Provention Bio Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

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

- Positive Phase 1b PREVAIL Study for PRV-3279 Announced Today

- Conference Call and Live Audio Webcast Scheduled for Today at 8:30 a.m. ET

OLDWICK, N.J., March 12, 2020 /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 fourth quarter and full year ended December 31, 2019.

"2019 was a transformational year for Provention Bio and the type 1 diabetes (T1D) landscape," stated Ashleigh Palmer, CEO of Provention Bio. "Data from the 'At-Risk' study published in the New England Journal of Medicine in June highlights the potential of PRV-031 (teplizumab) to prevent or delay onset of clinical T1D in individuals at risk of end-stage, insulin-dependent disease. Our receipt of Breakthrough Therapy and PRIME designations from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), respectively, recognizes and confirms the unmet T1D need and validates the transformative therapeutic potential of teplizumab."

Mr. Palmer continued, "Based on our discussions with the FDA late last year, we are now moving forward with preparing the various modules of our Biologics License Application (BLA), including generating the necessary drug substance comparability data to support our chemistry, manufacturing and controls (CMC) module. We remain on track to complete our rolling BLA submission in the fourth quarter of this year. In parallel with these efforts, in the first few months of 2020 we have commenced the build-out of our commercial leadership organization to support a potential launch of teplizumab as the first disease-modifying drug approved for T1D since insulin therapy in 1922."

Fourth Quarter 2019 and Recent Activities:

Announced Positive Data from Phase 1b PREVAIL Study of PRV-3279

In a separate press release issued today, Provention reported positive top-line results from the Phase 1b portion of the PREVAIL (PRV-3279 EVAluation In Lupus) study evaluating PRV-3279 in healthy volunteers. In the study, PRV-3279 was well-tolerated, with no serious adverse events. In addition, treatment with PRVB-3279 durably inhibited the function of B Cells without depletion. Based on these results, Provention plans to commence the Phase 2a portion of the PREVAIL study in lupus patients in the first half of 2021. The Phase 1b results will also enable a second development pathway for the prevention of immunogenicity of biotherapeutics such as gene therapy products.

Completed a Type B multidisciplinary meeting with the FDA to discuss the proposed contents of a BLA for PRV-031 (teplizumab)

In December 2019, Provention announced that it completed a Type B multidisciplinary meeting with the FDA to discuss the proposed contents of a BLA for teplizumab for the prevention or delay of T1D in at-risk individuals. Based on official FDA meeting minutes, Provention continues to anticipate commencement of a rolling BLA submission for teplizumab 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.

Conducted Initial PRIME Meeting with the EMA

The Company recently held a kick-off meeting with the EMA to discuss teplizumab. The Company believes it will be able to file a marketing authorization application (MAA) with the data from the At-Risk clinical study along with supplemental data from historical clinical studies of teplizumab. Provention plans to have additional meetings with the EMA and expects to file the MAA for teplizumab in 2021.

Commenced Build-out of Commercial Team

In January 2020, the Company appointed Jason Hoitt as Chief Commercial Officer. Mr. Hoitt brings 18 years of commercial experience in the biotechnology sector, most recently serving as Chief Commercial Officer at Dova Pharmaceuticals (recently acquired by Swedish Orphan Biovitrum AB, or Sobi). As Chief Commercial Officer and a member of Provention's senior leadership team, Mr. Hoitt will be responsible for the development and execution of Provention's global commercial strategy for teplizumab, building Provention's commercial capabilities, and continuing to evaluate potential partnerships for all indications and geographies.

In addition to Mr. Hoitt, Provention expanded the commercial team with the appointment of Dr. Jessica Blumstein as Vice President, Market Access and Distribution. Dr. Blumstein has 18 years of experience in the biotechnology sector, most recently as Head of Global Commercial Development and General U.S. Manager at Enzyvant Therapeutics. Dr. Blumstein was also Senior Director of Global Market Access at Sarepta Therapeutics for over two years prior to Enzyvant.

Hired Robert Adamoski to Lead Medical Affairs

Provention recently hired Robert Adamoski to lead its medical affairs activities for teplizumab. Mr. Adamoski brings over 20 years of industry experience to Provention. Mr. Adamoski was most recently at Corcept Therapeutics and his past experiences include roles at Gilead, Salix and Bayer.

Provention Highlighted Critical New Research Studies on Type One Diabetes

In February 2020, the Company highlighted several new research studies on the increasing prevalence of T1D and the importance of screening for this life-impacting and life-threatening autoimmune disease. The Juvenile Diabetes Research Foundation and Health Advances published a white paper estimating that 18 million people live with clinically diagnosed Stage 3 T1D globally, and an additional 2.3 million live with pre-symptomatic Stage 1 and Stage 2 T1D. At least 300,000 of these cases are in the United States. The research suggested that sustainable "cures" could alleviate the $30 billion economic burden in the United States and in the interim, disease modifying therapies, such as teplizumab can bring more than $3 billion in value annually.

A separate study published in the Journal of the American Medical Association, titled "Yield of a Public Health Screening of Children for Islet Autoantibodies in Bavaria, Germany", highlighted the importance of screening for T1D and the significant reduction in diabetic ketoacidosis (DKA) resulting from screening. The study, conducted by Dr. Anette-Gabriele Ziegler of the Institute of Diabetes Research, suggests that public health screening for T1D in pre-symptomatic stages may reduce disease burden and severity, as well as enable disease interception strategies with novel agents.

Financial Highlights:

As of December 31, 2019, Provention had cash and cash equivalents and marketable securities of $85.4 million. Net loss for the fourth quarter 2019 was $10.5 million, or $0.22 per basic and diluted share, compared to a net loss of $5.7 million, or $0.15 per basic and diluted share, for the same period in 2018. The increase in net loss is attributable to increases in research and development expenses of $3.5 million as well as an increase in general and administrative costs of $1.2 million.

Net loss for the full year of 2019 was $43.3 million, or $1.06 per basic and diluted share, compared to a net loss of $26.8 million, or $1.19 per basic and diluted share, for the same period in 2018. The increase in net loss year-over-year is primarily attributable to an increase in research and development costs of $13.7 million. Research and development expenses were driven by the PROTECT phase 3 clinical study of teplizumab, development costs for PRV-101, and internal personnel costs.

Provention expects to utilize $24 million to $29 million of cash for its operating needs in the first six months of 2020. Provention expects its current cash, cash equivalents and marketable securities will be sufficient to fund projected operating requirements for at least the next 12months.

Conference Call Information:

Provention will host a conference call and live audio webcast today at 8:30am 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 on the "Events and Webcasts" page under the Investors tab 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 focused on the prevention or interception of immune-mediated disease. Provention's mission is to source, transform and develop therapeutic candidates targeting the high morbidity, mortality and escalating costs of autoimmune diseases. Provention's diversified portfolio includes PRV-031 (teplizumab), a pre-commercial-stage candidate that has been shown to delay the onset of end-stage type one diabetes (T1D) in at-risk individuals with pre-symptomatic disease. Teplizumab has been granted Breakthrough Therapy designation from the U.S. Food and Drug Administration. The Company's portfolio includes additional clinical-stage product development candidates that have demonstrated proof-of-mechanism and/or proof-of-concept in other autoimmune diseases, including celiac disease and lupus.

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, 2019 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

PROVENTION BIO, INC.
SELECTED FINANCIAL DATA
(in thousands, except per share data)

	Three Months Ended December 31,		For the Years Ended December 31,	
	2019	2018	2019	2018
	(unaudited)			
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 8,463	$ 4,965	$ 36,359	$ 22,649
General and administrative	2,420	1,236	8,013	4,165
Total operating expenses	10,883	6,201	44,372	26,814
Loss from operations	(10,883)	(6,201)	(44,372)	(26,814)
Interest income	343	330	1,087	669
Change in fair value of warrant liability	—	—	—	(520)
Loss before income tax benefit	(10,540)	(5,871)	(43,285)	(26,665)
Income tax benefit	—	187	—	187
Net loss	(10,540)	(5,684)	(43,285)	(26,478)
Accretion on Series A Convertible Redeemable Preferred Stock	—	—	—	(276)
Net loss attributable to common stockholders	$ (10,540)	$ (5,684)	$ (43,285)	$ (26,754)
Net loss per common share, basic and diluted	$ (0.22)	$ (0.15)	$ (1.06)	$ (1.19)
Weighted average common shares outstanding, basic and diluted	47,641	37,357	40,747	22,441

	December 31, 2019	December 31, 2018
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 85,373	$ 58,539
Total assets	$ 85,996	$ 61,529
Total liabilities	$ 3,840	$ 1,871
Accumulated deficit	$ (79,061)	$ (35,776)
Total stockholders' equity	$ 82,156	$ 59,658

SOURCE Provention Bio, Inc.