# Provention Bio Announces Licensing Agreements with Janssen for Two Clinical-Stage Immunology Assets

**- Provention to initiate Phase 2a Study of PRV-6527 (JNJ-40346527) in patients with moderate to severe Crohn's disease**

**- Provention to initiate Phase 1/2 Study of PRV-300 (JNJ-42915925/CNTO 3157) in patients with moderate to severe ulcerative colitis**

LEBANON, N.J., Sept. 21, 2017 /PRNewswire/ -- Provention Bio, Inc., a clinical stage biopharmaceutical company dedicated to sourcing, developing and commercializing novel therapeutics aimed at intercepting and preventing immune-mediated diseases, announced today that it has entered into agreements with Janssen Pharmaceutica NV and Janssen Sciences Ireland UC [Janssen] to in-license two clinical-stage assets, PRV-6527 (JNJ-40346527), an oral Colony Stimulating Factor-1 Receptor (CSF-1R) small molecule inhibitor, and PRV-300 (JNJ-42915925/CNTO 3157), an anti-Toll-Like Receptor 3 (TLR3) monoclonal antibody.

PRV-6527 will be studied in a Phase 2a proof-of-concept (PoC) clinical trial in Crohn's disease, for which Provention anticipates initiating enrollment in the first half of 2018. PRV-300 will initially be evaluated in a Phase 1/2 proof-of-mechanism (PoM), PoC study in moderate-to-severe ulcerative colitis (UC), which Provention expects to also initiate in the first half of 2018. PRV-300 also has the potential to target additional indications, including severe influenza and emerging viral diseases.

The addition of PRV-6527 and PRV-300 expands Provention's drug development pipeline to three in-licensed programs, including the previously announced enterovirus vaccine platform, which Provention is developing to potentially prevent or delay the onset of type 1 diabetes (T1D) by vaccinating at-risk populations against Coxsackievirus B (CVB) infection. Research suggests that CVB infection could be responsible for more than half of T1D cases worldwide.

Provention was launched in the second quarter of 2017 to reduce the high morbidity, mortality, patient suffering, and escalating costs of debilitating autoimmune and inflammatory diseases by developing drugs and technologies that intervene before the targeted disease begins, re-appears or progresses. Provention obtained a $28.4 million founding financing in April 2017.

Ashleigh Palmer, co-founder and CEO of Provention Bio, stated, "The in-licensing of PRV6527 and PRV300 from Janssen continues to build momentum following our corporate launch last quarter and advances our strategic intent to source clinical-stage programs targeting the *interception or prevention* of immune-mediated diseases. Moreover, these two transactions showcase Provention's ability to leverage its expertise in translational medicine and 'rapid go/no-go' clinical trial design to acquire or in-license well-studied and characterized clinical-stage assets in the field of immune-mediated disease."

**Crohn's disease, CSF-1R and PRV-6527**

Crohn's disease is a chronic inflammatory bowel disease (IBD) characterized by inflammation of the gastrointestinal (GI) tract. Myeloid cells, a species of antigen-presenting cells, are believed to play a central role in Crohn's disease by presenting microbiome antigens to white blood cells in the gut. CSF-1R drives myeloid cell differentiation in the bone marrow resulting in the maturation of inflammatory dendritic cells and macrophages, which then populate the gut and other tissues and trigger inflammatory processes.

Provention's Phase 2a PoC study of PRV6527 will investigate the drug's ability to "intercept" the differentiation of these inflammatory dendritic cells and macrophages, preventing their migration to the intestinal mucosa in Crohn's disease. The study is expected to enroll approximately 80 patients with moderate to severe Crohn's disease; primarily patients who previously failed one biologic drug. The study will be randomized, double-blind and placebo-controlled, with dosing for 12 weeks. The primary endpoint will be clinical effect at week 12, and secondary proof-of-mechanism endpoints will be assessed, including endoscopy and the presence of inflammatory myeloid cells in the gut.

Francisco Leon, MD, Ph.D., scientific co-founder of Provention, said, "The CSF-1R pathway is overrepresented in Crohn's disease gut tissue, and unpublished data suggest a potential beneficial effect of PRV-6527 on Crohn's-like disease in mouse models. Our goal with the Phase 2a PoC study is to confirm this observation in patients

with moderate to severe Crohn's disease, who are still substantially underserved by conventional therapeutics. In particular, there is no oral medication approved for the treatment of moderate to severe Crohn's patients at this time."

**Ulcerative colitis, TL3 and PRV-300**

Like Crohn's disease, UC is an IBD that causes long-lasting inflammation and ulceration in the digestive tract. It affects the innermost lining of the colon and symptoms occur over time, rather than sudden onset. While current treatments for UC can reduce symptoms and bring about long-term remission in a subset of patients, there is no cure. A majority of patients experience debilitating relapses which can potentially be life-threatening.

Toll Like Receptors (TLRs) function as the body's "alarm system" by detecting a broad range of pathogens and initiating responses from the immune system. Increasing evidence suggests that TLR3 plays an important role in the pathology of emerging viral infections and the excessive immune response viruses can trigger. Additionally and importantly, TLR3 is believed to also play a key role in chronic inflammation triggered by non-virally derived endogenous RNA and double stranded RNA (dsRNA). Human biomarker and animal model studies show that TLR3 appears to be involved in the pathogenesis of UC.

Provention is planning to initiate Phase 1/2 PoC and PoM study of PRV-300 in 32 UC patients. The study will be a randomized, placebo-controlled, double-blinded study of intravenous anti-TLR3 administered for 12-weeks to patients with moderate to severe UC, who are biologic therapy naïve or experienced. The primary endpoint will be safety, and secondary and exploratory endpoints will include endoscopic and histologic findings, and mucosal mRNA signature.

"We know that PRV-300 suppresses the effects of viral infections and inflammation in animal models," said Provention's Chief Medical and Chief Operating Officer Eleanor L. Ramos, MD. "While our initial trials will target the demonstration of PoM in human patients with moderate to severe UC, we also intend to explore life-cycle expansion opportunities, including severe influenza in the hospital setting, as well as emerging viral diseases."

**About Provention Bio, Inc.**

Provention Bio, Inc. is a clinical stage biopharmaceutical company dedicated to sourcing, developing and commercializing novel therapeutics and cutting-edge solutions to intercept and prevent immune-mediated disease. Our "predict and prevent" therapeutic model is focused on developing drugs that intervene before the targeted disease begins, re-appears or progresses. This approach is unique in the biopharmaceutical industry and offers unprecedented potential to reduce the high morbidity, mortality and escalating costs of chronic autoimmune and inflammatory diseases, such as type 1 diabetes (T1D), Crohn's disease, and ulcerative colitis, as well as emerging viral infections. For more information on Provention Bio, please visit www.proventionbio.com.

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