



Prometheus Biosciences Achieves Milestone Payment from Dr. Falk Pharma GmbH Further Validating the Prometheus360™ Platform

June 21, 2021

-Prometheus receives \$10 million payment triggered by selection of clinical candidate for PR600-

-IND for PR600 expected in 3Q 2022-

SAN DIEGO, June 21, 2021 (GLOBE NEWSWIRE) -- Prometheus Biosciences, Inc. (Nasdaq: RXDX), a clinical-stage biotechnology company pioneering a precision medicine approach for the discovery, development, and commercialization of novel therapeutic and companion diagnostic products for the treatment of immune-mediated diseases, starting first with inflammatory bowel disease (IBD), today announced it has received a \$10 million milestone payment from Dr. Falk Pharma GmbH under its collaboration agreement to develop and commercialize Prometheus' second program, PR600. Prometheus has selected a clinical candidate for PR600, targeting an undisclosed member of the tumor-necrosis factor superfamily for the treatment of IBD and is initiating IND-enabling studies.

"Partnering with Dr. Falk on PR600 has enabled us to accelerate the PR600 program by sharing costs, resources, and drug development know-how, which has resulted in the achievement of this important milestone within the first year of our collaboration," said Mark McKenna, President and CEO of Prometheus. "We expect to file an Investigational New Drug Application for PR600 in the third quarter of 2022 and plan to explore its utility in other immune-mediated indications beyond IBD."

Under the collaboration agreement, which was executed in July 2020, Prometheus and Dr. Falk will share responsibility for the global development of PR600, with Dr. Falk contributing a certain portion of the external development costs associated with PR600 and its companion diagnostic. Dr. Falk acquired exclusive rights to commercialize PR600 in Europe, Australia and New Zealand, and Prometheus retains exclusive rights to commercialize PR600 in the United States and rest of world.

About Dr. Falk Pharma GmbH

Dr. Falk Pharma GmbH specializes in the development and marketing of pharmaceuticals used in hepatology and gastroenterology. Falk is one of the leading European companies in the field marketing its products by means of subsidiaries in selected countries and a network of sales partners. Further, the Falk Foundation, an independent organization associated with Dr. Falk Pharma, is well-known for its international symposia, forums and educational literature supporting medical doctors, patients and their families.

About Prometheus Biosciences

Prometheus Biosciences, Inc. is a clinical-stage biotechnology company pioneering a precision medicine approach for the discovery, development, and commercialization of novel therapeutic and companion diagnostic products for the treatment and diagnosis of immune-mediated diseases, starting first with IBD. The Company's precision medicine platform, Prometheus360™, combines proprietary bioinformatics discovery methods with one of the world's largest gastrointestinal bioinformatics databases to identify novel therapeutic targets and develop therapeutic candidates to engage those targets. Prometheus is headquartered in San Diego, CA.

Forward Looking Statements

Prometheus cautions readers that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on our current beliefs and expectations. Such forward-looking statements include, but are not limited to statements regarding Prometheus' expected timing to file an IND for PR600, the realization of future cost savings under the collaboration with Dr. Falk, and Prometheus' plans to explore PR600 in other indications beyond IBD. The inclusion of forward-looking statements should not be regarded as a representation by Prometheus that any of our plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: Prometheus' approach to the discovery and development of precision medicines based on Prometheus360 is unproven; potential delays in the commencement, enrollment and completion of preclinical studies and future clinical trials, including due to the COVID-19 pandemic; Prometheus' dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing, and potential supply chain disruptions related to the COVID-19 pandemic; Prometheus' ability to develop a companion diagnostic for PR600; Prometheus may not realize any benefits from our collaboration with Dr. Falk; and other risks described in our prior press releases and filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our most recent quarterly report on Form 10-Q and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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