NEWS RELEASE

Merck Announces Positive Top-line Results from Pivotal Phase 3 STELLAR Trial Evaluating Sotatercept for the Treatment of Adults with Pulmonary Arterial Hypertension (PAH)

10/10/2022

Sotatercept demonstrated significant improvement in exercise capacity and key secondary outcome measures compared to placebo when added to background therapy

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced positive top-line results from the pivotal Phase 3 STELLAR trial evaluating the safety and efficacy of sotatercept, an investigational activin receptor type IIA-Fc (ActRIIA-Fc) fusion protein being evaluated as an add-on to stable background therapy for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1). The trial met its primary efficacy outcome measure, demonstrating a statistically significant and clinically meaningful improvement in 6-minute walk distance (6MWD, which measures how far patients can walk in 6 minutes) from baseline at 24 weeks. Eight of nine secondary efficacy outcome measures achieved statistical significance, including the outcome measure of proportion of participants achieving multicomponent improvement (defined as improvement in 6MWD, improvement in N-terminal pro-B-type natriuretic peptide (NT-proBNP) level, and either improvement in WHO FC or maintenance of WHO FC II), and the outcome measure of time to death or the first occurrence of a clinical worsening event (TTCW). The Cognitive/Emotional Impacts domain score of PAH-SYMPACT®, which was assessed as the ninth and final secondary outcome measure, did not achieve statistical significance. The overall safety profile of sotatercept in STELLAR was in general consistent with what has been observed in Phase 2. Results from the study will be presented at an upcoming scientific congress.

“In the Phase 3 STELLAR study, sotatercept added to currently approved background therapy showed a profound effect on the primary efficacy outcome measure of improvement from baseline to 24 weeks in six-minute walk distance. The results from the secondary efficacy outcomes, including a favorable benefit seen in patients’ time to a clinical-worsening event, are especially noteworthy,” said Dr. Dean Y. Li, president, Merck Research Laboratories. “We believe that in totality, the results observed in the STELLAR study suggest that sotatercept has the potential to transform the treatment of patients with PAH. We are moving with urgency on our regulatory applications to bring this investigational therapy to these patients.”

About STELLAR

STELLAR (**NCT04576988**) is a pivotal Phase 3, randomized, double-blind, placebo-controlled, multicenter, parallel-group study designed to evaluate the safety and efficacy of sotatercept compared to placebo, as an add-on to background therapy for the treatment of adults with pulmonary arterial hypertension (WHO Group 1). The primary endpoint is exercise capacity, as measured by 6-minute walk distance (6MWD) 24 weeks following initiation of treatment. Nine secondary outcome measures were assessed: proportion of participants achieving multicomponent improvement (consisting of improvement in 6MWD, improvement in N-terminal pro-B-type natriuretic peptide (NT-proBNP) level, and either improvement in WHO FC or maintenance of WHO FC II); change from baseline in pulmonary vascular resistance (PVR); change from baseline in NT-proBNP levels; proportion of participants who improved in WHO FC; time to death or the first occurrence of a clinical worsening event (TTCW); proportion of participants who maintained or achieved a low risk score using the simplified French Risk score calculator; change from baseline in the Physical Impacts domain score of PAH; change from baseline in the Cardiopulmonary Symptoms domain score of PAH-SYMPACT®; and change from baseline in the Cognitive/Emotional Impacts domain score of PAH-SYMPACT®.

About pulmonary arterial hypertension (PAH)

Pulmonary arterial hypertension (PAH) is a rare, progressive and life-threatening blood vessel disorder characterized by the constriction of small pulmonary arteries and elevated blood pressure in the pulmonary circulation. Currently, an estimated 40,000 people in the U.S. and 30,000 people in the European Union are living with PAH and the disease progresses rapidly for many patients despite current standard of care treatment. PAH results in significant strain on the heart, leading to limited physical activity, heart failure and reduced life expectancy. The 5-year mortality rate for patients with PAH is approximately 43 percent.

About sotatercept

Sotatercept is an investigational, potential first-in-class activin receptor type IIA-Fc (ActRIIA-Fc) fusion protein in development for the treatment of adult patients with pulmonary arterial hypertension (WHO Group 1). Sotatercept

was designed to rebalance pro-proliferative (ActRIIA/Smad2/3-mediated) and anti- proliferative (BMPRII/Smad1/5/8-mediated) signaling associated with pulmonary arterial wall and right ventricular remodeling.

Sotatercept has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA), as well as Priority Medicines designation by the European Medicines Agency for the treatment of PAH.

Merck acquired exclusive rights to sotatercept in the pulmonary hypertension field through the acquisition of Acceleron Pharma Inc. Sotatercept 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, visit **www.merck.com** and connect with us on **Twitter**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., 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 the global outbreak of novel coronavirus disease (COVID-19); 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, 2021 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

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Source: Merck & Co., Inc.