



## Mirum Pharmaceuticals and GC Pharma Enter into Exclusive Licensing Agreement to Develop and Commercialize Maralixibat for Rare Liver Diseases in South Korea

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- GC Pharma to lead development and commercialization in South Korea

- Mirum seeks to expand global availability of maralixibat in rare liver diseases

FOSTER CITY, Calif. & YONGIN, South Korea--(BUSINESS WIRE)--Jul. 26, 2021-- Mirum Pharmaceuticals, Inc. (Nasdaq: MIRM) and GC Pharma (KRX:006280) today announced that they have entered into an exclusive licensing agreement, pursuant to which GC Pharma has agreed to develop and commercialize maralixibat in South Korea. Maralixibat is an investigational, orally administered medication being evaluated in Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA).

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20210726005832/en/>

Maralixibat targets the apical sodium dependent bile acid transporter (ASBT) ultimately resulting in lower levels of bile acids systemically. The U.S. Food and Drug Administration (FDA) has accepted a New Drug Application (NDA) for maralixibat for the treatment of cholestatic pruritus in patients with ALGS under priority review. The European Medicines Agency is reviewing maralixibat for the treatment of PFIC2. Mirum has commenced a global Phase 2b maralixibat study (EMBARK) for the treatment of BA.

Under the terms of the licensing agreement, GC Pharma has obtained the exclusive right to develop and commercialize maralixibat within South Korea for ALGS, PFIC, and BA. In exchange, Mirum is entitled to receive an upfront payment of \$5.0 million as well payments for the achievement of future regulatory and commercial milestones, with tiered double-digit royalties based on product net sales in the region.

"GC Pharma shares a vision for creating and delivering transformative treatments," said Chris Peetz, president and chief executive officer at Mirum. "We are excited about GC Pharma's proven track record commercializing treatments for rare diseases and the potential to pursue an expedited approval pathway for maralixibat for Alagille syndrome in South Korea."

"This collaboration is another significant milestone in delivering our vision for rare disorders," said EC Huh, Ph.D., president of GC Pharma. "We look forward to leveraging our capabilities to explore the development and commercialization of maralixibat."

### About Mirum Pharmaceuticals, Inc.

Mirum Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a late-stage pipeline of novel therapies for debilitating liver diseases. Mirum's lead product candidate, maralixibat, is an investigational oral drug in development for Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia. Mirum has submitted an NDA for maralixibat in the treatment of cholestatic pruritus in patients with ALGS. The NDA has been accepted for priority review by the FDA with a PDUFA action date of September 29, 2021. Additionally, Mirum's marketing authorization application for the treatment of pediatric patients with PFIC2 has been accepted for review (validated) by the European Medicines Agency. Mirum is also developing volixibat, also an oral ASBT-inhibitor, in primary sclerosing cholangitis, intrahepatic cholestasis of pregnancy, and primary biliary cholangitis. For more information, visit [MirumPharma.com](http://MirumPharma.com).

To augment its pipeline in cholestatic liver disease, Mirum has acquired the exclusive option to develop and commercialize gene therapy programs VTX-803 and VTX-802 for PFIC3 and PFIC2, respectively, from Vivet Therapeutics SAS, following preclinical evaluation and investigational new drug-enabling studies.

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### About GC Pharma

GC Pharma is a biopharmaceutical company that delivers life-saving and life-sustaining protein therapeutics and vaccines. Headquartered in South Korea, GC Pharma is the largest plasma protein product manufacturer in Asia and has been dedicated to quality healthcare solutions for more than half a century. Green Cross Corporation updated its corporate brand as GC Pharma in early 2018. Green Cross Corporation remains the company's registered, legal name. For more information, visit [GCcorp.com](http://GCcorp.com).

### Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the potential development and commercialization by GC Pharma of maralixibat in within South Korea for various indications, Mirum's receipt of upfront, milestone and royalty revenue in connection with the license agreement with GC Pharma, as well as the regulatory approval pathway for maralixibat. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "will," "could," "would," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Mirum's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Mirum's business in general, the impact of the COVID-19 pandemic, and the other risks described in Mirum's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release

speaking only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Mirum undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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