Provention Bio Announces U.S. FDA Filing of a Biologics License Application (BLA) and Priority Review for Teplizumab for the Delay or Prevention of Clinical Type 1 Diabetes in At-risk Individuals

-FDA sets PDUFA goal date of July 2, 2021-

-If approved, teplizumab will be the first disease-modifying therapy for type 1 diabetes-

RED BANK, N.J., Jan. 4, 2021 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a biopharmaceutical company dedicated to intercepting and preventing immune-mediated disease, today announced that the Biologics License Application (BLA) for teplizumab for the delay or prevention of clinical type 1 diabetes (T1D) in at-risk individuals has been filed by the U.S. Food and Drug Administration (FDA). The FDA also granted Provention's request for Priority Review and assigned a user fee goal date of July 2, 2021, under the Prescription Drug User-Fee Act (PDUFA).

"The FDA's acceptance of our BLA represents a significant achievement for Provention Bio in our mission to deliver the first potential disease-modifying T1D therapy and drive a paradigm shift in how individuals at risk of developing the disease are treated," stated Ashleigh Palmer, CEO and Co-Founder, Provention Bio. "We intend to work closely with the FDA to support their review while also preparing for a potential product launch in the third quarter of 2021."

In its acceptance letter, the FDA stated that it is currently planning to hold an advisory committee meeting, tentatively scheduled for May 27, 2021.

Priority Review is afforded to drugs that, if approved, would represent a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. Under the PDUFA, a Priority Review targets a review time of six months compared to a standard review time of ten months. The FDA previously granted teplizumab Breakthrough Therapy Designation.

About Teplizumab (PRV-031):

Teplizumab is an investigational anti-CD3 monoclonal antibody (mAb) with a filed BLA under Priority Review by the FDA for the delay or prevention of clinical T1D in at-risk individuals. More than 800 patients have received teplizumab in multiple clinical studies involving more than 1,000 subjects. In previous studies of newly diagnosed patients, teplizumab consistently demonstrated the ability to preserve beta-cell function, a measure of endogenous insulin production, and correspondingly reduced the need for exogenous insulin use. Teplizumab has been granted Breakthrough Therapy Designation by the FDA and PRIME designation by the European Medicines Administration. Provention Bio has submitted a Biologic License Application (BLA) to the FDA for teplizumab for the delay or prevention of clinical type 1 diabetes in at-risk individuals. Provention is currently also evaluating teplizumab in patients with newly diagnosed insulin-dependent T1D (the Phase 3 PROTECT study).

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 disease. The Company has submitted a Biologics License Application (BLA) to the FDA for its lead investigational drug candidate, teplizumab, for the delay or prevention of clinical type 1 diabetes in at-risk individuals. 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 FD. 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 regulatory review of the BLA submission for teplizumab and the potential approval and commercial launch of teplizumab, including timelines relating to the same and the potential therapeutic effects of teplizumab and the Company's product candidates. 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 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 delays in, or failure to obtain FDA approvals for teplizumab or other Company product candidates and the potential for noncompliance with FDA 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; 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 annual report on Form 10-K for the year ended December 31, 2019, 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, 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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