

Prometheus Biosciences and Dr. Falk Pharma Advance PR600 and Trigger Final Preclinical Milestone Payment

-Investigational New Drug Application for PR600 expected in 3Q 2022-

SAN DIEGO, January 3, 2022 – [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, today announced it has received its final preclinical milestone payment from Dr. Falk Pharma GmbH under its collaboration agreement to develop and commercialize Prometheus' second program, PR600. The milestone was based on Prometheus' development of a proprietary companion diagnostic for the PRA600 program.

"Dr. Falk Pharma has been an excellent partner for us on our PR600 program," said Mark McKenna, Prometheus' Chairman and Chief Executive Officer. "We are excited to initiate this program with its proprietary companion diagnostic in the clinic in 2022 and explore its utility in IBD and potentially other immune-mediated indications."

"It is our goal to find solutions that will ultimately help the millions of people living with inflammatory bowel disease and the Prometheus team has been a strong partner with a differentiated approach to help us exceed that goal," said Roland Greinwald, Ph.D., Managing Director Medicine and Pharmaceuticals, Dr. Falk Pharma. "We are excited to support this clinical candidate now coupled with Prometheus' companion diagnostic technology with the hope that it will enable our partnership to bring precision treatment to patients suffering from IBD."

Prometheus previously disclosed the selection of the clinical candidate and the initiation of IND-enabling studies for the PR600 program, which targets a member of the TNF super-family with a key impact on the function of memory T cells and T follicular helper cells in immune-mediated diseases. The company has since developed a companion diagnostic designed to select for patients with biomarkers that may enable a greater clinical response to PR600 than patients who do not have the relevant biomarkers. Investigational New Drug Application filing for PR600 is expected in the third quarter of 2022.

Under the collaboration agreement, which was executed in July 2020, Prometheus and Dr. Falk Pharma will share responsibility for the global development of PR600, with Dr. Falk Pharma contributing a portion of the external development costs associated with PR600 and its companion diagnostic. As part of the collaboration, Dr. Falk Pharma will be responsible for regulatory approvals and commercialization of any products in the European Union, United Kingdom, Switzerland, the countries of the European Economic Area (excluding Malta and the Republic of Cyprus), Australia and New Zealand. Prometheus will be responsible for regulatory approvals and commercialization in all other areas of the world, including the United States.

"The progress we have made in the PR600 program are a testament to the work executed by our world-class R&D group with the aid of our proprietary Prometheus360™ platform," said Olivier Laurent, Ph.D., Chief Scientific Officer of Prometheus. "We believe that Prometheus360™ gives us the ability to continuously identify novel targets, as well as matching companion diagnostic assays, and helps accelerate our timelines from early discovery and development into the clinic."

About Dr. Falk Pharma GmbH

Dr. Falk Pharma GmbH has been developing and marketing innovative medicines to treat a wide range of gastrointestinal disorders like inflammatory bowel disease or eosinophilic esophagitis as well as hepatobiliary disorders such as primary biliary cholangitis for over 60 years. As the international experts in digestive and metabolic medicine, the company brings together physicians, scientists, and patients to devise new and powerful approaches to patient care. Dr. Falk Pharma engages in pre-clinical and clinical stage

research that aims to meaningfully improve therapeutic practice as well as patient health and well-being. A family-owned business with a global presence, Dr. Falk Pharma has ten affiliates in Europe and Australia and is continuously growing. The company has its headquarters and R&D facilities in Freiburg, Germany, its pharmaceutical products are manufactured in Europe, mainly at sites in Germany, France and Switzerland.

Further information on Dr. Falk Pharma can be found online: <https://drfalkpharma.com>

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 of immune-mediated diseases. The Company's precision medicine platform, Prometheus360™, combines proprietary machine learning-based analytical approaches with one of the world's largest gastrointestinal bioinformatics databases to identify novel therapeutic targets and develop therapeutic candidates to engage those targets.

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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