Provention Bio Reiterates Regulatory Strategy for PRV-031 and Announces Completion of Follow-on Financing

- FDA Meeting Expected in Q4 2019 and BLA Submission for PRV-031 (teplizumab) Targeted for Q4 2020 -
- Total Net Proceeds of $62.7 million from Recent Offerings, Together with Current Cash Position, Expected to Fund Operations for Two Years -

OLDWICK, N.J., Sept. 24, 2019 /PRNewswire/ -- Provention Bio, Inc., (Nasdaq: PRVB), a clinical-stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today reiterated its regulatory strategy regarding PRV-031 (teplizumab) for the prevention or delay of clinical type 1 diabetes (T1D) in individuals at-risk of developing the disease. Based on written communications from the U.S. Food and Drug Administration (FDA) and FDA's designation of PRV-031 as a breakthrough therapy, the Company believes that existing clinical and non-clinical data for PRV-031 will be sufficient to support a Biologics License Application (BLA) submission for PRV-031 in the fourth quarter of 2020 for the at-risk indication. The Company expects to meet with the FDA in the fourth quarter of 2019 to discuss this expedited development plan.

"Our interactions with the FDA in connection with the 'At Risk' study of PRV-031 (teplizumab) provide us with the confidence to submit a regulatory filing by the end of 2020," stated Ashleigh Palmer, CEO of Provention Bio. "The proceeds from our financing will allow us to execute on our development plans as we work closely with the FDA to bring teplizumab to individuals at-risk of developing clinical T1D."

In the second quarter of 2019, the Company exchanged correspondence with the FDA regarding the regulatory path forward for PRV-031 for the prevention or delay of clinical T1D in individuals at-risk for developing the disease. Specifically, the FDA:

- Agreed, in principle, that the results from the "At-Risk" study, together with supportive data from prior PRV-031 studies in early onset T1D, may be sufficient for a BLA submission.
- Agreed that the safety database from the "At Risk" study and prior clinical studies in patients with early onset T1D appears adequate to support review of a BLA.
- Agreed that the current non-clinical package for PRV-031 is adequate to support the At-Risk indication.

In a later letter granting Breakthrough Therapy Designation (BTD), the FDA asked the Company to meet for a multidisciplinary, comprehensive discussion of the Company's PRV-031 program, including plans for expediting the manufacturing development strategy.

In connection with the Company's follow-on financing and private placement announced last week, the Company generated total net proceeds of $62.7 million. The net proceeds reflect an underwritten public offering of 5,750,000 shares of common stock at a price of $8.00 per share, including the full exercise of the over-allotment option, as well as the issuance of 2,500,000 shares of common stock at a price of $8.00 per share in a private placement with Amgen, Inc.

The net proceeds from the financing, together with its current cash position, are expected to fund the Company's operations for two years.

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), Crohn's disease, 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 but not limited to, statements relating to the Company's studies. 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. 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.

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