Lupin Pharma Canada Announces Partnership with Endoceutics for the Commercialization of INTRAROSA®

Brings to the Canadian market the first prescription drug for the local treatment of postmenopausal vulvovaginal atrophy that does not carry any serious warnings and precautions, a long-awaited innovation in women's health.

Quebec, Canada, March 08, 2021: Lupin Pharma, a subsidiary of global pharma major Lupin Ltd, today announced a partnership with Endoceutics, a women's health focused innovative Canadian biotech company, to commercialize INTRAROSA® in Canada. INTRAROSA® is Endoceutics' flagship product indicated for the treatment of postmenopausal vulvovaginal atrophy offered as a vaginal ovule containing 6.5 mg of Prasterone.

The lack of sex hormones associated with menopause may cause the tissues of the vulva and vagina to become thin and dry. Prasterone is used to develop sex hormones in the vagina by replacing the natural sex hormones that are lacking in some women. It may improve the symptoms of vulvovaginal atrophy such as vaginal dryness, pain during sexual activity (dyspareunia), irritation and itching.

Commenting on the partnership, **Dr. Sofia Mumtaz, President, Lupin Pharma Canada** said, "We are very pleased to partner with Endoceutics to bring this long-awaited innovative product to the Canadian market. INTRAROSA® will not only expand and strengthen our product portfolio into Women's Health in Canada but will cater to satisfy the unmet medical needs."

"We are very excited to be working closely with Lupin Pharma. We believe it is the partner of choice to make INTRAROSA® available to Canadian women in need of innovative treatment," commented **Dennis Turpin, President and Chief Executive Officer, Endoceutics.**

It is estimated that over 50% of postmenopausal women suffer from the symptoms of vulvovaginal atrophy and that less than 10% of these women are treated with prescription medicines.

About INTRAROSA®

INTRAROSA® was developed in Quebec City, Canada by Endoceutics. INTRAROSA® will be manufactured by Endoceutics in Mont-Saint-Hilaire, Canada.

INTRAROSA® is indicated for postmenopausal vulvovaginal atrophy, it is a vaginal ovule containing 6.5 mg of Prasterone. It comes in blister packs of 28 ovules, with 6 reusable applicators. The recommended dose is one vaginal ovule inserted once a day at bedtime, using the provided applicator or fingers.[1]

Prasterone is a natural steroid compound, inactive by itself, with no estrogenic, androgenic, or other hormonal activity. Following intravaginal administration, it is transformed inside the vaginal cells into estrogens and androgens, and the sex steroids made intracellularly are also inactivated locally inside the same cells, thus avoiding exposure to other tissues. This mechanism is

comparable to the physiological functioning observed in normal postmenopausal women, where the peripheral tissues make and inactivate their own intracellular sex steroids exclusively from circulating endogenous Prasterone, explaining why serum estrogens and androgens remain at low concentrations following menopause and during intravaginal administration of INTRAROSA®.[1]

The effectiveness of INTRAROSA® on moderate to severe dyspareunia and vaginal dryness, two symptoms of vulvovaginal atrophy due to menopause, was confirmed in two pivotal 12-week placebo-controlled efficacy trials.[1]

Statistically significant beneficial effects (p=0.017 to < 0.0001) were observed at 2 weeks on pH as well as on parabasal and superficial cells, with 52% to 81% of the 12-week effects observed by 2 weeks. For the effect on pain with sexual activity and vaginal dryness, the severity score decreased by 40% and 65% at 2 weeks compared to 12 weeks, an effect which became statistically significant at 8 weeks (p=0.004 and 0.004, respectively).[1]

INTRAROSA® is approved for commercialisation in the US, Europe, UK, Canada, Hong-Kong, Israel, United Arab Emirates, Switzerland, Lebanon, and Macau.

Contraindications[1]

- INTRAROSA® is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation.
- INTRAROSA® is contraindicated in women with undiagnosed abnormal genital bleeding.

About Lupin Limited

Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products and APIs in over 100 markets in the U.S., India, South Africa and across Asia Pacific (APAC), Latin America (LATAM), Europe and Middle East regions.

The Company enjoys leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has significant presence in the anti-infective, gastro-intestinal (GI), central nervous system (CNS) and women's health areas. Lupin is the third largest pharmaceutical company in the U.S. by prescriptions. For the nine months ended December 31, 2020, the Company invested 9.8% of its revenues on research and development.

Lupin has 15 manufacturing sites, 7 research centers, more than 20,000 professionals working globally, and has been consistently recognized as a 'Great Place to Work' in the Biotechnology & Pharmaceuticals sector.

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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

For further information or queries please contact –

LUPIN	**ENDOCEUTICS**
Shweta Munjal Head – Corporate Communications Email: shwetamunjal@lupin.com Arvind Bothra Head – Investor Relations/Corporate M&A Email: arvindbothra@lupin.com Manjira Sharma General Manager – Corporate Communications Email: manjirasharma@lupin.com	info@endoceutics.com (418) 653-0033

References

1. INTRAROSA® Product Monograph. Endoceutics, Inc. October 2019