Provention Bio Provides Regulatory Update on Biologics License Application for Teplizumab for the Delay or Prevention of Clinical Type 1 Diabetes in At-Risk Individuals

- Conference call and webcast to be held today at 5:00 p.m. Eastern Time -

RED BANK, N.J., April 8, 2021 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a biopharmaceutical company dedicated to intercepting and preventing immune-mediated disease, today announced that the Company received a notification on April 2, 2021 from the U.S. Food and Drug Administration (FDA), stating that, as part of its ongoing review of the Company's Biologic License Application (BLA) for teplizumab for the delay or prevention of clinical type 1 diabetes, the FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time. The FDA stated in the correspondence that the notification does not reflect a final decision on the information under review.

Additionally, during an informal discussion on April 2, 2021 regarding the agenda for the upcoming Advisory Committee meeting scheduled for May 27, 2021, the FDA informed the Company that it had completed its review of the data and analysis submitted by the Company for its single, low-dose pharmacokinetic/pharmacodynamic (PK/PD) bridging study conducted in healthy volunteers. This study evaluated the PK/PD comparability of drug product originating from drug substance manufactured by AGC Biologics, which the Company plans to use for commercialization, and drug product originating from historic drug substance manufactured by Eli Lilly used for the TN-10 study submitted for the teplizumab BLA. The FDA indicated that based on the data it has reviewed to date, the Agency's position is that the PK profiles of the two drug products evaluated in the PK/PD bridging study were not comparable and that additional data would be required before the FDA's considerations could be satisfied. As a follow up, today, the FDA stated to the Company that it is willing to discuss these issues concurrently with its ongoing review.

The FDA intends to continue the review of clinical data submitted in the BLA and to conduct the Advisory Committee meeting, scheduled on May 27, 2021.

"While we believe the FDA's initial feedback will likely result in a delay in timelines within which teplizumab has the potential to be approved by FDA and be made available for at-risk T1D patients, we believe in the comparability of the drug product produced by our partner AGC biologics with Eli Lilly manufactured product. We look forward to working closely with the Agency to address its additional data requirement, so we can deliver teplizumab to patients as soon as possible," said Ashleigh Palmer, CEO and Co-Founder, Provention Bio. "Additionally, we remain enthusiastic about the clinical efficacy and safety data submitted in connection with the BLA in support of teplizumab's potential to address the high unmet needs of at-risk T1D patients and look forward to meeting with the FDA's Advisory Committee and hearing from patients, KOLs and other key stakeholders next month."

Conference Call and Webcast Information:

Provention Bio will discuss these business updates via conference call today at 5:00 pm ET. To access the call, please dial 1-877-870-4263 (domestic) or 1-412-317-0790 (international) ten minutes prior to the start time and ask to be connected to the "Provention Bio Call". An audio webcast will also be available on the "Events and Webcasts" page of the Investors section of the Company's website, www.proventionbio.com. An archived webcast will be available on the Company's website approximately two hours after the conference call.

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 type 1 diabetes (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. It 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 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 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.

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 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 and safety of teplizumab. 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, 2020 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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