

## Canada's Drug Agency Recommends WINREVAIR® (sotatercept) for Reimbursement

**KIRKLAND, QC, November 7, 2024** – Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced that Canada's Drug Agency (CDA) has recommended WINREVAIR® (sotatercept) for reimbursement in combination with standard pulmonary arterial hypertension (PAH) therapy, for the treatment of adults with World Health Organization [WHO] Group 1 PAH and Functional Class (FC) II or III.

Sotatercept is the first activin signaling inhibitor therapy for PAH in Canada, a new class of therapy that works by improving the balance between pro-proliferative and anti-proliferative signaling to modulate vascular proliferation in PAH patients.

"We are excited about the prospects of a novel treatment option for patients who are suffering from pulmonary arterial hypertension," said Dr. John Granton, Director of the Pulmonary Hypertension (PH) program at the University Health Network in Toronto.

"As the mother of a daughter who was diagnosed with severe Pulmonary Arterial Hypertension (PAH) in 2014 at the age of 24 and the Board Chair at PHA Canada, I am very aware of the burdens that this rare disease continues to inflict on our patients," said Joan Paulin, the Board Chair of PHA Canada. "Our goal, as an organization now is to ensure that all eligible patients, no matter where they live in Canada, are provided access," added Paulin.

The next steps toward product accessibility include the pan-Canadian Pharmaceutical Alliance (pCPA) engaging with Merck Canada to begin negotiations for WINREVAIR®, so that it may be publicly funded by participating drug plans in Canada. It has been 8 years since a new pharmacological therapy has been launched in Canada for PAH.

WINREVAIR® is the subject of a licensing agreement with Bristol Myers Squibb.

### About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable, and healthy future for all people and communities. For more information about our operations in Canada, visit [www.merck.ca](http://www.merck.ca) and connect with us on [LinkedIn](#) and [X @MerckCanada](#).

## **Forward-Looking Statement of Merck & Co. Inc., Rahway, NJ, USA**

This news release of Merck & Co., Inc., Rahway, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company’s Annual Report on Form 10-K for the year ended December 31, 2023 and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site ([www.sec.gov](http://www.sec.gov)).

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