Merck Announces FDA Approval of WINREVAIR™ (sotatercept-csrk)

Provided to investors as a reference

March 2024

Forward-Looking Statement

This presentation 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.

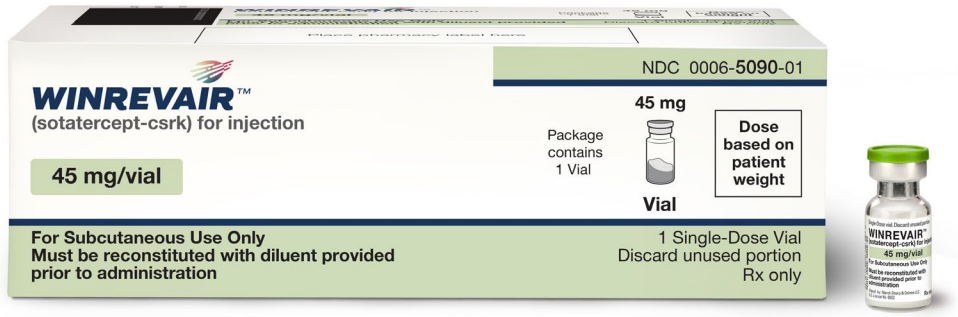
Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; 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).

WINREVAIR: A first-in-class activin signaling inhibitor and the first biologic approved for PAH in the U.S.

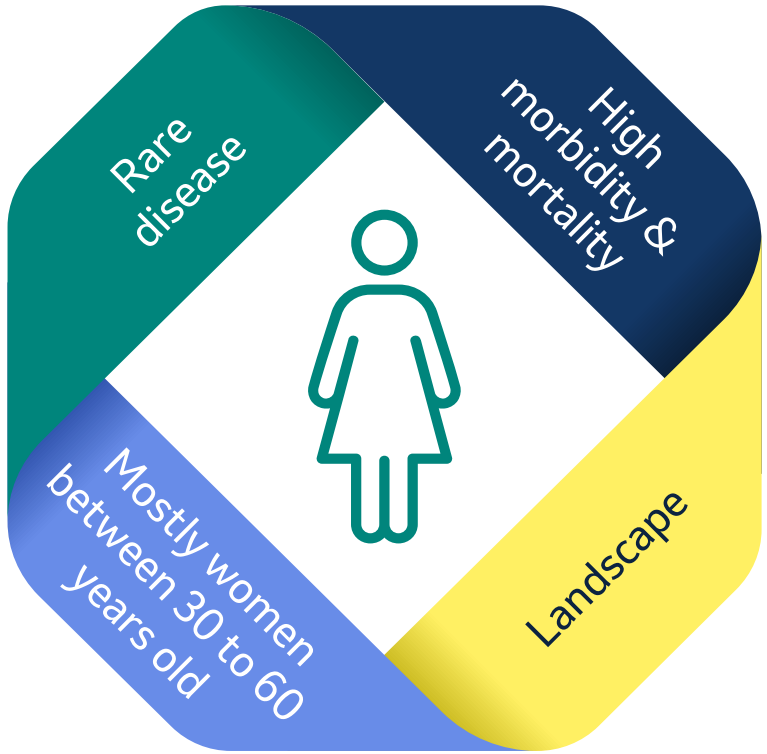
The U.S. FDA has approved WINREVAIR™ (sotatercept-csrk) for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.

- WINREVAIR is a novel therapeutic option that targets a new PAH treatment pathway.
- Received Orphan Drug designation and Breakthrough Therapy designation from the U.S. FDA for the treatment of PAH.
- Administered by subcutaneous injection, enabling patient or caregiver administration where appropriate with guidance, training and follow-up from a healthcare provider.
- Merck is committed to evaluating WINREVAIR in additional patient populations and for additional uses, including ongoing Phase 3 trials in PAH and a Phase 2 trial in another type of pulmonary hypertension (PH).



Unmet medical needs in PAH remain high

An estimated 40,000 people in the U.S. are diagnosed and living with PAH, a progressive rare disease.



PAH is a potentially debilitating condition with an estimated 5-year mortality rate of 43%.

PAH disproportionately affects women - 4 times more than men.

The first innovative PAH medicine approved in 9 years that contains a novel therapeutic agent.

The journey of a typical patient with PAH

PAH disproportionately affects women and timing of symptom onset generally occurs between the ages of 30 to 60.

Presenting Symptoms

Delay in seeking care and misdiagnosis can be common due to non-specific symptoms, which become increasingly limiting:

- Breathlessness or dyspnea
- Fatigue
- Syncope
- Dizziness
- Chest pain
- Swollen ankles, arms

Delayed Diagnosis

Patients often visit multiple specialists and go through various diagnostic tests.

The average time from symptom onset to PAH diagnosis can be >2 years.

Initial Treatment

According to current treatment guidelines, combination therapy is generally recommended as initial therapy in PAH.

Disease Progression

Despite improvement following initial treatment, many patients start to experience worsening symptoms and/or function, which can prompt addition of treatment.

Transplant Referral

Lung or heart-lung transplantation remains an important option when response to optimized combination therapy is inadequate.

Right Heart Failure

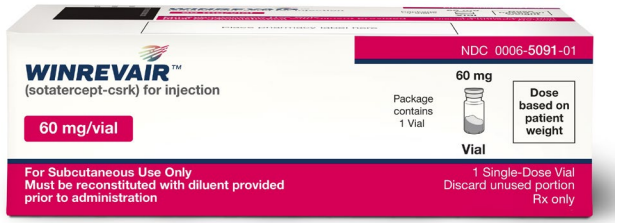
Disease progression can lead to right heart failure, which can be a life-threatening condition.

Value of WINREVAIR

Access: We are working to ensure WINREVAIR is accessible to all appropriate patients who may benefit. Support for eligible patients is available through the Merck Access Program.

Price: The cost of WINREVAIR to payers will vary based on the dosage prescribed by a patient's HCP. WINREVAIR is a subcutaneous injection administered every 3 weeks and is distributed in single-vial or double-vial kits, with weight-based dosing. Appropriate patients or their caregivers may administer WINREVAIR with guidance, training and follow-up from their HCP. Patients on their starting dose are generally expected to utilize a single-vial kit. For the label-recommended target dose, based on estimates from the STELLAR clinical trial, we expect approximately two-thirds of patients to utilize single-vial kits. WINREVAIR will be priced at $14,000 per vial across all kit configurations. A specific patient's out-of-pocket cost is dependent on many factors, including their insurance coverage and benefit design, which may include an out-of-pocket maximum.

Commitment: We continue to evaluate WINREVAIR in a broad clinical development program, which includes ongoing Phase 3 trials in PAH populations and a Phase 2 trial in another type of PH.



WINREVAIR financial modeling considerations

- An estimated 40,000 patients in the U.S. are currently diagnosed and living with PAH.
- WINREVAIR is a subcutaneous injection administered every 3 weeks and is distributed in single-vial or double-vial kits, with weight-based dosing. WINREVAIR will be available in 4 kit configurations: 2 single-vial kits containing either one 45mg vial or one 60mg vial, and 2 double vial kits containing either two 45mg vials or two 60mg vials. Patients on their starting dose are generally expected to utilize a single-vial kit. For the label-recommended target dose, based on estimates from the STELLAR clinical trial, we expect approximately two-thirds of patients to utilize single-vial kits.
- WINREVAIR will be priced at $14,000 per vial across all kit configurations.
- Appropriate patients or their caregivers may administer WINREVAIR with guidance, training and follow-up from their HCP. Based on our understanding of this patient population and their use of current therapies, we anticipate that the vast majority of patients will self-administer, or will have their caregiver administer.
- Patients will access the product via a network of specialty pharmacies, and we estimate that WINREVAIR will be available for dispensing by these specialty pharmacies in the U.S. by the end of April.
- We expect payer mix to be weighted heavily towards Medicare and Medicaid patients, with commercially-insured patients representing around a third or more of patients.[1] Based on the label and the fact that the product will be predominantly dispensed through a network of specialty pharmacies, we anticipate that WINREVAIR will be largely covered under a patient's pharmacy benefit, including under Medicare Part D for Medicare patients.
- Similar to other products covered by a patient's pharmacy benefit, Merck will be providing certain government mandated discounts on WINREVAIR, including, starting in 2025, responsibility for costs in the initial coverage and catastrophic phases required through the benefit redesign of the Medicare Part D program under the IRA.

1) Merck, through its 501(c)(3) charitable organization, the Merck Patient Assistance Program, Inc., will provide WINREVAIR free of charge to eligible patients who do not have insurance or whose insurance does not cover their prescription.

MERCK