Provention Bio Announces Extension of FDA User Fee Goal Date for Teplizumab to November 17, 2022

RED BANK, N.J., June 30, 2022 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB) (the "Company"), a biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today announced that the U.S. Food and Drug Administration (FDA) has extended its review period by three months for the Biologics License Application (BLA) for teplizumab. The extended User Fee Goal date is November 17, 2022.

The Company was also informed that if no major deficiencies are identified during the review period, the FDA plans to communicate proposed labeling and, if necessary, any post-marketing requirement or commitment requests by October 17, 2022.

As part of its ongoing review and communications, the FDA informed the Company yesterday that it considers a timely response to an information request made earlier this month to be a Major Amendment to the BLA resubmission, requiring additional time for the Agency's review.

"We are committed to collaborating closely with the Agency as it completes its review," said Ashleigh Palmer, Co-Founder and CEO of Provention Bio. "We want to thank the FDA for its continued diligence as we continue to work towards bringing this potential first disease modifying therapy to patients with type 1 diabetes in the United States, for whom there is currently no approved treatment other than a life-time of exogenous insulin therapy."

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 BLA for teplizumab, its lead investigational drug candidate, for the delay of progression to Stage 3 clinical type 1 diabetes in at-risk individuals has been filed by the 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.

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 medical need in T1D at-risk patients, the potential therapeutic effects and safety of teplizumab in at-risk T1D patients, FDA's review of the BLA resubmission, including label negotiations, and potential for approval of teplizumab and potential regulatory and commercialization timelines. These statements may be identified by the use of forward-looking words such as "may," among others. These forward-looking statements are based on the Company'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 FDA disagreeing with the Company's interpretation of data and analysis and information in the BLA resubmission; delays in or failure to obtain FDA approvals for teplizumab or other Company product candidates and the potential for noncompliance with FDA regulations; any inability to successfully work with FDA to address its concerns and requests in a timely manner or at all during the review process for teplizumab, including any inability to provide the FDA with data, analysis or other information sufficient to support an approval of the BLA for teplizumab; any inability to satisfactorily address matters PK comparability, product quality, safety or any other FDA requirements during the BLA review process to obtain an approval of teplizumab; 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; the Company's dependence upon third parties; substantial competition; the Company's need for additional financing and the risks listed under "Risk Factors" in the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2022 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, whether as a result of new information, future developments or otherwise, except as may be required by applicable law. The information set forth herein speaks only as of the date hereof.

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