Provention Bio Reiterates Regulatory Guidance for PRV-031 (Teplizumab) Following Meeting with the FDA

Expects to Complete Submission of a BLA for PRV-031 (Teplizumab) in Q4 2020

Company to Host Conference Call at 8:30 AM Eastern Time

OLDWICK, N.J., Dec. 12, 2019 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a clinical stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today announced that it completed a Type B multidisciplinary meeting with the U.S. Food and Drug Administration (FDA) to discuss the proposed contents of a Biologics License Application (BLA) for PRV-031 (teplizumab) for the prevention or delay of type 1 diabetes (T1D) in individuals at-risk of developing T1D. Based on official FDA meeting minutes, Provention continues to expect that it will commence a rolling BLA submission for PRV-031 in the middle of 2020 and is targeting completion of the submission in the fourth quarter of 2020. The Company does not anticipate the need to conduct any additional clinical trials in the at-risk population prior to BLA submission.

"Our discussion with the FDA was extremely productive, and reinforces our confidence in the strength of our existing clinical, pre-clinical, and safety data packages and our ability to proceed with our BLA submission as planned," stated Ashleigh Palmer, CEO, Provention Bio. "Consistent with the advantages afforded to us by the Breakthrough Therapy designation for PRV-031, our discussion with the FDA also focused on how to facilitate a rolling submission of the various BLA modules, including the chemistry, manufacturing and controls (CMC) module. We are now focused on preparing the clinical and pre-clinical modules for anticipated submission by the middle of 2020. In parallel, we are undertaking necessary steps to demonstrate comparability of to-be-commercialized material with that previously used in clinical studies and, thereafter, expect to submit our CMC module in the fourth quarter of 2020. We look forward to continuing to work closely with the FDA as we prepare our submission for this groundbreaking therapy."

For the CMC module, the FDA confirmed that it would require the demonstration of comparability between the study drug previously manufactured by MacroGenics and Eli Lilly and the to-be-commercialized drug substance and drug product scheduled for production by Provention and its contract manufacturing partners.

The Type B meeting discussion with the FDA continues to support Provention's belief that results from the "At-Risk" study, together with adequate confirmatory evidence from prior teplizumab studies in early onset T1D, will be sufficient for a BLA submission. The FDA provided guidance on specific analyses of data from the Company's clinical database of over 800 patients for inclusion in the BLA submission, specifically the impact of PRV-031 on C-peptide levels in T1D patients. C-peptide is a byproduct of endogenous insulin production and a universally accepted measure of the amount of insulin naturally produced by functional beta cells in the pancreas.

The FDA also confirmed that the safety database from the "At Risk" study and prior teplizumab clinical studies in patients with early onset T1D appears adequate to support the submission and review of a BLA.

Conference Call and Webcast Information
Provention Bio will discuss the PRV-031 regulatory update via conference call today, Thursday, December 12, 2019 at 8:30 am ET. A webcast presentation will also be available on the Investors page of the Company's website, www.proventionbio.com. To access the call, please dial 1-877-870-4263 (domestic) or 1-412-317-0790 (international) five minutes prior to the start time and ask to be connected to the "Provention Bio Call". A webcast replay of the call will be available beginning at approximately 10:30 am ET on the day of the call.

About Provention Bio, Inc.
Provention Bio, Inc. (Nasdaq: PRVB) is a clinical-stage biopharmaceutical company leveraging a transformational drug development strategy that is focused on the prevention or interception of immune-mediated disease. Provention's mission is to in-license, transform and develop therapeutic candidates targeting the high morbidity, mortality and escalating costs of autoimmune and inflammatory diseases including: type 1 diabetes (T1D), celiac disease and lupus. Provention's diversified portfolio includes advanced-stage product development candidates that have undergone clinical testing by other companies.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995, including statements related to timing of submission of the BLA. 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 Provention'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 failure to obtain FDA approvals or clearances and noncompliance with FDA regulations; uncertainties of patent protection and litigation; limited research and development efforts and dependence upon third parties; substantial competition; our need for additional financing and the risks listed under "Risk factors" in our annual report on Form 10-K for the year ended December 31, 2018 and any subsequent filings with the Securities and Exchange Commission (SEC). 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. The information set forth herein speaks only as of the date hereof.

Investors:
Sam Martin, Argot Partners
sam@argotpartners.com
212-600-1902

Media:
David Rosen, Argot Partners
david.rosen@argotpartners.com
212-600-1902

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