Provention Bio Reports Third Quarter 2020 Financial Results and Provides Business Update

- Completed rolling submission of the Biologics License Application (BLA) for teplizumab in the delay or prevention of clinical type 1 diabetes (T1D) in at-risk individuals -

- Launched two closely-aligned national T1D early-stage disease and screening education campaigns -

RED BANK, N.J., Nov. 5, 2020 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a biopharmaceutical company dedicated to intercepting and preventing autoimmune disease, today reported financial results for the third quarter ended September 30, 2020, and provided a business update.

"We are excited about the progress the Provention Bio team has made in recent months as we work to redefine the treatment landscape for T1D and other autoimmune diseases," stated Ashleigh Palmer, CEO, Provention Bio. "Earlier this week, we announced our achievement of a major milestone with the completion of the rolling BLA submission for teplizumab for the delay or prevention of clinical T1D in at-risk individuals. In parallel with our regulatory efforts, we are focused on preparing for a potential product approval and launch in mid-2021. We recently introduced two national campaigns to educate key stakeholders about early-stage T1D and the potential advantages of screening populations at risk of developing clinical-stage disease. In parallel with teplizumab, we are advancing our portfolio of additional therapeutic candidates targeting the interception or prevention of autoimmune disease. We recently initiated a Phase 2 trial for PRV-015, an anti-IL-15 human monoclonal antibody which, if approved, has the potential to be the first therapeutic for the treatment of non-responsive celiac disease."

Third Quarter 2020 and Recent Corporate Highlights:

Completed Rolling Submission of the Biologics License Application (BLA) to the FDA for Teplizumab for the Delay or Prevention of Clinical T1D in At-risk Individuals

Earlier this week, Provention announced the completion of the rolling submission of a BLA to the U.S. Food and Drug Administration (FDA) for teplizumab for the delay or prevention of clinical T1D in at-risk individuals with the submission of the chemistry, manufacturing and controls (CMC) and administrative information modules. In September, the Company announced submission of the clinical module. The FDA has 60 days to review the final submission to determine if the BLA is complete. If deemed complete, the submission will be considered acceptable for filing and review, and the FDA will set a PDUFA goal date. Provention has expressly requested a Priority Review in conjunction with the submission. A Priority Review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review).

Commenced National Type 1 Diabetes Campaigns Focused on Screening and Disease State Education

In October, Provention announced two closely aligned early-stage disease and screening education campaigns, "Connected by T1D" and "Type 1 Tested", focused on creating awareness of the importance of screening individuals at disproportionate risk due to having a family member(s) with T1D. Early and routine autoantibody screening is the call-to-action in each campaign with the goal of doctors, patients and families making more informed decisions that may decrease the likelihood of diabetic ketoacidosis (DKA) and other risks.

Initiated Phase 2b PROACTIVE Study of PRV-015 (anti-IL-15) in Non-responsive Celiac Disease (NRCD)

In August 2020, Provention announced the initiation of the Phase 2b PROACTIVE (**PRO**vention **A**mgen **C**eliac Protec**TIVE**) study of PRV-015 which is being developed under an agreement with Amgen. The placebo-controlled, double-blind, randomized study will examine the efficacy and safety of three dose levels of PRV-015 as compared to placebo in approximately 220 adults with NRCD.

Appointed John K. Jenkins, MD to the Board of Directors

In August 2020, Provention announced the appointment of John K. Jenkins MD, the former Director of the Office of New Drugs at the FDA's Center for Drug Evaluation and Research (CDER), to the Company's Board of Directors. Dr. Jenkins currently serves as Principal, Drug and Biological Products for Greenleaf Health, an FDA-focused strategic regulatory consulting firm, where he offers extensive experience guiding companies through regulatory processes.

Successfully Completed Commercial-Scale PPQ Runs

In August 2020, Provention announced the completion of three back-to-back, commercial scale, drug substance process performance qualification (PPQ) batches at AGC Biologics, the Company's contract manufacturer. These batches served as a foundation for the CMC module of the recently completed BLA submission.

Financial Highlights:

Net loss for the third quarter 2020 was $31.3 million, or $0.56 per basic and diluted share, compared to a net loss of $9.8 million, or $0.24 per basic and diluted share, for the same period in 2019. The increase in net loss was primarily attributable to teplizumab related CMC costs, PROTECT study costs, BLA preparation costs, precommercial costs, and medical affairs expenses.

As of September 30, 2020, Provention had cash, cash equivalents and marketable securities of $147.2 million. Cash-based operating expenses were $28.7 million for the three months ended September 30, 2020 and included teplizumab CMC expenses of $8.5 million and $6.0 million of precommercial expenses. Provention expects to utilize $24 million to $28 million of cash for its operating needs in the fourth quarter of 2020.

Conference Call and Webcast Information:

Provention Bio will discuss these business updates and third quarter financial results via conference call today at 8:00 am ET. To access the call, please dial 1-866-682-6100 (domestic) or 1-862-298-0702 (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 and will be available for seven days following the 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 has submitted a BLA to the FDA for its lead investigational drug candidate, teplizumab, for the delay or prevention of clinical type 1 diabetes (T1D) in at-risk individuals. 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 or follow us on Twitter: @Proventiobio

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 FD. 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, the potential therapeutic effects of teplizumab and the Company's product candidates, the Company's expected operating expenses for the fourth quarter and the Company's financial and other business plans, including further development and clinical trial plans for its other product candidates.. 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 or clearances 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, 2019, quarterly reports on form 10-Q, 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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Provention Bio, Inc.
Selected Financial Data (unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 21,657	$ 7,324	$ 45,779	$ 27,896
General and administrative	9,749	2,649	21,288	5,593
Total operating expenses	31,406	9,973	67,067	33,489
Loss from operations	(31,406)	(9,973)	(67,067)	(33,489)
Interest income	105	204	539	744
Loss before income tax benefit	(31,301)	(9,769)	(66,528)	(32,745)
Income tax benefit	—	—	523	—
Net loss	$ (31,301)	$ (9,769)	$ (66,005)	$ (32,745)
Net loss per common share, basic and diluted	$ (0.56)	$ (0.24)	$ (1.29)	$ (0.85)
Weighted average common shares outstanding, basic and diluted	56,339	40,512	51,098	38,424

	September 30, 2020	December 31, 2019
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 147,158	$ 85,373
Total assets	$ 151,803	$ 85,996
Total liabilities	$ 16,404	$ 3,840
Accumulated deficit	$ (145,066)	$ (79,061)
Total stockholders' equity	$ 135,399	$ 82,156

SOURCE Provention Bio, Inc.
