

Inside Information/Regulated Information

Mithra and Searchlight Pharma Announce Estelle® Approval in Canada

First E4-based product approved internationally

- Canadian regulatory approval is the first in the world for the novel combined oral contraceptive Estelle®
- Innovative product developed by Mithra containing the unique native estrogen Estetrol (E4) and drospirenone (DRSP)
- Approval supported by two large multinational Phase 3 studies conducted in 3,725 women
- Commercial launch in Canada anticipated mid-summer 2021

LIEGE (Belgium – 7:30AM CET) and MONTREAL (Canada – 7:00AM EST), March 8, 2021

– Mithra and Searchlight Pharma announce today that Health Canada has approved Estelle® under the trademark Nextstellis®, the first and only combined oral contraceptive (COC) product based on the unique native estrogen Estetrol (E4). Once launched, E4 will be the first new estrogen in a COC in the Canadian market in over half a century, and will be the only COC alternative to ethinyl estradiol-based COC pills in Canada.

“Combined oral contraceptives continue to be the most common method of hormonal birth control in Canada and worldwide,” said Dr. Dustin Costescu, MD, MS, FRCSC, Associate Professor and Family Planning Specialist, Department of Obstetrics and Gynaecology at McMaster University. “That is why it’s so important to continuously innovate and develop products that meet the current needs of patients and their families. From the time The Pill was invented, there was recognition that convenience and contraception comes with a small risk from venous thromboembolism [blood clots]. Science has been able to reduce the dose, but we can only go so low. It’s time to change the hormone.”

Developed by Mithra, Estelle® is composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP) in a 24/4 dosing regimen. E4 is a naturally occurring native estrogen produced in the human body, with a unique mechanism of action that displays tissue selective activity. E4 shows agonist activity on the vagina, the uterus and the endometrium, the bones and the brain, and antagonistic activities in breast tissue. Neutral impact on lipids and a distinct metabolic and hemostatic profile provide further differentiation based on its unique mechanism of action. E4 is synthesized from plant-based sources and represents the first native estrogen available in any contraceptive product in Canada.

Clinical safety data

Health Canada's approval of Estelle® is based on two multinational, multicentre Phase 3 clinical studies of 3,725 women who were 16 to 50 years of age, and who had a Body Mass Index (BMI) up to 35kg/m². Estelle® demonstrated contraceptive efficacy across all evaluated age and BMI ranges. The studies also demonstrated good bleeding profiles, cycle control, and tolerability, and with low rates of adverse reactions.

“Although contraceptive choice is improving for women in Canada, we still have more limited contraceptive choices compared to other developed countries,” said Dr. Amanda Black, MD, MPH, FRCSC, Professor of Obstetrics and Gynecology at The University of Ottawa. “For this reason, the approval of an additional novel contraceptive option in Canada is incredibly welcome. Beyond just having an additional choice that further empowers women, there is a lot of enthusiasm to introduce potentially safer contraceptives to the market, and Nextstellis® is one such product. An abundance of clinical safety data should be reassuring to physicians and patients alike.”

First approval in the world

The approval in Canada is the first marketing authorization for Estelle® in any jurisdiction, anywhere in the world. Regulatory reviews remain ongoing in the United States and European Union, with expected marketing authorizations in H1 2021.

“Our teams are both proud and excited to see the outcome of so many years of research finally made available to women”, said Leon Van Rompay, CEO of Mithra. “This approval is the first and is highly symbolic since it is being announced on International Women’s Day. We congratulate Searchlight Pharma on becoming the first partner worldwide to achieve regulatory approval and are supporting them fully to ensure a Canadian market launch in the summer of 2021. As one of the most important global markets, the Canadian approval unlocks the opportunity to introduce a product we believe represents a new era in Women’s Health and contraception in particular. We look forward to obtaining the next approvals in Europe and the United States expected in the first half of 2021.”

“We are excited that Canada is the first market globally to approve Nextstellis®, and that Searchlight Pharma can now move forward with its commercial launch and making this new contraceptive option available to Canadian women,” said Mark Nawacki, President & CEO of Searchlight Pharma. “The introduction of Nextstellis® represents a major advancement in the contraceptive options available, and we are proud to have played a part in helping to support healthcare providers and women in their contraceptive choices.”

Currently, the Canadian hormonal contraceptive market is worth approximately EUR 228 million a year, with combined oral contraceptives accounting for about 66% of the market¹. Nextstellis® will complement and deepen Searchlight Pharma’s industry-leading women’s health product portfolio which includes Addyi® (flibanserin), a first-in-class medication in Canada for the treatment of Hypoactive Sexual Desire Disorder (HSDD) in both pre and post-menopausal women up to age 60, as well as market-leading brands such as Mona Lisa® IUDs for contraception, and menopausal treatments such as Divigel® and Estragyn™ Vaginal Cream.

¹ IQVIA 2020

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About Estelle®

Estelle® is Mithra's novel combined oral contraceptive (COC) product based on Estetrol (E4)15 mg and drospirenone (DRSP) 3 mg. E4 is a native estrogen that is produced by the human fetus, passing the maternal blood at relatively high levels during pregnancy. The E4 used in Estelle® is derived from plant sources. In two phase III clinical studies conducted in nearly 3,800 women, Estelle® showed positive top-line results against primary efficacy and safety endpoints and achieved positive secondary endpoints including good bleeding profile, cycle control, and tolerability. Mithra has signed 15 licensing deals for Estelle® with a number of leading women's health companies covering Canada, United States, Europe, Japan, South Korea, ASEAN, Russia, Brazil, Middle East, North Africa, Southern Africa, Hong Kong, Taiwan and Australia.

About Mithra

Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women's Health by offering new choices through innovation, with a particular focus on contraception and menopause. Mithra's goal is to develop products offering better efficacy, safety and convenience, meeting women's needs throughout their life span. Its three lead development candidates are built on Mithra's unique native estrogen platform, Estetrol (E4): Estelle®, a new era in oral contraception, PeriNesta®, the first complete oral treatment for perimenopause and Donesta®, the next-generation hormone therapy. Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO. Active in more than 100 countries around the world, Mithra has an approximate headcount of 300 staff members and is headquartered in Liège, Belgium. www.mithra.com

About Searchlight Pharma Inc.

Searchlight Pharma Inc., headquartered in Montreal, aspires to become a leading Canadian-based specialty healthcare company through best-in class execution of the search, acquisition, commercialization, and focused development of innovative and unique specialty healthcare products that improve life-long human health and wellness. With a core focus on women's health, urogynecology, and urology, our team is committed to improving people's lives by bringing the right products to market. Follow us, learn more about what we do, and get to know our product portfolio at www.searchlightpharma.com.

Important information

The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may",

"will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should", and include statements the Company makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. The Company's actual results may differ materially from those predicted by the forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.