Provention Bio and Huadong Announce Strategic Collaboration to Develop and Commercialize PRV-3279 in Greater China

- Provention Bio to receive $6 million upfront payment; up to $11.5 million in research, development and manufacturing funding; and up to $172 million in potential development, regulatory and commercial milestone payments -

RED BANK, N.J., Feb. 17, 2021 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd., today announced that the companies have entered into a strategic collaboration to develop and commercialize PRV-3279, a DART® (bispecific antibody-based molecule) targeting the B cell surface proteins CD32B and CD79B, in Greater China (mainland China, Hong Kong, Macau and Taiwan). Provention Bio will retain all rights to PRV-3279 in the rest of the world.

This collaboration provides Provention Bio access to the second largest pharmaceutical market in the world via Huadong's development, regulatory, and commercial capabilities. PRV-3279 represents the addition of an exciting autoimmune asset to Huadong's growing autoimmunology portfolio. Provention Bio plans to begin a Phase 2a trial of PRV-3279 in systemic lupus erythematosus (SLE) in the second half of 2021 and expects a portion of such trial to be conducted in China.

"Huadong's extensive development and commericalization experience in the Greater China region along with their strategic goal of being a leader in the autoimmune therapeutic space created the opportunity for a strong, strategic and mutually beneficial partnership between our two companies," stated Ashleigh Palmer, CEO and co-founder of Provention Bio. "This collaboration is a reflection of PRV-3279's potential to intercept and prevent life-altering and life-threatening autoimmune diseases and we look forward to working closely with Huadong to develop and commercialize PRV-3279 in Greater China as we simultaneously further the development of the program in the rest of the world."

"Provention Bio is a well regarded biopharmaceutical company innovating to intercept and prevent serious autoimmune disorders. PRV-3279 has the potential to intercept SLE disease progression and improve the quality of life of people living with SLE," added Liang Lu, Chairman of Huadong Medicine. "The SLE patient population is substantial in China, with very few treatment options. Leveraging Huadong's clinical and regulatory capabilities, we will work closely with Provention Bio to accelerate the clinical development of PRV-3279 in Greater China, to benefit SLE patients as soon as possible."

Under the terms of the agreement, Provention Bio will receive an upfront payment of $6 million, and up to $11.5 million in funding over the next three years to cover costs anticipated to be incurred by Provention Bio in connection with research, development and manufacturing activities. Provention Bio is eligible to receive additional milestone payments of up to $172 million if certain regulatory and commercial objectives are achieved. Provention Bio is also eligible to receive low-to-mid double digit royalties as a percentage net sales of PRV-3279 by Huadong in Greater China.

Huadong will be primarily responsible for development and commercialization of PRV-3279 in Greater China with the oversight of a joint steering committee comprised of individuals from both companies. Provention Bio will continue to be responsible for the development and commercialization of PRV-3279 in the United States and other geographies.

About PRV-3279:

PRV-3279 is a humanized diabody (a bispecific DART molecule) targeting the B cell surface proteins, CD32B and CD79B. Simultaneous engagement of the CD32B and CD79B receptors triggers inhibition of B cell function and suppression of autoantibody production, thereby regulating B cells without causing depletion. Provention is initially developing PRV-3279 for the interception of systemic lupus erythematosus (SLE), a chronic autoimmune disorder characterized by an abnormal overactivation of B cells and subsequent pathologic production of auto-antibodies. PRV-3279 also has the potential to prevent or reduce the immunogenicity of biotherapeutics, including but not limited to gene therapy vectors and transgenes.

About Provention Bio, Inc.:

Provention Bio, Inc. (Nasdaq: PRVB) is a biopharmaceutical company focused on advancing the development of investigational therapies that may intercept and prevent debilitating and life-threatening immune-mediated diseases. The Biologics License Application (BLA) for teplizumab, its lead investigational drug candidate, for the delay or prevention of clinical type 1 diabetes in at-risk individuals has been filed by the U.S. Food and Drug Administration (FDA). The Company's pipeline includes additional clinical-stage product candidates that have demonstrated in pre-clinical or clinical studies proof-of-mechanism and/or proof-of-concept in other autoimmune diseases, including celiac disease and lupus. Visit www.ProventionBio.com for more information and follow us on Twitter: @ProventionBio.

About Huadong Medicine:

Huadong Medicine Co., Ltd. (SZ.000963) is a leading Chinese pharmaceutical company based in Hangzhou, China. Founded in 1993, Huadong Medicine has fully integrated R&D, manufacturing, distribution, sales and marketing capabilities. Huadong Medicine's product portfolio and pipeline are specialized in oncology, immunology, nephrology and diabetes. The Company's annual revenue in 2019 exceeded 5 billion USD. Huadong Medicine has 12,000 employees, and one of the most extensive commercial coverage and marketing capabilities in China. 'Patient Centered, Science Driven' is Huadong's value. For additional information, please visit www.eastchinapharm.com/en.

Internet Posting of Information:

Provention Bio, Inc. uses its website, www.proventionbio.com, as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation F.D. Such disclosures will be included on the Company's website in the "News" section. Accordingly, investors should monitor this portion of the Company's website, in addition to following its press releases, SEC filings and public conference calls and webcasts.

Forward Looking Statements:

Certain statements in this press release are forward-looking, including but not limited to, statements relating to the Company's studies, the potential safety, health benefits of and planned research and development efforts for PRV-3279. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Provention's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to delays in, or failure to obtain FDA or comparable foreign regulatory approvals or clearances and noncompliance with FDA of comparable foreign agency regulations; the potential impacts of COVID-19 on our business and financial results; changes in law, regulations, or interpretations and enforcement of regulatory guidance; uncertainties of patent protection and litigation; dependence upon third parties; substantial competition; our need for additional financing and the risks listed under "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2019, our quarterly reports on form 10-Q, and any subsequent filings with the Securities and Exchange Commission. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Provention does not undertake an obligation to update or revise any forward-looking statement. The information set forth herein speaks only as of the date hereof.

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