Provention Bio Completes Rolling Submission of the Biologics License Application (BLA) for Teplizumab for the Delay or Prevention of Clinical Type 1 Diabetes in At-risk Individuals

- Submission of chemistry, manufacturing and controls (CMC) and administrative information modules represent completion of the Company's BLA submission for teplizumab -

RED BANK, N.J., Nov. 2, 2020 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a biopharmaceutical company dedicated to intercepting and preventing autoimmune disease, today announced the completion of the rolling submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for teplizumab for the delay or prevention of clinical type one diabetes (T1D) in at-risk individuals with the submission of the chemistry, manufacturing and controls (CMC) and administrative information modules.

The FDA has 60 days to review the final submission to determine if the BLA is complete. If deemed complete, the application will be considered acceptable for filing and review, and the FDA will set a PDUFA goal date.

In August 2019, teplizumab was granted Breakthrough Therapy Designation (BTD) by the FDA. As afforded by the BTD, Provention has expressly requested a Priority Review in conjunction with the completion of the final submission. A Priority Review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review). If approved by FDA, Teplizumab has the potential to be the first disease-modifying therapy for T1D.

"Our submission of the final modules of the rolling BLA represents a significant milestone for Provention Bio and a critical step toward the potential first major advancement in T1D therapeutics since insulin was introduced a century ago," stated Ashleigh Palmer, CEO and Co-Founder, Provention Bio. "We are extremely grateful to the entire Provention team and our key clinical, regulatory and manufacturing partners, as we could not have achieved this goal without their tireless dedication and determination. We look forward to continuing on our path toward changing the current treatment paradigm for T1D and, if approved, bringing teplizumab, designated by the FDA as a Breakthrough Therapy, to the U.S. market in 2021."

About Teplizumab (PRV-031):
Teplizumab is an anti-CD3 monoclonal antibody (mAb) being developed for the delay or prevention of type 1 diabetes (T1D). 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 U.S. Food and Drug Administration (FDA) and PRIME designation by the European Medicines Administration. Provention Bio has completed a rolling submission of the Biologic License Application 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 BLA to the FDA for its lead investigational drug candidate, teplizumab, for the delay or prevention of clinical type 1 diabetes (T1D) 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 or follow us on Twitter: @Proventiobio

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, the potential therapeutic effects of teplizumab and the Company's business plans. 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 or clearances for teplizumab 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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