

Merck & Co links up with Lycera in \$300 million deal for autoimmune disease drugs

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Pharma giant Merck & Co (NYSE: MRK) has signed a deal with fellow USA-based drug start-up Lycera Corp to discover, develop and commercialize small molecules that target T-helper 17 (Th17) cells, key mediators of inflammation. The collaboration will focus on developing drug candidates that have the potential to treat major autoimmune diseases such as rheumatoid arthritis, psoriasis, inflammatory bowel disease and multiple sclerosis and could earn Lycera more than \$300 million.

Under the terms of the accord, Lycera will receive \$12 million in upfront cash, significant committed research funding and is eligible to receive up to \$295 million in research, development and regulatory milestone payments if multiple major indications are approved. Lycera is also entitled to up to low double digit tiered royalty payments and sales milestones on global sales from any products that are developed as a result of the collaboration.

“We are delighted to be working with Merck, which brings industry leading expertise in drug discovery, development and commercialization to this collaboration,” said Gary Glick, founder and chief scientific officer of Lycera, which has been without a chief executive since last fall when incumbent Bill Sibold quit. “This joint partnership is a significant validation of Lycera’s discovery capabilities and our Th17 program, and enables us to expand the scope of our research in this promising area to expedite our discovery efforts as well as our timeline to enter the clinic.”

Lycera will collaborate with Merck through an affiliate, on discovery efforts and preclinical development of candidates targeting the retinoic acid related orphan receptor (ROR γ t). Merck is responsible for clinical development and will have worldwide marketing and commercialization rights to any resulting products, subject to a profit share option in the USA retained by Lycera to all products resulting from the collaboration.

Significant unmet needs in autoimmune diseases

“Autoimmune diseases continue to represent a significant unmet medical need globally,” said Don Nicholson, vice president and head of worldwide discovery, Respiratory and Immunology Franchise, Merck Research Laboratories, noting that “Lycera has established a strong reputation for innovation in this area and we look forward to working together to advance this program.”

About 50 million Americans suffer from at least one of these autoimmune disorders, in which “T” cells that normally help us ward off bacterial and viral infections direct their assault against healthy tissues.

Th17 cells are characterized by the production of interleukin-17 (IL-17), a highly inflammatory cytokine that plays an important role in the pathogenesis of immune-mediated diseases, including psoriasis, rheumatoid arthritis, multiple sclerosis, inflammatory bowel disease (colitis) and asthma. ROR γ t is the key transcription factor that orchestrates the differentiation of Th17 cells, inducing transcription of the genes encoding IL-17. Mice with ROR γ t deficient T cells have attenuated disease and lack tissue-infiltrating Th17 cells. Thus, ROR γ t is a key regulator of immune homeostasis and is a potential therapeutic target for immune diseases. Lycera has developed a proprietary program that targets Th17 cells and has identified novel, potent and specific inhibitors of ROR γ t that reduce IL-17 production in primary cells and in vivo.

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