



About Endoceutics

Endoceutics is a private pharmaceutical company operating in the field of women's health and hormone-sensitive cancer prevention and treatment. Following approval by the US FDA of Intrarosa™ in November 2016, for the treatment of dyspareunia, a symptom of vulvovaginal atrophy due to menopause, Endoceutics focuses on developing non estrogen-based therapies for sexual dysfunction and the other symptoms of menopause, , including hot flashes, osteoporosis, muscle loss and type 2 diabetes. Hormonal therapies for breast, uterine and prostate cancer, male hypogonadism as well as endometriosis are also under development. Endoceutics has five Phase III product candidates addressing large market opportunities and two Phase I/II product candidates. Endoceutics has exclusive worldwide rights to patents, patent applications, technology and know-how related to all its products.

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