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Sigyn Therapeutics™ Announces Completion of Animal Studies

Sigyn Therapy™ Safe and Well Tolerated During Six-hour Treatments

SAN DIEGO, CA, Feb. 23, 2022 (GLOBE NEWSWIRE) -- via NewMediaWire – Sigyn Therapeutics, Inc. (OTC Markets:"SIGY"), a medical technology company focused on the treatment of pathogen-associated conditions that induce sepsis, today reported the successful completion of an *in vivo* animal study that demonstrated Sigyn Therapy to be safe and well tolerated.

Sigyn Therapy is a novel blood purification technology designed to perform functions that are beyond the reach of drugs and overcome the limitations of current devices to treat life-threatening inflammatory conditions, including sepsis, the leading cause of hospital deaths. Data resulting from the *in vivo* study will be incorporated into an Investigational Device Exemption (IDE) that the Company plans to submit to the U.S. Food and Drug Administration (FDA) to support the potential initiation of human clinical studies.

In the study, an adult version of Sigyn Therapy was administered via standard dialysis machines utilizing conventional blood-tubing sets, for periods of up to six hours in eight (8) porcine (pig) subjects, each weighing approximately 40-45 kilograms. The study was comprised of a pilot phase (two subjects), which evaluated the feasibility of the study protocol in the first-in-mammal use of Sigyn Therapy; and an expansion phase (six subjects) to further assess treatment safety and refine pre-treatment set-up and operating procedures.

Overall, Sigyn Therapy was well tolerated by all eight animal subjects and no serious adverse events were reported in any treated animal. Important criteria for treatment safety – including hemodynamic parameters, serum chemistries and hematologic measurements – were stable across all subjects.

Of the eight treatments, seven were administered for the entire six-hour treatment period. One treatment was halted early due to the observation of a clot in the device, which was believed to be the result of a procedural deviation from the device priming instructions in the pre-treatment set-up. In another treatment, a decrease in activated clotting time values to below prescribed levels resulted in additional anticoagulant dosing during a completed six-hour treatment. No serious adverse events were observed in either of these two treatments.

A video of Sigyn Therapy being administered on January 7, 2022 can be accessed through the following link: https://tinyurl.com/Sigyn-Therapy-Video-010722

The study was conducted by a clinical team at Innovative BioTherapies, Inc. (IBT), under a contract with the University of Michigan to utilize animal care, associated institutional review oversight, as well as surgical suite facilities located within the North Campus Research

Complex. IBT is uniquely experienced in providing development services that support the clinical advancement of extracorporeal devices. The treatment protocol of the study was reviewed and approved by the University of Michigan Institutional Animal Care and Use Committee (IACUC).

In parallel with conducting these *in vivo* studies, the Company reported the completion of *in vitro* blood plasma studies that validated the ability of Sigyn Therapy to address a broad-spectrum of relevant therapeutic targets, which included endotoxin (gram-negative bacterial toxin); peptidoglycan and lipoteichoic acid (gram-positive bacterial toxins); viral pathogens (including SARS-CoV-2); hepatic toxins (ammonia, bile acid & bilirubin); CytoVesicles (extracellular vesicles that transport inflammatory cargos); and tumor necrosis factor alpha (TNF alpha), interleukin-1 beta (IL-1b), and interleukin 6 (IL-6), which are pro-inflammatory cytokines whose dysregulated production can induce sepsis and other life-threatening inflammatory conditions.

“Based on its demonstrated ability to extract pathogens, toxins and inflammatory mediators from blood plasma, we believe Sigyn Therapy may hold promise for addressing significant unmet needs in global health that remain beyond the reach of drugs,” stated Jim Joyce, co-founder and CEO of Sigyn Therapeutics. “The successful completion of our animal study marks the achievement of a major milestone for our company as we take another step toward fulfilling our clinical vision for saving lives.”

About Sigyn Therapeutics™

Sigyn Therapeutics is a medical technology company focused on the treatment of pathogen-associated conditions that precipitate sepsis, the leading cause of hospital deaths worldwide. Sigyn Therapy™ is a multi-function blood purification technology that extracts pathogen sources of life-threatening inflammation in concert with the broad-spectrum elimination of inflammatory mediators from the bloodstream.

In vitro blood purification studies have validated the ability of Sigyn Therapy to address endotoxin (gram-negative bacterial toxin); peptidoglycan and lipoteichoic acid (gram-positive bacterial toxins); viral pathogens (including SARS-CoV-2); hepatic toxins (ammonia, bile acid & bilirubin); CytoVesicles (extracellular vesicles that transport inflammatory cargos); and relevant proinflammatory cytokines (TNF-a, IL-1b, IL-6) that underlie the cytokine storm that precipitates sepsis. Beyond these broad-spectrum capabilities, animal studies have demonstrated the safe administration of Sigyn Therapy.

Therapeutic opportunities for Sigyn Therapy include, but are not limited to, emerging bioterror and pandemic threats; drug-resistant pathogens; hepatic encephalopathy; and community-acquired pneumonia, which is a leading cause of death among infectious diseases, the leading cause of death in children under five years of age, and a catalyst for approximately 50% of sepsis and septic shock cases.

To support widespread implementation, Sigyn Therapy is a single-use disposable device designed for use on the established infrastructure of hemodialysis and continuous renal replacement therapy (CRRT) machines located in hospitals and clinics worldwide. Incorporated within Sigyn Therapy is a formulation of adsorbent components that provide more than 200,000 square meters (~50 acres) of surface area on which to adsorb and remove bloodstream targets. Unlike devices that concentrate therapeutic targets in the

blood-path, Sigyn Therapy extracts targets from the bloodstream, thereby eliminating their ability to interact with blood cells during treatment.

To learn more, visit www.SigynTherapeutics.com

Cautionary Note Regarding Forward-Looking Statements

This information in this press release contains forward-looking statements of Sigyn Therapeutics, Inc. (“Sigyn”) that involve substantial risks and uncertainties. All statements contained in this summary are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that involve risks and uncertainties. Statements containing words such as "may," "believe," "anticipate," "expect," "intend," "plan," "project," "will," "projections," "estimate," "potentially" or similar expressions constitute forward-looking statements. Such forward-looking statements are subject to significant risks and uncertainties and actual results may differ materially from the results anticipated in the forward-looking statements. These forward-looking statements are based upon Sigyn's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Factors that may contribute to such differences may include, without limitation, the Company's ability to clinically advance Sigyn Therapy in human studies required for market clearance, the Company's ability to manufacture Sigyn Therapy, the Company's ability to raise capital resources, and other potential risks. The foregoing list of risks and uncertainties is illustrative but is not exhaustive. Additional factors that could cause results to differ materially from those anticipated in forward-looking statements can be found under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, and in the Company's other filings with the Securities and Exchange Commission, including its quarterly Reports on Form 10-Q. All forward-looking statements contained in this report speak only as of the date on which they were made. Except as may be required by law, the Company does not intend, nor does it undertake any duty, to update this information to reflect future events or circumstances.

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