# Provention Bio Resubmitting Biologics License Application for Delay of Clinical Type 1 Diabetes in At-Risk Individuals Following Type B Meeting with the FDA

**- Company to Host Conference Call Tomorrow, January 28th at 8:00 AM ET -**

RED BANK, N.J., Jan. 27, 2022 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB) (the "Company"), a biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today announced its intent to resubmit the teplizumab Biologics License Application (BLA) for the delay of clinical type 1 diabetes in at-risk individuals following its Type B pre-BLA resubmission meeting with the U.S. Food and Drug Administration (FDA).

The purpose of the Type B pre-BLA resubmission meeting was to discuss FDA feedback and obtain agreement on Provention's proposed clinical pharmacology data package, including data and analysis from the pharmacokinetic/pharmacodynamic (PK/PD) substudy completed by the Company to address the FDA's PK comparability considerations contained in the complete response letter (CRL) issued last July. In preliminary meeting comments, the FDA noted that the data package presented does not adequately support PK comparability because predicted primary PK parameters are indicative of a lower exposure. To address this concern, the FDA proposed, and the Company agreed, to use PK modeling to adjust the 14-day dosing regimen for the planned commercial product to match the exposure of clinical material used in prior clinical trials by ensuring that the 90% confidence intervals for relevant PK parameters fall within the target 80-125% range. On this basis, the FDA agreed that Provention could proceed to resubmit the BLA.

Based on the Company and FDA's agreed upon PK modeling, and the Company's experience with various doses and regimens tested in prior clinical trials, the Company will propose in the BLA resubmission a modified 14-day course of therapy to address the FDA's comparability considerations. The BLA resubmission will also include responses to address the CRL's Chemical, Manufacturing, and Controls (CMC) and product quality considerations, as agreed with the FDA at a Type A meeting held in August last year. The Company believes it will be in a position to resubmit the BLA in the first quarter.

"We are very pleased and excited to be working towards resubmitting the teplizumab BLA, taking the FDA's feedback into account, which gets us another step closer to our goal of delivering teplizumab to individuals and their families who are at risk of developing end-stage, insulin-dependent type 1 diabetes," said Ashleigh Palmer, Co-Founder and CEO of Provention Bio. "We could not be more appreciative of the high level of collaboration and guidance we've experienced throughout this regulatory review process under the FDA's Breakthrough Therapy Designation (BTD). We look forward to re-submitting the BLA as soon as possible and facilitating the FDA's review and decision-making. We continue to prepare the Company for a potential launch of teplizumab with prudently gated spending and planning."

Under applicable FDA guidelines, the FDA has 30 days to review the BLA resubmission, determine whether it is complete and acceptable for review, and provide the due date for action. Under BTD and Priority Review designation, the FDA's guidance is to complete its review within 6 months of the BLA resubmission date.

**Conference Call and Webcast Information:**

Provention Bio will discuss these updates results via conference call tomorrow, Friday, January 28, 2022 at 8:00 am ET. To access the call, please dial 1-888-347-7861 (domestic) or 1-412-902-4247 (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 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's pipeline includes clinical-stage product candidates that have demonstrated in pre-clinical or clinical studies proof-of-mechanism and/or proof-of-concept in autoimmune diseases, including type 1 diabetes, 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, the Company's plans to incorporate FDA feedback into and re-file the BLA for teplizumab, its ability to successfully address the FDA's PK comparability considerations, the timing of the BLA resubmission and FDA's review and teplizumab's potential approval and commercialization timeline. These statements may be identified by the use of forward-looking words such as "will," "believe," and "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; 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 find a satisfactory solution to address its concerns in a timely manner or at all, 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 cited in the CRL including relating to PK comparability, product quality, the safety update required by FDA or any other FDA requirements for 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 September 30, 2021 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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