

Merck & Hanmi to develop, commercialise therapy for NASH

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Merck will be granted an exclusive license to develop, manufacture and commercialize efinopegdutide in the United States and globally to treat nonalcoholic steatohepatitis (NASH).



Merck, and Hanmi Pharmaceutical (Korea-based pharmaceutical company) have 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).

Efinopegdutide (metabolic diseases) 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.

"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.

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. 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," said Dr. Se Chang Kwon, CEO and president, Hanmi Pharmaceutical.