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FOR IMMEDIATE RELEASE

REVEN PHARMACEUTICALS REPORTS POSITIVE RESULTS REGARDING THE CLINICAL SAFETY AND PRECLINICAL EFFICACY OF ITS COVID-19 DRUG CANDIDATE REJUVEINIX (RJX)

Wednesday, November 11, 2020, 7:30 AM ET

Golden, Colorado (BUSINESS WIRE)— Reven Holdings, Inc. ("Reven") is a privately held clinical stage biotechnology and pharmaceutical company dedicated to the discovery and development of novel treatment platforms for cancer, viral illnesses—including COVID-19—and inflammatory disorders.

Reven today announced the publication of a peer-reviewed article in the prestigious medical journal, ***Frontiers in Pharmacology, Section: Respiratory Pharmacology***. In this new publication, the Reven Pharmaceuticals team reports positive results regarding the clinical safety and preclinical efficacy of its COVID-19 drug candidate Rejuveinix (RJX). According to the publication, no participant experienced clinically significant or serious side effects in a double-blind, placebo-controlled, randomized, two-part, ascending dose-escalation Phase 1 study in 76 healthy volunteer human subjects. Hence, RJX showed a very favorable clinical safety profile and tolerability. Furthermore, experiments in animal models of sepsis, cytokine storm, ARDS, and multiorgan failure have provided the scientific proof of concept that RJX can both prevent as well as reverse acute lung and liver injury associated with sepsis and cytokine storm, and improve the survival outcome at a dose level that is more than 10-times lower than its maximum tolerated and safe dose for human subjects. Notably, RJX not only protected animals against death by preventing progression of severe systemic inflammation, but it also caused reversal of already established and otherwise invariably fatal systemic inflammation.

Reference for the Publication:

Uckun FM, Carlson J, Orhan C, Powell J, Pizzimenti NM, Van Wyk H, Ozercan IH, Volk M, Sahin K. Rejuveinix Shows a Favorable Clinical Safety Profile in Human Subjects and Exhibits Potent Preclinical Protective Activity in the Lipopolysaccharide-Galactosamine Mouse Model of Acute Respiratory Distress Syndrome and Multi-Organ Failure. **Front. Pharmacol**. 2020; 11:594321. doi: 10.3389/fphar.2020.594321. Published on November 10, 2020

RJX is an intravenous (IV) formulation of a patented first-in-class pharmaceutical composition containing a specific mixture of anti-oxidant and anti-inflammatory ingredients that is being developed for more effective treatment of patients with inflammatory disorders, including COVID-19 patients with viral sepsis, multi-system inflammation, cytokine release syndrome (CRS), shock, ARDS, and multi-organ failure.

End of last month, the U.S Food and Drug Administration (FDA) has approved the Investigational New Drug (IND) application for RJX as a potential treatment for COVID-19 patients. The FDA-approved clinical trial is a randomized, double-blind, placebo-controlled, multi-institutional Phase 2 study designed to evaluate the efficacy and safety of RJX in 249 hospitalized COVID-19 patients, including 186 with mild-moderate disease who have high-risk features for progression to severe disease and ARDS (Cohort 1) and 63 patients with hypoxemic respiratory failure receiving either non-invasive positive pressure ventilation (NIPPV) or high flow oxygen, who have not yet developed ARDS to require mechanical ventilation (Cohort 2). The study will begin immediately at approximately 14 U.S. health centers treating COVID-19 patients. Reven anticipates topline data from the trial in the second quarter of 2021.

"Since RJX is a potent anti-oxidant and anti-inflammatory agent that has been shown to reduce the tissue-level oxidative stress in multiple organs in animal models of severe systemic inflammation, shock, cytokine storm, and multiorgan failure, we are hopeful that it will contribute to the prevention of progression of COVID-19 and its faster resolution in high-risk patients" said Fatih Uckun, MD PhD, Chief Medical Officer and Chief Scientific Officer of Reven, who is the first author of the new article.

Dr. Uckun added: "Based on the role inflammatory cytokines as well as oxidative stress play in the multisystem inflammatory syndrome in children (MIS-C) with COVID-19, and the ability of RJX to suppress the production of the inflammatory cytokines, including IL-6, TNF-α, and TGF-β, we hypothesize that RJX will also emerge as a clinically useful adjunct to the available supportive of care in pediatric COVID-19 patients who develop MIS-C."

"This new article emphasizes our commitment to advancing our anti-inflammatory and anti-oxidant treatment platforms to address unmet needs in COVID-19 therapy," stated Peter Lange, Reven's Chief Executive Officer.

"In addition to rapidly advancing the clinical development of our lead anti-oxidant treatment platform RJX for COVID-19 related viral sepsis, we are dedicated to developing new and effective anti-oxidant treatment platforms that are rationally optimized for other forms of sepsis and difficult-to-treat inflammatory disorders", added Michael Volk, Reven's Chief Strategy Officer.

"Scientific data from multiple studies suggest a tremendous therapeutic potential for the RJX platform and provide the foundation for our optimism regarding the commercialization potential of RJX" said Brian Denomme, Reven's President and Chief Operating Officer.

About Rejuveinix (RJX)

RJX is an intravenous (IV) formulation of a patented first-in-class pharmaceutical composition containing a specific mixture of anti-oxidant and anti-inflammatory ingredients that is being developed for more effective treatment of patients with inflammatory disorders, including COVID-19 patients with viral sepsis and acute respiratory distress syndrome (ARDS). The clinical safety and tolerability of RJX was confirmed in a recently completed double blind, placebo-controlled Phase 1 dose-escalation study in healthy volunteers (ClinicalTrials.gov Identifier: NCT03680105).

About Reven Holdings, Inc.
Reven Holdings, Inc., a Delaware corporation, through its Golden/Colorado-based operating company Reven, LLC (d.b.a Reven Pharmaceuticals), is developing new drugs for difficult-to-treat diseases. As a clinical stage biopharmaceutical company, Reven's overarching goal is to develop effective treatments for serious health conditions caused by infectious, inflammatory, cardiovascular, and metabolic diseases. Its lead product, RJX, is being developed as a treatment platform against complications of COVID-19, sepsis, cardiovascular diseases, and diabetes.

Reven's Cautionary Note on Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, prospects, plans and objectives of management are forward-looking statements. Words such as "may", "on-track", "expect", "anticipate" "hope", "vision", "optimism", "design", "exciting", "promising", "will", "conviction", "estimate," "intend," "believe" and similar expressions are intended to identify forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about future plans, the progress, timing, clinical development, scope and success of future clinical trials, the reporting of clinical data for the company's product candidates and the potential use of the company's product candidates to treat various disease indications. Each of these forward-looking statements involves risks and uncertainties, and actual results may differ materially from these forward-looking statements. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing market competition, changes in the regulatory environment, failure of collaborators to support or advance collaborations or product candidates, and unexpected litigation or other disputes. These risks are not exhaustive; the company faces known and unknown risks, including the risk factors described in the company's periodic SEC filings. Forward-looking statements are based on expectations and assumptions as of the date of this press release. Except as required by law, the company does not assume any obligation to update forward-looking statements contained herein to reflect any change in expectations, whether as a result of new information regarding future events, or otherwise.

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