Reven, LLC
600 Corporate Circle, Ste D
Golden, CO 80401 – USA
https://www.reven.com

Reven's Patented, First-in-Class Anti-inflammatory Treatment Platform for Sepsis on Track for Clinical Testing in COVID-19 Patients

September 14, 2020

GOLDEN, Colo.–(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 had recently submitted a Pre-Investigational New Drug (Pre-IND) application to the U.S. Food and Drug Administration (FDA) to obtain feedback and guidance for its clinical evaluation of the anti-inflammatory/anti-oxidant investigational drug product Rejuveinix (RJX) in the treatment of COVID-19. Reven today announced that FDA has responded favorably to its Pre-IND application.

Following the FDA guidance, as the next step Reven is planning to promptly submit an Investigational New Drug (IND) application and clinical protocol to the Agency. The clinical study will be a randomized, double-blind, placebo-controlled, multi-institutional trial comparing a combination of the standard of care with a placebo to a combination of the standard of care with RJX for the treatment of COVID-19. The clinical trial design, mechanism of action and the rationale for developing RJX as a treatment modality for prevention of cytokine storm and other complications of COVID-19 are all discussed in a published article in the current issue (Volume 10, Issue 3, 2020) of the peer-reviewed medical journal Clinical Investigation:

Kristina Cabala, Jackie Earabino, Peter Pacult, Fatih M. Uckun. Rationale for a randomized, placebo-controlled, Phase 2 study of Rejuveinix (RJX) in COVID-19 patients with acute lung injury and hypoxemic respiratory failure. Clin. Invest. (Lond.) (2020) 10(2), 185-189. DOI: 10.4172/ Clinical-Investigation.1000168.

Link: https://www.openaccessjournals.com/journals/clinical-investigation-current-issue.html

"We are grateful to the FDA for their valuable guidance in the pre-IND process. We hope that the diligent and careful clinical development of RJX ultimately contributes to a better survival and faster recovery in COVID-19," stated Fatih Uckun, M.D., PhD, the Chief Medical Officer of Reven.

"I am delighted to have the opportunity to work with Dr. Uckun as part of Reven's leadership team as we diligently advance the RJX clinical trial program with the vision of bringing a new treatment option to high-risk COVID-19 patients who are in urgent need for therapeutic innovations," added Michael Volk, co-founder and Chief Strategy Officer of Reven.

Reven Pharmaceuticals, Inc.
600 Corporate Circle, Ste D
Golden, CO 80401 – USA
https://www.reven.com

About Rejuveinix (RJX)

RJX is an intravenous (IV) formulation of physiologically compatible compounds that is being developed for more effective treatment of patients with sepsis, 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, is a biopharmaceutical company. Reven's vision is to make a difference in the world by making its products accessible to everyone suffering the effects of vascular and metabolic related diseases. Reven is committed to being the premier, research-intensive biopharmaceutical company that advances the health and well-being of people around the world. Its primary product, RJX, targets patients suffering from COVID-19, sepsis, vascular and metabolic related diseases as well as specific patient populations suffering from Peripheral Arterial Disease (PAD) and other cardiovascular related medical conditions.

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,

Reven Pharmaceuticals, Inc.
600 Corporate Circle, Ste D
Golden, CO 80401 – USA
https://www.reven.com

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.

Contacts

Natalie Pizzimenti, Medical Scientific Liaison
+1 (586)– 242-9590
natalie.pizzimenti@reven.com

Fatih Uckun, Chief Medical Officer and Chief Scientific Officer
+1 (720) – 432-9696
fatih.uckun@reven.com