News Release

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REVEAL Lite 2 Risk Calculator Offers Simplified Model to Assess One-Year Mortality Risk Status in Patients with Pulmonary Arterial Hypertension (PAH)

Data published in the journal CHEST

SOUTH SAN FRANCISCO, CA – February 3, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results from an analysis determining the validity of the Registry to Evaluate Early and Long-Term PAH Disease Management (REVEAL) Lite 2 risk calculator, an abridged version of the REVEAL 2.0 risk calculator, in patients with pulmonary arterial hypertension (PAH), a rapidly progressive disease with no known cure.[1,2,3] The analysis showed that REVEAL Lite 2 offers a simplified method of risk assessment using six non-invasive and modifiable variables that may be implemented routinely in daily clinical practice and can be used in conjunction with REVEAL 2.0, and differentiates patients among low, intermediate and high risk of one-year mortality. The results were published in the journal *CHEST*, the official publication of the American College of Chest Physicians.

For patients with PAH, risk assessment is necessary to evaluate disease progression and inform treatment decisions based on an individual's prognosis.[1,4] While the need for timely and regular risk assessment in PAH is widely acknowledged, real-world evidence indicates that risk assessment in the clinical setting may be

suboptimal; evidence suggests that some physicians encounter barriers to practical implementation, including the complexity of tools and invasive procedures.[5,6]

"In order to effectively identify appropriate treatment protocol, physicians need to be able to risk stratify patients to better characterize their disease," said Raymond Benza*, MD, FACC, FAHA, FACP, primary study investigator and Professor of Medicine at The Ohio State University. "Risk calculators that assess fewer and noninvasive variables without compromising discrimination and accuracy may help both expedite and enhance strategic decision making in the routine clinical setting."

REVEAL Lite 2 is an abridged version of the REVEAL 2.0 risk calculator that uses six (rather than 13) exclusively noninvasive and modifiable variables, which include functional class (FC), vital signs (systolic BP [SBP] and heart rate), 6-min walk distance (6MWD), brain natriuretic peptide (BNP)/N-terminal prohormone of brain natriuretic peptide (NT-proBNP), and renal insufficiency (by estimated glomerular filtration rate [eGFR])—and was validated in a series of analyses (Kaplan-Meier, concordance index, Cox proportional hazard model, and multivariate analysis).

In total, 2,529 of the 3,515 patients enrolled in the REVEAL Registry™† were eligible for inclusion in this analysis. Approximately 50 percent of patients had idiopathic PAH (IPAH) and 25 percent had connective tissue-associated PAH (CTD-PAH). Most patients (nearly 87 percent) were classified as New York Heart Association (NYHA) FC II/III. When REVEAL Lite 2 was applied at the time of patient enrollment (N=3,046 PAH patients), the c-index, known as the concordance index, was 0.71 (95% CI, 0.69-0.73), indicating good discrimination. The c-index was calculated separately using REVEAL Lite 2 for IPAH (n=1,171) and CTD-PAH (n=649) subgroups. Some limitations to consider are that REVEAL Lite 2 must be validated in a non-derivative cohort and that patients in REVEAL were treated at specialized PAH centers within the US only. REVEAL Lite 2 is intended to complement REVEAL 2.0.

"We have a long-standing commitment to the PAH community, and we're proud to sponsor the REVEAL Registry to continue to help facilitate and advance the understanding of PAH disease management with the goal to help improve patient

outcomes," said Siân Walker[**], Head of Medical Affairs, Janssen US, Pulmonary Hypertension.

To read the full manuscript and learn more about the REVEAL Lite 2 risk assessment tool, please visit https://journal.chestnet.org/article/S0012-3692(20)34296-3/fulltext.

[*]Dr. Raymond Benza has received research support from Janssen and has served as a paid consultant to the company.
[**]Siân Walker Peasego is an employee of Actelion Pharmaceuticals US Inc
[†]The REVEAL Registry™ is a registered trademark of Actelion Pharmaceuticals Ltd.

About Pulmonary Arterial Hypertension (PAH)

PAH is a specific form of pulmonary hypertension (PH) that 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 an increased blood pressure to develop within the lungs. PAH is a serious, progressive disease with a variety of etiologies and has a major impact on patients' functioning as well as their physical, psychological and social wellbeing. There is currently no cure for PH and it is often fatal.[1,2,3] However, the last decade has seen significant advances in the understanding of the pathophysiology of PAH, transforming the prognosis for PAH patients from symptomatic improvements in exercise tolerance 10 years ago, to delayed disease progression today.

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. Follow us at www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS.

Cautions Concerning Forward-looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the REVEAL 2.0 and REVEAL Lite 2 risk assessment tools. 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 any of the 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 December 29, 2019, 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.

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