

Theramex Australia Enters Partnership With Endoceutics For Intrarosa® For The Treatment Of Postmenopausal Vulvovaginal Atrophy

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SYDNEY --Theramex, a leading global speciality pharmaceutical company dedicated to women's health, has expanded its original agreement with Endoceutics to commercialise Intrarosa® (prasterone) in Australia. Intrarosa is the first and only locally acting DHEA (dehydroepiandrosterone) treatment indicated for postmenopausal women experiencing moderate to severe symptoms associated with vulvovaginal atrophy (VVA).¹

Intrarosa is formulated as a 6.5 mg prasterone pessary administered once daily, at bedtime.¹ Intrarosa versus placebo has demonstrated significant improvement in VVA symptoms, including moderate to severe dyspareunia or pain at sexual activity, the most frequent symptom of VVA due to menopause (pain at sexual activity decreased by 1.42 severity score unit from baseline or 0.36 unit over placebo [P=0.0002]). There was also a significant improvement in moderate to severe vaginal dryness (vaginal dryness present in 84.0% of women improved at 12 weeks by 1.44 severity score unit compared to baseline, or 0.27 unit over placebo [P=0.004]).^{2,3} In a separate Phase III, open-label, single-arm study, after 52 weeks of Intrarosa, women who self-reported moderate to severe dyspareunia as their most bothersome symptom at baseline had a 66.1% decrease in dyspareunia severity (P=<0.001).⁴

Robert Stewart, CEO of Theramex, said: *"The kind of symptoms women experience with vulvovaginal atrophy are not trivial and will often worsen over time if left untreated. This is why this agreement is so important to us, to help women in this stage of their lives. Until now we have been helping women in Europe with VVA, and now we are delighted to be able to do the same in Australia."*

Jake Breen, General Manager Australia, added: *"With this move we continue to show our commitment to offering women different solutions to treat the symptoms of menopause. Intrarosa provides an important new treatment option to relieve VVA symptoms and maintain vaginal health without significant release of oestrogens in the blood"*.

VVA, also known as genitourinary syndrome of the menopause, triggers painful physical changes to the vagina which can steadily worsen if left untreated.⁵ VVA has a significant negative impact on women's lives ranging from sexual satisfaction (72%) and intimacy (66%), to enjoyment of life (40%) and sleep (34%).⁵ Despite an estimated 1 in 2 women experiencing VVA after menopause, 75% do not seek treatment, most commonly because of low awareness and embarrassment to discuss symptoms.⁵⁻⁸

Intrarosa received FDA approval for the treatment of moderate to severe dyspareunia in November 2016 and by the EMA for the treatment of VVA in January 2018. Since July 2019, it has been commercialised by Theramex in Europe, after the agreement with Endoceutics.

About Theramex

Theramex is a leading global speciality pharmaceutical company dedicated to women and their health. We support women at every stage of their lives by providing a broad portfolio of innovative and established brands covering contraception, fertility, menopause and osteoporosis. 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 patient-focused and effective solutions that care for and support women through every stage of life. Visit <http://www.theramex.com.au>

About Endoceutics

Endoceutics, Inc. is focused on women's health. Endoceutics also manufactures its innovative INTRAROSA as well as other drugs on behalf of its partners and customers. Endoceutics has the expertise for clinical development, registration and commercialization of its products and it has a portfolio of drugs at various stages of development. Endoceutics' mission is to provide women the quality of life they deserve.

For more information, please visit www.endoceutics.com

¹ Intrarosa, Summary of Product Characteristics.

² Labrie F et al. *Menopause* 2016;23(3):243–56.

³ Archer DF et al. *Menopause* 2015;22(9):950–63.

⁴ Labrie F et al. *Maturitas* 2015;81:46-56.

⁵ Nappi RE et al. *Climacteric* 2016;19(2):188–97.

⁶ Palacios S. *Maturitas* 2009;63(4):315–8.

⁷ Nappi RE, Kokot-Kierepa M *Climacteric* 2012 Feb; 15(1):36–44.

⁸ Naumova I, Castelo-Branco C *Int J Womens Health* 2018; 10: 387–395.

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