



NEWS RELEASE

Merck and Hanmi Pharmaceutical Enter into Licensing Agreement to Develop Efinopegdutide, an Investigational Once-Weekly Therapy for Nonalcoholic Steatohepatitis (NASH)

8/4/2020

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Hanmi Pharmaceutical today announced that the companies have entered into an exclusive licensing agreement for the development, manufacture and commercialization of efinopegdutide (formerly HM12525A), Hanmi's investigational once-weekly glucagon-like peptide-1 (GLP-1)/glucagon receptor dual agonist, for the treatment of nonalcoholic steatohepatitis (NASH).

"Data from phase 2 studies has provided compelling clinical evidence that warrants further evaluation of efinopegdutide for the treatment of NASH," said Dr. Sam Engel, associate vice president, Merck clinical research, diabetes and endocrinology, Merck Research Laboratories. "We continue to build on our proud legacy of developing meaningful medicines for the treatment of metabolic diseases and look forward to advancing this candidate."

Under the agreement, Merck will be granted an exclusive license to develop, manufacture and commercialize efinopegdutide in the United States and globally. Hanmi will receive an upfront payment of \$10 million and is eligible to receive milestone payments up to \$860 million associated with the development, regulatory approval and commercialization of efinopegdutide, as well as double-digit royalties on sales of approved product. Hanmi retains an option to commercialize efinopegdutide in Korea.

"This licensing agreement supports Hanmi's goals of developing and providing innovative therapies to the patients who need them," said Dr. Se Chang Kwon, CEO and president, Hanmi Pharmaceutical. "We believe that Merck's

strong scientific expertise in metabolic diseases makes it well positioned to advance this candidate forward and maximize its potential for patients around the world.”

About efinopegdutide

Efinopegdutide is a GLP-1/glucagon receptor dual agonist, which activates both the GLP-1 and glucagon receptors. The safety and efficacy of efinopegdutide has previously been evaluated in multiple Phase 1 and Phase 2 clinical trials, including for the treatment of severely obese individuals with and without type 2 diabetes mellitus.

About Merck

For more than 125 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world’s most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit www.merck.com and connect with us on **Twitter**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

About Hanmi Pharmaceutical

Hanmi Pharmaceutical is a Korea-based pharmaceutical company, fully integrated with strong focus in R&D which is strategically designed in 3 major fields: 1) Biologics: LAPSCOVERY platform applied long-acting pipelines. Key targeting areas are diabetes and obesity; 2) NCE: Mainly oncology targeted pipelines; and 3) Fixed-dose combination programs. The company has worked closely with global partners on various co-developments and collaborations. Hanmi continues to further expand through "Open Innovation Strategy" by finding potential partners for innovative solutions.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, 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 products that the products 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 recent 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 2019 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

View source version on [businesswire.com](https://www.businesswire.com/news/home/20200804005172/en/): <https://www.businesswire.com/news/home/20200804005172/en/>

Merck Media:

Pam Eisele

(267) 305-3558

Sienna Choi

(908) 740-1256

Merck Investors:

Peter Dannenbaum

(908) 740-1037

Michael DeCarbo

(908) 740-1807

Source: Merck & Co., Inc.