Merck and the Bill & Melinda Gates Medical Research Institute Announce Licensing Agreement for Novel Candidate Tuberculosis Antibiotics

RAHWAY, N.J., and Cambridge MA., October 18, 2022 – Merck, (NYSE: MRK), known as MSD outside the United States and Canada, and the Bill & Melinda Gates Medical Research Institute (Gates MRI) today announced a licensing agreement for two preclinical antibacterial candidates for evaluation as potential components of combination regimens for the treatment of tuberculosis (TB). These candidates were discovered by Merck scientists as part of the TB Drug Accelerator (TBDA). The TBDA is a collaboration established among biopharmaceutical companies, research organizations and universities to accelerate the discovery and development of novel therapeutic candidates against TB. The initiative was established with support and leadership from the Bill & Melinda Gates Foundation.

“Tuberculosis is one of the world’s most significant infectious causes of human disease and death,” said Dr Emilio Emini, chief executive officer, the Bill & Melinda Gates Medical Research Institute, “and the development of novel therapies to simplify and more effectively treat TB has been a long-standing goal of scientific and medical research. The two novel compounds discovered by Merck scientists, and now licensed to the Gates MRI for further development and distribution, may represent potentially important constituents of future TB therapeutic regimens.”

Under the agreement, Merck has granted the Gates MRI an exclusive global license for MK-7762 and MK-3854. In furtherance of its charitable purpose, Gates MRI will conduct non-clinical and clinical studies of these candidates to determine their potential for inclusion in new affordable combination treatment regimens for TB with the aim of shortening the duration of treatment irrespective of resistance to the currently available TB drugs.

“At Merck we have a proud legacy of addressing some of the world’s most challenging infectious diseases,” said Dr. Dean Y Li, president, Merck Research Laboratories. “With the expertise and capabilities of the Gates MRI, MK-7762 and MK-3854 are positioned for rigorous evaluation of their potential as key components of novel TB treatment regimens.”

In vitro and in vivo evaluation of MK-7762 and MK-3854 have shown that both candidates have potent antibacterial activity against Mycobacterium tuberculosis, the organism that causes tuberculosis, including some strains known to be resistant to current therapies.

About Tuberculosis
Tuberculosis is a major global cause of illness, disability, and is one of the leading causes of death from an infectious disease worldwide, responsible for an estimated 1.5 million deaths per year.

The most commonly used drug regimen for the treatment of drug-sensitive TB requires patients to take multiple drugs for up to six months with routine clinical monitoring. Patients with drug-resistant forms of the infection can face longer and more complex treatment journeys, often with significant side effects that require increased monitoring. The need for drug-resistance testing prior to treatment initiation is an added challenge. A substantially shorter drug regimen for the treatment of both drug-susceptible and drug-resistant forms of TB could provide a significant benefit to both patients and health systems and may overcome the need for accompanying drug-resistance testing.

About the Bill & Melinda Gates Medical Research Institute
The Bill & Melinda Gates Medical Research Institute is a non-profit medical research organization dedicated to the development and effective use of novel biomedical interventions addressing substantial global health concerns, for which investment incentives are limited, including malaria, tuberculosis, enteric and diarrheal diseases, and diseases that impact maternal, newborn, and child health. For further information please visit [www.gatesmri.org](http://www.gatesmri.org).

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](http://www.merck.com) and connect with us on [Twitter](https://twitter.com), [Facebook](https://www.facebook.com), [Instagram](https://www.instagram.com), [YouTube](https://www.youtube.com) and [LinkedIn](https://www.linkedin.com).

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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