

Sumitomo Pharma Announces Availability of ORGOVYX® (relugolix) in Canada, the First and Only Oral Androgen Deprivation Therapy Treatment for Men with Advanced Prostate Cancer

MISSISSAUGA, ON, March 12, 2024 [/PRNewswire/](#) -- Sumitomo Pharma Canada, Inc., announced today that ORGOVYX® (relugolix), an oral gonadotropin-releasing hormone (GnRH) receptor antagonist, is now available for prescription in Canada for the treatment of adult patients with advanced prostate cancer. The availability of ORGOVYX follows the Health Canada approval of ORGOVYX in October 2023 for the treatment of advanced prostate cancer.

"Lowering the body's testosterone level is a first-line treatment approach for men with advanced prostate cancer," said Fred Saad, M.D., FRCS, Professor and Chairman of the Department of Surgery and Director of Genitourinary Oncology at the University of Montreal. "Now, physicians in Canada have a once-daily oral GnRH antagonist treatment option in their armamentarium that helps men with advanced prostate cancer by lowering testosterone levels without leading to testosterone flares."

The Health Canada approval of ORGOVYX was based on efficacy and safety data from the Phase 3 HERO study in men with advanced prostate cancer. In the Phase 3 HERO study, 97% of men who received ORGOVYX lowered their testosterone (< 50 ng/dL) by Day 29 through Week 48, compared to 89% of those who received leuprolide acetate injections. The most frequent adverse events reported in at least 10% of men in the ORGOVYX group were hot flush, musculoskeletal pain, fatigue, constipation, and diarrhea.

"An estimated 24,700 Canadian men were diagnosed with prostate cancer last year, making the disease the most common cancer experienced by men in the country," said Lisa Mullett, SVP, General Manager of Sumitomo Pharma Canada, Inc. "With the availability of ORGOVYX as of today, we are pleased to offer Canadian physicians an oral GnRH antagonist treatment option with proven safety and tolerability for their patients with advanced prostate cancer."

About Advanced Prostate Cancer

Prostate cancer is the most common cancer in Canadian men, and, in 2023 approximately 24,700 men were diagnosed.¹ Prostate cancer is considered advanced when it has spread or come back after initial treatment and may include biochemical recurrence (rising prostate-specific antigen in the absence of metastatic disease on imaging), locally advanced disease, or metastatic disease.

Front-line medical therapy for advanced prostate cancer typically involves androgen deprivation therapy, which reduces testosterone to very low levels, commonly referred to as castrate levels (< 50 ng/dL). Luteinizing hormone-releasing hormone (LHRH) receptor agonists, such as leuprolide acetate, are depot injections and the current standard of care for androgen deprivation therapy. LHRH receptor agonists may be associated with mechanism-of-action limitations, including an initial surge in testosterone levels that may exacerbate clinical symptoms, which is known as clinical or hormonal flare, and potentially delayed testosterone recovery after the drug is discontinued.

About ORGOVYX® (relugolix)

ORGOVYX (relugolix) is the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist approved by the U.S. Food and Drug Administration, the European Commission, and Health Canada for the treatment of adult patients with advanced prostate cancer. As a GnRH antagonist, ORGOVYX blocks the GnRH receptor, thereby reducing the release of the luteinizing and follicle-stimulating hormones, and consequently reducing the production of testicular testosterone, a hormone known to stimulate the growth of prostate cancer.

About Sumitomo Pharma

Sumitomo Pharma Co., Ltd. is a global pharmaceutical company based in Japan with key operations in the U.S. (Sumitomo Pharma America, Inc.), Canada (Sumitomo Pharma Canada, Inc.) and Europe (Sumitomo Pharma Switzerland GmbH) focused on addressing patient needs in psychiatry & neurology, oncology, urology, women's health, rare disease, and cell & gene therapies. With several marketed products in the U.S., Canada, and Europe, a diverse pipeline of early- to late-stage assets, and in-house advanced technology capabilities, we aim

to accelerate discovery, research, and development to bring novel therapies to patients sooner. For more information, please visit <https://www.us.sumitomo-pharma.com> and [LinkedIn](#) to follow us.

The Sumitomo Pharma icon is a trademark of Sumitomo Pharma Co., Ltd., used under license. SUMITOMO PHARMA is a trademark of Sumitomo Pharma Co., Ltd., used under license.

SUMITOMO is a registered trademark of Sumitomo Chemical Co., Ltd., used under license.

Sumitomo Pharma America, Inc. is a U.S. subsidiary of Sumitomo Pharma Co., Ltd.

ORGOVYX is a trademark of Sumitomo Pharma Switzerland GmbH.

© 2024 Sumitomo Pharma America, Inc. All rights reserved.

For a copy of this release, visit Sumitomo Pharma America's and Sumitomo Pharma Canada's website at www.us.sumitomo-pharma.com and www.ca.sumitomo-pharma.com.

Reference

- Fraser M, Mohammad A. The landscape of prostate cancer research in Canada. doi: 10.1200/JCO.2023.41.6_suppl.394 Journal of Clinical Oncology 41, no. 6_suppl (February 20, 2023) 394-394.

SOURCE Sumitomo Pharma America

For further information: IR & Media Contact: Maya Frutiger, VP, Head of Corporate Communications, Sumitomo Pharma America, Inc., CorpComms@us.sumitomo-pharma.com

<https://news.us.sumitomo-pharma.com/2024-03-12-Sumitomo-Pharma-Announces-Availability-of-ORGOVYX-R-relugolix-in-Canada,-the-First-and-Only-Oral-Androgen-Deprivation-Therapy-Treatment-for-Men-with-Advanced-Prostate-Cancer>