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MEDIA RELEASE

Theramex to Exclusively License Intrarosa® In Europe, Australia, Russia and The Ukraine from Endoceutics

- *Intrarosa® is an innovative treatment for vulvovaginal atrophy in post-menopausal women*
- *Strengthens Theramex's position as a leader in Women's Health*

London, UK and Quebec City, Canada, July 19th, 2018; Today, Theramex and Endoceutics announced they have entered into a definitive agreement granting Theramex the license to commercialise Intrarosa® (Prasterone) across countries in Europe, Australia, Russia as well as select countries within the Commonwealth of Independent States (CIS). Intrarosa is a unique non-estrogen prescription therapy approved for the treatment of vulvar and vaginal atrophy (VVA) in postmenopausal women experiencing moderate to severe symptoms.¹ VVA can lead to dryness, irritation and dyspareunia (or pain during sexual activity).

Anish Mehta, Chief Executive Officer at Theramex said "*Intrarosa is a novel medicine that offers an effective treatment for a very common condition in postmenopausal women. We are pleased to be able to continue the ground-breaking work of Dr Fernand Labrie, the founder and Chief Executive Officer of Endoceutics. With our strong heritage and commitment to Women's Health, we are looking forward to making Intrarosa available to women to better address this condition.*"

"*Intrarosa is an excellent addition to our portfolio of products that help women manage the symptoms of menopause. This deal is an example of our commitment to become the leading healthcare company dedicated to Women's Health*", added Anish Mehta.

Dr Fernand Labrie, founder and Chief Executive Officer of Endoceutics said "*As a non-estrogen treatment, Intrarosa is a novel vaginal prescription therapy that locally replaces inside the cells what is missing for patients with vulvovaginal atrophy. Intrarosa improves the body's natural ability to produce hormones locally and intracellularly, thus correcting the symptoms, such as pain during sexual activity, without influencing other tissues. Since Intrarosa is not an estrogen-based product, patients should feel more comfortable seeking a treatment in line with physiology and all circulating steroids remaining within normal values.*"

Dr Labrie also added *"I'm pleased to be working closely with Theramex, a company that shares our vision of helping women live better, symptom-free lives. I believe their expertise and knowledge of the Women's Health community will make Intrarosa accessible to women across countries including those in Europe, Russia and Australia who presently struggle to find effective solutions for these very intimate, and yet very common, symptoms of menopause."*

VVA is a common condition affecting up to 50% of postmenopausal women^{2,3}. In women with VVA, the wall of the vagina and surrounding tissues become thinner and cause symptoms such as dryness, irritation and soreness around the genital area and pain at sexual activity (also called dyspareunia). In clinical trials, Intrarosa was shown to improve the structure of the vaginal tissues and reduce pain during sexual intercourse. In the clinical trials, Intrarosa was well tolerated.^{1,4,5}

While the deal terms have not been disclosed, countries within the license agreement are: Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Poland, Romania, Serbia, Slovakia, Slovenia, United Kingdom, the Russian Federation, Kazakhstan, and the Ukraine. Intrarosa was first approved by the US Food and Drug Administration in November 2016 for the treatment of moderate to severe dyspareunia, a symptom of VVA due to menopause⁵ and by the European Medicines Agency in January 2018 for the treatment of VVA.

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Media Contacts

Janet Kettels (for Theramex) Mobile: (+44) 7738 506 476; janet@kettelscommunications.com

Audrey Dumoulin (for Endoceutics); Tel.: (+1) 418 653 0033 x213;
audreydumoulin@endoceutics.com

Laura Glover (for any media queries): Tel.: (+44) 203 196 8540; laura.glover@havasso.com

About Theramex

Theramex is a leading, global specialty pharmaceutical company dedicated to women and their health. With a broad portfolio of innovative and established brands covering contraception, fertility, menopause and osteoporosis, we support women at every stage of their lives. Our commitment is to listen to and understand our patients, serve their needs, and offer healthcare solutions to help improve their lives. Our vision is to be a lifetime partner for women and the healthcare professionals who treat them by providing innovative, effective and safe solutions that care for and support women as they advance through each stage of their lives. For more information, visit www.theramex.com.

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 or genitourinary syndrome of menopause, Endoceutics has focused its efforts 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. Visit www.endoceutics.com.

References

1. INTRAROSA® Summary of Product Characteristics (SMPC):
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004138/WC500243734.pdf [accessed 5 June 2018]
2. INTRAROSA® European Medicines Agency EPAR:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/004138/WC500243737.pdf [accessed 5 June 2018]
3. 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. Women's Health*, 5, 437-447, 2013.
4. INTRAROSA® European Medicines Agency EPAR Summary:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/004138/WC500243732.pdf [accessed 5 June 2018]
5. INTRAROSA® Product Information:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208470s000lbl.pdf [accessed 5 June 2018]