NEWS RELEASE

Merck Expands Tulisokibart Clinical Development Program With Initiation of Phase 2b Trials in Three Additional Immune-Mediated Inflammatory Diseases

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Tulisokibart, an investigational anti-TL1A monoclonal antibody currently in Phase 3 trials for ulcerative colitis and Crohn's disease, to be studied in hidradenitis suppurativa, radiographic axial spondyloarthritis and rheumatoid arthritis

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced it has initiated three Phase 2b trials evaluating the safety and efficacy of tulisokibart (MK-7240), an investigational humanized monoclonal antibody targeting tumor necrosis factor (TNF)-like cytokine 1A (TL1A), in patients with three immune-mediated inflammatory diseases:

- MK-7240-12 (**NCT06956235**) studying patients with moderate to severe hidradenitis suppurativa(HS)
- MK-7240-013 (**NCT07133633**) studying patients with radiographic axial spondyloarthritis(r-axSpA; also known as ankylosing spondylitis)
- MK-7240-014 (**NCT07176390**) studying patients with rheumatoid arthritis(RA)

Global recruitment of these trials has begun, targeting enrollment of more than 640 patients across the three studies.

"The expansion of our tulisokibart clinical development program reflects Merck's ongoing commitment to addressing the burden of immune-mediated inflammatory diseases," said Dr. Aileen Pangan, vice president and head of immunology, global clinical development, Merck Research Laboratories. "We're excited to further evaluate the potential of tulisokibart as a treatment for patients across multiple diseases in rheumatology and dermatology."

With the initiation of these Phase 2b trials, tulisokibart is now being investigated in a total of six diseases. Merck is also currently conducting two Phase 3 studies evaluating the efficacy and safety of tulisokibart in patients with two different types of inflammatory bowel disease (IBD), **ATLAS-UC** (**NCT06052059**) in ulcerative colitis (UC) and **ARES-CD** (**NCT06430801**) in Crohn's disease (CD), and a Phase 2 study in systemic sclerosis-associated interstitial lung disease (SSc-ILD) (**NCT05270668**). For an overview of Merck's clinical development program in immunology, please click **here**.

About hidradenitis suppurativa (HS)

Hidradenitis suppurativa is a chronic inflammatory skin condition that affects hair follicles and is characterized by small, painful abscesses under the skin in areas of the body such as the armpits, groin, buttocks and breasts. Hidradenitis suppurativa affects a variable proportion of the population, with prevalence estimates ranging from 0.1% to 0.8%.

About radiographic axial spondyloarthritis (r-axSpA)

Radiographic axSpA (also known as ankylosing spondylitis) is characterized by chronic inflammation and pain involving the spine and the joints that connect the bottom of the spine to the pelvis. As its name suggests, damage associated with r-axSpA is visible on X-rays. Worldwide, it is thought to affect 0.1% to 1% of all people.

About rheumatoid arthritis (RA)

Rheumatoid arthritis is a chronic autoimmune condition characterized by the inflammation of joints, which can lead to pain, swelling and stiffness. Rheumatoid arthritis can also affect other parts of the body, including the skin, eyes, mouth, heart and lungs. Globally, it is estimated that 17.9 million people are affected by RA, which represents a 13.2% increase since 1990.

About tulisokibart

Tulisokibart is an investigational humanized monoclonal antibody directed to a novel target, tumor necrosis factor (TNF)-like cytokine 1A (TL1A), that is associated with both intestinal inflammation and fibrosis. Tulisokibart is thought to bind both soluble and membrane-bound human TL1A. Clinical studies suggest that tulisokibart may inhibit inflammatory pathways involved in inflammatory bowel disease (IBD), and help reduce intestinal fibrosis, which may be important in altering disease progression in IBD. Merck is developing tulisokibart for the treatment of immune-mediated inflammatory diseases including ulcerative colitis (UC), Crohn's disease (CD), systemic sclerosis-associated interstitial lung disease (SSc-ILD), hidradenitis suppurativa (HS), radiographic axial spondyloarthritis (r-axSpA), and rheumatoid arthritis (RA).

Merck's commitment to immunology

Advances in our understanding of human biology have led to the emergence of innovative medicines and new

modalities that aim to change approaches to treatment of immune-mediated inflammatory diseases. Our scientists are applying their expertise to the discovery and development of therapies to help people with immune-mediated inflammatory diseases. Our research efforts are focused on investigating novel targets such as TL1A and CD30L and their potential role in many immune-mediated inflammatory diseases.

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 **X (formerly 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 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, 2024 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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