Provention Bio Announces FDA Acceptance of the Biologics License Application (BLA) Resubmission for Teplizumab for the Delay of Clinical Type 1 Diabetes in At-Risk Individuals

- FDA Sets Goal Date of August 17, 2022-
-If Approved Teplizumab will be the First Disease-Modifying Therapy for Type 1 Diabetes -

RED BANK, N.J., March 21, 2022 — Provention Bio, Inc. (Nasdaq: PRVB) (the "Company"), a biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today announced that the resubmitted Biologics License Application (BLA) for teplizumab for the delay of clinical type 1 diabetes (T1D) in at-risk individuals has been considered a complete, class 2 response to the July 2021 action letter by the U.S. Food and Drug Administration (FDA). The FDA has assigned a user fee goal date of August 17, 2022. The FDA previously granted teplizumab Breakthrough Therapy Designation.

"We are delighted to have received the Agency's acceptance of our BLA resubmission as a complete response to the July 2021 CRL and are excited to have taken yet another significant step towards the potential approval of teplizumab for at-risk T1D individuals as the first ever disease-modifying therapy to delay the onset of this debilitating and life-threatening disease," said Ashleigh Palmer, Co-Founder and CEO of Provention Bio. "Today's announcement is the result of tremendous dedication and hard work by our team, in conjunction with our collaborative and constructive interactions with the FDA which we look forward to continuing through the ongoing review process."

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, FDA's review of the BLA resubmission and potential for approval of teplizumab and potential regulatory 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 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-K for the year ended December 31, 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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