# Merck Strengthens Immunology Pipeline with Acquisition of Prometheus Biosciences, Inc.

April 16, 2023

**PRA023 is a novel, late-stage candidate for ulcerative colitis and Crohn's disease and other autoimmune conditions**

**Prometheus Biosciences' comprehensive data set enables target discovery and precision medicine approach in inflammation and immunology**

RAHWAY, N.J. and SAN DIEGO, April 16, 2023 (GLOBE NEWSWIRE) -- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Prometheus Biosciences, Inc. ("Prometheus") (Nasdaq: RXDX) today announced that the companies have entered into a definitive agreement under which Merck, through a subsidiary, has agreed to acquire Prometheus for $200.00 per share in cash for a total equity value of approximately $10.8 billion.

"At Merck, we are committed to delivering on our purpose to save and improve lives and continue to identify and secure opportunities where compelling science and value creation align," said Robert M. Davis, chairman and chief executive officer, Merck. "The agreement with Prometheus will accelerate our growing presence in immunology where there remains substantial unmet patient need. This transaction adds diversity to our overall portfolio and is an important building block as we strengthen the sustainable innovation engine that will drive our growth well into the next decade."

Prometheus 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 lead candidate, PRA023, is a humanized monoclonal antibody (mAb) directed to tumor necrosis factor (TNF)-like ligand 1A (TL1A), a target associated with both intestinal inflammation and fibrosis.

"Prometheus was established to revolutionize the treatment of immune-mediated diseases through the application of a powerful precision medicine approach," said Mark McKenna, chairman and chief executive officer of Prometheus Biosciences. "This agreement with Merck, a leader in biopharmaceutical research and development, allows Prometheus to maximize the potential for PRA023, while continuing to apply our technology and expertise to fuel further discoveries to address the needs of patients with immune disorders."

Prometheus is developing PRA023 for the treatment of immune-mediated diseases including ulcerative colitis (UC), Crohn's disease (CD), and other autoimmune conditions. In December 2022, the company announced positive results for PRA023 from ARTEMIS-UC, a Phase 2, placebo controlled, study evaluating safety and efficacy in patients with moderate to severely active UC and APOLLO-CD a Phase 2A, open-label, study evaluating safety and efficacy in patients with moderate to severe CD. The findings were recently presented at the 18th Congress of European Crohn's and Colitis Organisation (ECCO).

"By applying a portfolio of powerful analytic tools to a comprehensive collection of IBD samples, Prometheus identified important disease insights that have now yielded a promising late-stage candidate," said Dr. Dean Y. Li, president, Merck Research Laboratories. "I look forward to working with the talented Prometheus team to establish a new paradigm of precision treatment for immune diseases."

Under the terms of the acquisition agreement, Merck, through a subsidiary, will acquire all of the outstanding shares of Prometheus. The acquisition is subject to Prometheus Biosciences shareholder approval. The closing of the proposed transaction will be subject to certain conditions, including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. The transaction is expected to close in the third quarter of 2023.

A copy of the merger agreement pursuant to the transaction will be filed with the Securities and Exchange Commission ("SEC") and will be publicly available. In addition, Merck and Prometheus will file annual, quarterly and current reports and other information with the SEC, which are available to the public from commercial document-retrieval services and at the SEC's website at www.sec.gov. Copies of the documents filed with the SEC by Merck may be obtained at no charge on Merck's internet website at www.merck.com or by contacting Merck at 126 East Lincoln Avenue P.O. Box 2000, Rahway, NJ 07065 USA, or (908) 740-4000. Copies of the documents filed with the SEC by Prometheus may be obtained at no charge on Prometheus' internet website at https://www.prometheusbiosciences.com or by contacting Prometheus at 3050 Science Park Road, San Diego, CA 92121 or (646) 241-4400.

**Advisors**
Morgan Stanley & Co. LLC acted as financial advisor to Merck in this transaction and Paul, Weiss, Rifkind, Wharton & Garrison LLP as its legal advisors. Centerview Partners LLC and Goldman Sachs & Co. LLC acted as financial advisors to Prometheus and Latham & Watkins LLP as the company's legal advisor.

**About inflammatory Bowel Disease**
Inflammatory bowel disease (IBD) is a term used to collectively describe Crohn's disease and ulcerative colitis. These conditions are characterized by chronic inflammation of the gastrointestinal (GI) tract. Prolonged inflammation results in damage to the tissues lining the GI tract. Both ulcerative colitis and Crohn's disease usually are characterized by diarrhea, rectal bleeding, abdominal pain, fatigue and weight loss.

**About PRA023**
PRA023 is a humanized monoclonal antibody directed to tumor necrosis factor (TNF)-like ligand 1A (TL1A). PRA023 binds both soluble and

membrane associated human TL1A with high affinity and specificity. Prometheus is developing PRA023 for the treatment of immune-mediated diseases including UC, CD, and other autoimmune conditions.

**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**.**

**Investor Call**
Merck will hold an investor call on Monday, April 17, at 8:00 a.m. EDT to discuss this proposed acquisition. Journalists who wish to ask questions are requested to contact a member of Merck's Media Relations team at the conclusion of the call. To listen to the call, please visit https://www.merck.com/investor-relations/events-and-presentations/.

**About Merck**
At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world - and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

**Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA**
This news release of Merck & Co., Inc., Rahway, N.J., USA includes statements that are not statements of historical fact, or "forward-looking statements," including with respect to Merck's proposed acquisition of Prometheus. Such forward-looking statements include, but are not limited to, the ability of Merck and Prometheus to complete the transactions contemplated by the merger agreement, including the parties' ability to satisfy the conditions to the consummation of the merger contemplated thereby and the other conditions set forth in the merger agreement, statements about the expected timetable for completing the transaction, Merck's and Prometheus's beliefs and expectations and statements about the benefits sought to be achieved in Merck's proposed acquisition of Prometheus, the potential effects of the acquisition on both Merck and Prometheus, the possibility of any termination of the merger agreement, as well as the expected benefits and success of Prometheus's product candidates. These statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. There can be no guarantees that the conditions to the closing of the proposed transaction will be satisfied on the expected timetable or at all, with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, uncertainties as to the timing of the merger; the risk that competing offers or acquisition proposals will be made; the possibility that various conditions to the consummation of the merger contemplated thereby may not be satisfied or waived (including the failure to obtain the requisite vote by Prometheus's stockholders); the effects of disruption from the transactions contemplated by the merger agreement and the impact of the announcement and pendency of the transactions on Prometheus's business; the risk that stockholder litigation in connection with the merger may result in significant costs of defense, indemnification and liability; general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2022 Annual Report on Form 10-K and Merck's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

**Forward-Looking Statements of Prometheus Biosciences**
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 Prometheus' current beliefs and expectations. Such forward-looking statements include but are not limited to statements regarding the company's plans to advance PRA023 into Phase 3 trials in UC and CD, including the timing thereof. The inclusion of forward-looking statements should not be regarded as a representation by Prometheus that any of its 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: topline results Prometheus reports are based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial; interim results of a clinical trial do not predict final results and the clinical outcomes may materially change following more comprehensive reviews of the data, as follow-up on the outcome of any particular patient continues and as more patient data become available, including from Cohort 2 of the ARTEMIS-UC trial; potential delays in the commencement, enrollment and completion of clinical trials and preclinical studies; the results of clinical trials are not necessarily predictive of future results; Prometheus' dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; Prometheus' ability to develop diagnostics for its therapeutic product candidates; unexpected adverse side effects or inadequate efficacy of its product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; planned future trials of PRA023 may not support regulatory registration; regulatory developments in the United States and foreign countries; Prometheus' ability to maintain undisrupted business operations due to the COVID-19 pandemic, including delaying or otherwise disrupting its preclinical studies, clinical trials, manufacturing and supply chain; and other risks described in the company's prior press releases and filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Prometheus' most recent annual report on Form 10-K 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 Prometheus undertakes 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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