News Release

Merck Announces Health Canada Approval of ENFLONSIA® for the prevention of RSV in newborns and infants

Approval is based on the CLEVER and SMART Clinical Trial Results

KIRKLAND, QC., February 5 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that Health Canada has approved ENFLONSIA® (clesrovimab) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates (newborns) and infants born during or entering their first RSV season.

ENFLONSIA® is a monoclonal antibody (mAb) that can help provide protection for up to five months—typical of an RSV season. The Health Canada approval marks an important milestone in expanding RSV prevention options for newborns and infants across Canada. Timing of availability may vary across provinces and territories and will depend on factors including provincial and territorial reimbursement programs.

"RSV can lead to serious respiratory illness, including bronchiolitis and pneumonia, in both healthy and at-risk infants, and remains one of the leading causes of infant hospitalization," said Matthew Thornhill, Executive Director, Vaccines Business Unit at Merck Canada. "The approval of ENFLONSIA® adds a new option for RSV prevention in infants, supporting efforts to address an important public health concern."

Health Canada's approval is supported by results from Merck's clinical development program, including the pivotal Phase 2b/3 CLEVER trial (MK-1654-004) and the Phase 3 SMART trial (MK-1654-007).

For complete information, refer to the ENFLONSIA® product monograph.

About Clinical Data Supporting Health Canada's Approval

The CLEVER trial (MK-1654-004; NCT04767373) was a Phase 2b/3, randomized, double-blind, placebo-controlled, multisite study to evaluate the efficacy of ENFLONSIA® (clesrovimab) in healthy early and moderate preterm infants (≥ 29 to < 35 weeks gestational age (GA)) and late preterm and full-term infants (≥ 35 weeks GA) entering their first RSV season. Participants were randomized 2:1 to receive a 105 mg dose of clesrovimab (N=2 411) or saline placebo (N=1 203) by intramuscular (IM) injection.

The primary endpoint was the incidence of RSV-associated medically attended lower respiratory infection (MALRI) characterized as cough or difficulty breathing and requiring ≥ 1 indicator of LRI (wheezing, rales/crackles) or severity (chest wall in-drawing/retractions,

hypoxemia, tachypnoea, dehydration due to respiratory symptoms) from Day 1 through Day 150 after dosing. Medically attended includes all health care professional visits in settings such as outpatient clinic, clinical study site, emergency department, urgent care center, and/or hospital.

The key secondary endpoints were RSV-associated hospitalization through Day 150 after dosing and RSV-associated MALRI through Day 180 after dosing.

The trial demonstrated positive results for its primary and key secondary endpoints.

The safety profile of clesrovimab was generally comparable to placebo. The most frequent adverse reaction was injection-site erythema, reported in 4.4% subjects receiving clesrovimab occurring within 5 days post-dose. The majority of cases were mild to moderate in intensity. Additionally, injection-site swelling and rash were reported at a rate of 3.2% and 2.3% within 5 days and 14 days post-dose, respectively.

The approval is also supported by results from the Phase 3 SMART trial (MK-1654-007; NCT04938830) evaluating the safety and efficacy of ENFLONSIA® versus palivizumab in infants at increased risk for severe RSV disease.

About RSV

Respiratory syncytial virus (RSV) is a common respiratory virus that typically causes mild, cold-like symptoms, but it can also affect the lungs. Symptoms may include a runny nose, cough, fever, trouble feeding, wheezing, or difficulty breathing. Nearly all children are infected with RSV by the age of two. While most recover quickly, RSV can lead to serious illness such as bronchiolitis and pneumonia, which may require hospitalization and, in rare cases, can be fatal. Newborns and infants under 12 months—especially those younger than six months or with underlying heart or lung conditions—are at highest risk.

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 about our operations in Canada, visit www.merck.ca and connect with us on LinkedIn @MerckCanada.

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 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).

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