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Reven Selects APCER Life Sciences as Its Service Provider in Pharmacovigilance, Safety Monitoring, Quality Assurance and Regulatory Affairs for Its Upcoming COVID-19 Clinical Trial

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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 is planning to initiate a randomized, double-blind, placebo-controlled, multi-institutional clinical trial of its lead anti-inflammatory/anti-oxidant investigational drug product Rejuveinix (RJX) in the treatment of COVID-19. The upcoming clinical trial is designed to evaluate the safety and efficacy of RJX in COVID-19 patients.

Reven today announced that it selected the global specialty drug safety services provider APCER Life Sciences (APCER) as its preferred vendor to provide pharmacovigilance (PVG), safety monitoring, quality assurance and regulatory affairs services for its COVID-19 clinical project. Fatih Uckun, MD, PhD, the Chief Medical Officer and Chief Scientific Officer of Reven, explained: "According to a fit-for-purpose safety management plan, APCER will (i) set up a global integrated PVG safety database, (ii) provide clinically trained safety specialists and physicians to triage serious and non-serious adverse event (AE) cases, (iii) perform detailed case entry and follow-up, quality reviews and medical reviews, (iv) manage the serious adverse event (SAE) reporting, as well as (v) coordinate safety monitoring processes to immediately identify suspected unexpected serious adverse reactions (SUSARS) and enable their on-time reporting to regulators, investigators and institutional review boards (IRBs)." "I also look forward to working with the APCER team as we perform signal evaluation and management for RJX and develop our risk evaluation and mitigation strategies," Dr. Uckun added.

"Both Dr. Uckun and I have previously worked with the APCER team and we have been impressed by their dedication as well as the quality of their services. Our current arrangement with APCER will help maximize patient safety and optimize regulatory oversight during the COVID-19 study," added Renae Townsend, the Director of Clinical Operations at Reven. "Our IND (Investigational New Drug) application package for the development of RJX against COVID-19 is completed, and we are planning to roll out our clinical program in the very near future. We look forward to collaborating with the APCER team in our efforts to maximize the safety of our patients," added Michael Volk, Director and Chief Strategy Officer of Reven.

Dr Vineet Kacker, Cofounder and Global Technical Head of APCER, said, "We are excited to embark on this partnership with Reven and supporting their efforts in exploring potential therapies for treatment of COVID-19."

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Kunwar Kishore B. Arora, Global COO of APCER, added, "Being chosen as a safety partner by Reven for RJX, for the treatment of COVID-19, is a testament to our strong scientific and medical expertise, deep regulatory knowledge and robust approach towards risk management. We are pleased to work with Reven for this and other important treatments."

About APCER

APCER provides comprehensive drug safety/pharmacovigilance, medical information, medical writing, regulatory services, quality assurance and risk management programs to pharmaceutical and biotech companies globally. APCER brings medicinal / scientific expertise through its healthcare professionals & physicians to address full pharmacovigilance requirements for North America, UK & Europe. APCER's clients benefit from its vast experience in regulatory submissions across 100+ countries and consultative approach towards audit /inspection readiness.

APCER has scalable operations across five global offices which house more than 750 employees: Princeton, NJ, USA; London, UK; Germany, Wan Chai, Hong Kong, New Delhi and Ahmedabad, India.

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, Rejuveinix (RJX), targets patients suffering from COVID-19, sepsis,

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vascular and metabolic related diseases as well as specific patient populations suffering 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, 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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