Innovative Medicine

OPSYNVI® (macitentan and tadalafil) Becomes the First and Only Health Canada-Approved Once Daily Fixed Dose Combination Treatment for Patients with Pulmonary Arterial Hypertension (PAH)

Canadians living with PAH, a rare disease for which there is no cure, now have a new treatment option

October 15, 2021

Toronto, ON, (October 15, 2021) – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that Health Canada approved OPSYNVI® (macitentan 10mg and tadalafil 40mg) for the long-term treatment of pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) to reduce morbidity in patients of WHO functional class (FC) II or III whose PAH is idiopathic, heritable, or associated with connective tissue disease or congenital heart disease.

OPSYNVI® should be used in patients who are currently treated concomitantly with stable doses of macitentan 10mg and tadalafil 40mg (20mg x 2) as separate tablets.

PAH is a specific, rare form of pulmonary hypertension (PH) that affects the right side of the heart and causes the walls of the pulmonary arteries (blood vessels leading from the right side of the heart to the lungs) to become thick and stiff, narrowing the space for blood to flow, and causing increased blood pressure to develop within the lungs. If left untreated, PH can lead to right ventricle failure, a serious type of heart failure.[1]

“PAH is a progressive disease that can affect people of any age or ethnic background. While there is no cure, there have been considerable advancements in care and we now have a gold standard option to improve pulmonary vascular resistance, lessen disease morbidity and reduce right heart impact,” said Dr. Lisa Mielniczuk, Director of the Pulmonary Hypertension Program at the Ottawa Heart Institute and Co-Vice Chair of the Pulmonary Hypertension Association of Canada’s Board of Directors.* “Canadians living with PAH often have co-morbidities and are taking multiple treatments which can understandably lead to a high pill burden and reduced medication adherence. As a combination therapy, OPSYNVI® conveniently offers two therapies in one daily pill simplifying treatment for patients.”

Health Canada’s approval is based on three comparative bioavailability studies, which demonstrated the bioequivalence of a single dose of macitentan 10 mg and tadalafil 40 mg as the OPSYNVI® fixed dose combination tablet to OPSUMIT® (macitentan 10 mg) and ADCIRCA® (tadalafil 40 mg) co-administered as individual tablets in healthy patients.

“As part of our commitment to investing in research and understanding the science to advance innovative treatment options, today marks an important day for Canadians living with Pulmonary Arterial Hypertension,” said Neil Davie, Ph.D., Global Therapeutic Area Head and Research & Development External Innovation Leader, Pulmonary Hypertension, Janssen-Cilag Ltd.** “This new once daily treatment helps simplify patient care for the long-term treatment of PAH.”

# # #

About OPSYNVI®

Macitentan
Macitentan (OPSUMIT®) is indicated for the long-term treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce morbidity in patients of WHO Functional Class II or III whose PAH is either idiopathic or heritable, or associated with connective tissue disease or congenital heart disease. OPSUMIT® is effective when used as monotherapy or in combination with phosphodiesterase-5 inhibitors.

The recommended dose of OPSUMIT® is 10 mg once daily.

Patent Owner Actelion, EX2015, p. 1
Actelion Pharmaceuticals Ltd.
IPR2025-01139

Johnson&Johnson

About the Janssen Pharmaceutical Companies of Johnson & Johnson
At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology and Pulmonary Hypertension.

Learn more at www.janssen.com/canada. Follow us at @JanssenCanada.

*Dr. Mielniczuk was not compensated for any media work. She has been compensated as a consultant.

**Janssen Inc. and Janssen-Cilag Ltd are Janssen Pharmaceutical Companies of Johnson & Johnson. All trademark rights used under license.
***ADCIRCA® is a registered mark of Eli Lilly and Company.

Cautions Concerning Forward-Looking Statements
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding OPSYNVI®. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Inc., any of the other Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including ;technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov , www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

[1] Pulmonary Hypertension Association of Canada "What is Pulmonary Hypertension" Accessed October 9, 2021 https://phacanada.ca/What-is-PH/About-PH

Media contact:
Jennifer Dent
Jdent1@its.jnj.com

Investor Relations:
Jennifer McIntyre
Office: +1 732 524 3922

Cardiopulmonary

Patent Owner Actelion, EX2015, p. 2
Actelion Pharmaceuticals Ltd.
IPR2025-01139

Johnson&Johnson

Media

Key links

Terms of use

Privacy statement

Cookie policy

Customize Cookie Settings

Digital Accessibility Statement

Get in touch

Contact

Do not sell or share my personal information
Limit the use of my sensitive personal information

© Johnson & Johnson and its affiliates 2025

Patent Owner Actelion, EX2015, p. 3
Actelion Pharmaceuticals Ltd.
IPR2025-01139