Provention Bio Reports Third Quarter 2019 Financial Results

- PRV-031 (teplizumab) Granted Breakthrough Therapy and PRIME Designations -
- Meeting with FDA for PRV-031 (Teplizumab) Scheduled for Fourth Quarter 2019; BLA Submission Targeted for Fourth Quarter 2020 -
- Strong Cash Balance of $95.1 Million as of September 30, 2019 -

OLDWICK, N.J., Nov. 5, 2019 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a clinical stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today reported financial results for the third quarter ended September 30, 2019.

"The PRV-031 program continues to build momentum, with positive developments on the regulatory front that strengthen our confidence in the path forward for the prevention or delay of the onset of clinical type 1 diabetes (T1D) in at-risk individuals," stated Ashleigh Palmer, CEO, Provention Bio. "Recent Breakthrough Therapy and PRIME designations from the FDA and European Medicines Agency (EMA), respectively, recognize and confirm the unmet need of these individuals and we believe validate the transformative potential of this therapeutic candidate. Based on our interactions with the FDA, we believe that the existing clinical efficacy and safety, as well as non-clinical data, has the potential to support a BLA filing with the FDA in the fourth quarter of next year, and look forward to confirming this expedited regulatory path at a multi-function, Type B meeting with the Agency this quarter."

"We believe the progress of our PRV-031 T1D at-risk program not only represents a unique opportunity in its own right, but also more broadly validates Provention's founding strategic intent to develop other novel therapies that intercept or prevent immune-mediated diseases. We continue to advance our programs, including the ongoing PROTECT Phase 3 clinical study evaluating PRV-031 in newly diagnosed T1D patients and our ongoing Phase 1b PREVAIL clinical trial evaluating PRV-3279. PRV-3279 has the potential to intercept the pathophysiology of systemic lupus erythematosus (SLE) and other B cell-mediated autoimmune diseases, as well as manage clinically relevant immunogenicity associated with gene therapies and certain recombinant protein therapeutics."

Third Quarter 2019 and Recent Highlights:

PRV-031 (Teplizumab) Granted PRIME Designation by the EMA
In October 2019, Provention announced the EMA has granted PRV-031 (teplizumab) PRIority MEdicines (PRIME) designation for the prevention or delay of clinical type 1 diabetes (T1D) in individuals at-risk of developing the disease. PRIME designation is awarded by the EMA to promising medicines that demonstrate the potential to address substantial unmet medical need based on clinical data. The EMA considers PRIME designations a priority and provides them with special support, including enhanced interactions and dialogue, as well as a pathway for accelerated evaluation and review.

PRV-031 (Teplizumab) Granted Breakthrough Therapy Designation (BTD)
In August 2019, the FDA granted Breakthrough Therapy Designation to PRV-031 for the prevention or delay of clinical T1D in individuals at risk of developing the disease. BTD is an FDA program designed to expedite the development and review of therapeutic candidates intended to treat serious or life-threatening diseases.

Initiated Phase 1b/2a PREVAIL Clinical Trial Evaluating PRV-3279 in Lupus
In August 2019, Provention announced that it dosed the first patients in its PREVAIL (PRV-3279 EVAluation In Lupus) study, a Phase 1b/2a clinical trial evaluating PRV-3279. Results from a prior single ascending dose Phase 1 study established proof of mechanism and showed that PRV-3279 was well-tolerated. Provention expects top-line results from the Phase 1b portion of the clinical study in the first quarter of 2020, with plans to initiate the Phase 2a portion of the study in lupus patients later in 2020.

Sean Doherty appointed to the Board of Directors
In September 2019, Provention announced the appointment of Sean Doherty to Provention's Board of Directors. Mr. Doherty is the Executive Chairman of the JDRF T1D Fund and former Bain Capital Managing Director, bringing extensive financial expertise and a deep knowledge of the therapeutics landscape for immune-mediated diseases. Mr. Doherty's 20 years of operational, investment, risk management and governance experience bring tremendous value to the Provention team.

Announced Top-Line Results from Phase 2a PRINCE Clinical Trial with PRV-6527
In October 2019, Provention announced top-line results from its randomized, placebo-controlled Phase 2a PRINCE

clinical trial evaluating twice-daily PRV-6527, an oral Colony Stimulating Factor-1 Receptor (CSF-1R) small molecule inhibitor. Under the terms of the in-license agreement, Janssen now has 90 days to exercise its option to re-acquire this asset to support further development in inflammatory bowel disease.

Financial Highlights:

As of September 30, 2019, Provention had cash and cash equivalents totaling $95.1 million. In September 2019, Provention completed a public follow on offering of 5,750,000 shares and a concurrent private placement with Amgen of 2,500,000 of its common stock, at a price of $8.00 per share, resulting in aggregate net cash proceeds from the sale of the shares, after deducting underwriting discounts and offering expenses, of $62.7 million. Provention expects its operating cash expenses to be in the range of $10 to $12 million in the fourth quarter of 2019. Provention expects its current cash and cash equivalents will be sufficient to fund projected operating requirements into the second half of 2021. Working capital was $91.4 million as of September 30, 2019. Going forward, Provention expects to invest in the regulatory, clinical, manufacturing, and pre-commercial activities related to PRV-031 (teplizumab) as well as the continued development of PRV-3279, PRV-101, and PRV-015.

Net loss for the third quarter 2019 was $9.8 million, or $0.24 per basic and diluted share, compared to a net loss of $5.4 million, or $0.17 per basic and diluted share, for the same period in 2018. The increase in net loss was attributable to an increase in research and development costs of $3.2 million primarily associated to an increase in clinical development expenses for PRV-031, as well as an increase in general and administrative costs of $1.4 million.

Net loss for the nine months ended September 30, 2019 was $32.7 million, or $0.85 per basic and diluted share, compared to a net loss of $21.1 million, or $1.21 per basic and diluted share, for the same period in 2018. The increase in net loss was attributable to an increase in research and development costs of $10.2 million primarily associated with an increase in clinical development expenses for PRV-031, PRV-101, and PRV-3279 and increased internal personnel and consultant costs to support our clinical programs. Also contributing to the increase in net loss was an increase in general and administrative costs of $2.7 million.

Conference Call and Webcast Information
Provention Bio will discuss these results via conference call today at 4:30 pm ET. 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". An audio webcast will also be available in the "Events and Webcasts" page in the Investors page 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 30 days following 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), 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. 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.

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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,	
	2019	**2018**	**2019**	**2018**
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 7,324	$ 4,140	$ 27,896	$ 17,684
General and administrative	2,649	1,272	5,593	2,929
Total operating expenses	9,973	5,412	33,489	20,613
Loss from operations	(9,973)	(5,412)	(33,489)	(20,613)
Interest income	204	237	744	339
Change in fair value of warrant liability	—	(217)	—	(520)
Loss before income tax benefit	(9,769)	(5,392)	(32,745)	(20,794)
Income tax benefit	—	—	—	—
Net loss	(9,769)	(5,392)	(32,745)	(20,794)
Accretion on Series A Convertible Redeemable Preferred Stock	—	(25)	—	(276)
Net loss attributable to common stockholders	$ (9,769)	$ (5,417)	$ (32,745)	$ (21,070)
Net loss per common share, basic and diluted	$ (0.24)	$ (0.17)	$ (0.85)	$ (1.21)
Weighted average common shares outstanding, basic and diluted	40,512	32,000	38,424	17,414

Balance Sheet Data:	**September 30, 2019**	**December 31, 2018**
Cash and cash equivalents	$ 95,088	$ 58,539
Total assets	$ 96,371	$ 61,529
Total liabilities	$ 4,960	$ 1,871
Accumulated deficit	$ (68,521)	$ (35,776)
Total stockholders' equity	$ 91,411	$ 59,658

SOURCE Provention Bio, Inc.

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http://investors.proventionbio.com/2019-11-05-Provention-Bio-Reports-Third-Quarter-2019-Financial-Results