Provention Bio Announces Completion of Enrollment of Phase 1b Clinical Trial of PRV-300 in Moderate-to-Severe Ulcerative Colitis

- Top-line data from the "PULSE" clinical trial expected in the second quarter of 2019

OLDWICK, N.J., Oct. 23, 2018 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a clinical-stage biopharmaceutical company focused on immune-mediated diseases, announced today that it has completed enrollment in the Phase 1b clinical trial of PRV-300 in patients with moderate-to-severe ulcerative colitis (UC). Provention is developing PRV-300, an anti-TLR3 monoclonal antibody, to intercept upstream disease processes in UC patients.

"Completion of enrollment of our Phase 1b clinical trial of PRV-300 in ulcerative colitis is an important operational milestone for Provention," said Ashleigh Palmer, co-founder and CEO of Provention Bio, Inc. "The relative speed, efficiency and agility by which we were able to design, initiate and complete enrollment of this study demonstrates some of Provention's core capabilities that underpin our transformational drug development strategy to reposition and advance candidates that have been underdeveloped or deprioritized, yet have human data indicating the potential to prevent or intercept immune-mediated disease."

The Phase 1b clinical trial of PRV-300 (**P**rovention **UI**cerative colitis **S**afety, pharmacokinetic and pharmacodynamic **E**valuation or PULSE) was initiated in the first quarter of 2018 following the in-licensing of the drug from Janssen in the second quarter of 2017. The trial completed the planned target enrollment of 36 patients with moderate-to-severe UC. The primary endpoint of the study is safety, with secondary endpoints designed to evaluate the effect of PRV-300 on endoscopic and histologic endpoints, and a biopsy-based mucosal gene expression signature. These criteria are intended to determine proof-of-mechanism and, potentially, proof-of-concept, allowing Provention to potentially advance directly to Phase 2b. Top-line data from PULSE is expected in the second quarter of 2019.

About PRV-300

PRV-300 (previously known as JNJ-42915925) is a first-in-class, fully human, IgG4κ monoclonal antibody (mAb) that binds the extracellular domain of TLR3 with high specificity and affinity. Toll-like receptors (TLRs) are sensor molecules of the innate immune system, which detect certain microbial pathogens and initiate protective immune responses. There is increasing evidence that TLR3 plays an important role in the pathologic response to emerging viral infections and the excessive immune reactions they can trigger. TLR3 has also been implicated in chronic pathologic inflammation triggered by non-viral RNA. This appears to be the case in inflammatory disorders such as UC. Provention believes the blockade of TLR3 by PRV-300 may provide an effective therapy to intercept the upstream stages in the pathophysiology of UC and potentially prevent relapse or exacerbation.

About Ulcerative Colitis
Ulcerative colitis is the most common form of inflammatory bowel disease (IBD). It is a "relapsing-remitting" disease with chronic destructive inflammation and epithelial injury in the gastrointestinal tract. There is considerable morbidity associated with UC, which often leads to surgical removal of the colon and a severely reduced quality of life. Substantial unmet medical needs and suffering remain despite current anti-inflammatory and immune suppressive therapeutics.

About Provention Bio, Inc.
Provention Bio, Inc. 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 diverse portfolio was assembled with product candidates that have undergone clinical testing but may have been underdeveloped or deprioritized assets at other companies. Provention's mission is to in-license, transform and develop clinical-stage, or nearly clinical-stage, therapeutic candidates targeting the high morbidity, mortality and escalating costs of autoimmune and inflammatory diseases including: type 1 diabetes (T1D), Crohn's disease, ulcerative colitis, lupus, and certain life-threating viral diseases. For more information on Provention Bio, please visit www.proventionbio.com.

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 factors listed under "Risk Factors" in our quarterly report on Form 10-Q for the quarter ended June 30, 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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