Sumitomo Pharma Announces Authorization in Canada of ORGOVYX® (relugolix) for the Treatment of Men with Advanced Prostate Cancer

– ORGOVYX is the First and Only Oral Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist Approved for Advanced Prostate Cancer in Canada –

MISSISSAUGA, Ontario, Oct. 23, 2023 /PRNewswire/ -- Sumitomo Pharma Canada, Inc., announced today that Health Canada has approved ORGOVYX® (relugolix), an oral gonadotropin-releasing hormone (GnRH) receptor antagonist, for the treatment of men with advanced prostate cancer. The approval is based on efficacy and safety data from the Phase 3 HERO study of ORGOVYX in men with advanced prostate cancer. ORGOVYX is expected to be available for prescription in Canada in Q1 2024.

"Roughly 1 in 8 Canadian men will develop prostate cancer in their lifetime, and the ability to suppress testosterone, primarily achieved through androgen deprivation therapy (ADT), is foundational in the treatment of the advanced stages of the disease," said Fred Saad, M.D., FRCS, Professor and Chairman of the Department of Surgery and Director of Genitourinary Oncology at the University of Montreal. "In the HERO study, ORGOVYX demonstrated rapid, sustained, and profound testosterone suppression when compared to leuprolide. ORGOVYX is the first approved ADT in Canada that can be administered orally, and once daily, offering a safe and effective option for advanced prostate cancer patients in the country."

"We're pleased that with Health Canada's approval of ORGOVYX, we are helping to expand upon treatment options for Canadian men living with advanced prostate cancer," said Lisa Mullett, General Manager of Sumitomo Pharma Canada, Inc. "We are committed to making ORGOVYX available to patients across Canada early in the new year."

The Health Canada approval was based on the results of the Phase 3 HERO study, a randomized, open-label, parallel-group, multinational clinical study evaluating the safety and efficacy of ORGOVYX in over 1,000 men with androgen-sensitive advanced prostate cancer who required at least one year of continuous ADT. In the Phase 3 study, ORGOVYX met the primary endpoint and demonstrated superiority in sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks compared to those receiving leuprolide acetate injections, the current standard of care. The most frequent adverse events reported in at least 10% of men in the ORGOVYX group were hot flush, musculoskeletal pain, fatigue, constipation, and mild to moderate diarrhea.

ORGOVYX was previously approved by the U.S. Food and Drug Administration on December 18, 2020 and granted marketing authorization by the European Commission for advanced hormone-sensitive prostate cancer on April 29, 2022.

About Advanced Prostate Cancer
Prostate cancer is the most common cancer in Canadian men, and, in 2023 an estimated 24,700 men will be 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. However, LHRH receptor agonists may be associated with mechanism-of-action limitations, including the potentially detrimental initial surge in testosterone levels that can exacerbate clinical symptoms, which is known as clinical or hormonal flare, and 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 and reduces 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.

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.

References

- 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.

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

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