PRESS RELEASE

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ACTELION RECEIVES COMPLETE RESPONSE LETTER FROM U.S. FDA FOR OPSUMIT® (MACITENTAN) SUPPLEMENTAL NEW DRUG APPLICATION

SOUTH SAN FRANCISCO, Calif., Jan. 16, 2019 -- Actelion Pharmaceuticals Ltd, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, today announced it has received a complete response letter from the U.S. Food and Drug Administration (FDA) for its supplemental New Drug Application (sNDA) for OPSUMIT® (macitentan) in the treatment of adults with inoperable chronic thromboembolic pulmonary hypertension (CTEPH, WHO Group 4) to improve pulmonary vascular resistance (PVR) and exercise capacity. The complete response letter indicates additional data are needed to evaluate the use of OPSUMIT in the treatment of CTEPH.

“We will work closely with the FDA to review the information outlined in their letter and gain a full understanding of next steps. We are committed to making a difference in the lives of people living with pulmonary hypertension and CTEPH,” said Martin Fitchet, M.D., Global Head of Actelion Research & Development, Janssen Research & Development, LLC.

The proposed new indication is based on investigational data from MERIT-1 (Macitentan for the treatment of inoperable chronic thromboembolic pulmonary hypertension), a Phase II study to assess the efficacy, safety and tolerability of macitentan 10 mg in patients with inoperable CTEPH (WHO Group 4). Data from MERIT-1 has been published in *The Lancet Respiratory Medicine*.[1]

OPSUMIT is a foundational therapy that is an orally active endothelin receptor antagonist (ERA) currently approved in the U.S. for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH. For all female patients, OPSUMIT is available only through a restricted program called the OPSUMIT Risk Evaluation and Mitigation Strategy (REMS). Please see full Prescribing Information, including the Boxed Warning for embryo-fetal toxicity.

ABOUT ACTELION

Actelion, a leader in Pulmonary Hypertension, became part of the Janssen Pharmaceutical Companies of Johnson & Johnson following its acquisition in June 2017. Actelion's medicines have helped to expand and strengthen Janssen's portfolio with leading, differentiated in-market medicines and promising late-stage compounds. Janssen has added Pulmonary Hypertension as a therapeutic area of focus to maintain the leadership position Actelion has built in this rare disease area. Learn more at www.actelion.com. Follow us at @actelion_com.

ABOUT THE JANSSEN PHARMACEUTICAL COMPANIES OF JOHNSON & JOHNSON
At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal.

Cautions Concerning Forward-Looking Statements
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding OPSUMIT. 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 Actelion Pharmaceuticals Ltd, 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 31 December, 2017, 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. Neither 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.

Reference:
1. *The Lancet Respiratory Medicine*. Macitentan for the treatment of inoperable chronic thromboembolic pulmonary hypertension (MERIT-1): results from the multicentre, phase 2, randomised, double-blind, placebo-controlled study; Sept, 2017; https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(17)30305-3/fulltext

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