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Sigyn Therapeutics Reports the Successful Completion of a Study to Address Gram-Positive Bacterial Toxins Associated with Sepsis

In the Past Year, Sigyn Therapy™ Has Been Validated to Address a Broad-Spectrum of Inflammatory Mediators, Gram-Negative Bacterial Toxins, Gram-Positive Bacterial Toxins and Viral Pathogens

SAN DIEGO, CA, Dec. 01, 2021 (GLOBE NEWSWIRE) -- via [NewMediaWire](#) – Sigyn Therapeutics, Inc. (OTC Markets: SIGY), a medical technology company focused on the treatment of pathogen-associated indications that precipitate sepsis, today announced that preclinical *invitro* studies have validated the ability of Sigyn Therapy to deplete the presence of gram-positive bacterial toxins from human blood plasma.

Sigyn Therapy is a dual-function blood purification technology that extracts pathogen sources of life-threatening inflammation in concert with the broad-spectrum elimination of inflammatory mediators that fuel sepsis, the leading cause of hospital deaths worldwide.

Candidate pathogen-associated indications for Sigyn Therapy include but are not limited to the treatment of emerging bioterror and pandemic threats, drug-resistant pathogens, hepatic encephalopathy, and community-acquired pneumonia, which is the leading cause of death among infectious diseases, the leading cause of death in children under 5 years of age, and a catalyst for ~50% of sepsis and septic shock cases.

In the bacterial toxin study, the Company is reporting that clinically relevant levels of the gram-positive bacterial toxins peptidoglycan (PG) and lipoteichoic acid (LTA) were infused into 1000ml of human blood plasma and circulated through an adult version of Sigyn Therapy at normal treatment blood-flow rates. The *invitro* clearance of both targets was rapid, with an ~50% reduction of PG at one hour and a ~70% reduction of LTA at two hours. In addition to being potent activators of sepsis, there is a heightened interest in gram-positive pathogens based on the continuing emergence of drug resistant species, including antibiotic-resistant *Staphylococcus aureus* (MRSA).

The data resulting from the study will be incorporated into an Investigational Device Exemption (IDE) that the Company is preparing for submission to the United States Food and Drug Administration (FDA) to support the initiation of human clinical studies.

“We created Sigyn Therapy to perform functions that are beyond the reach of drugs and to overcome the constraints of blood purification technologies limited to the individual targeting of either cytokines, endotoxin, or viruses,” stated Jim Joyce, Chairman and CEO of Sigyn Therapeutics. “Since reporting the outcome of our first study one year ago today, we have

collected an expansive amount of data that supports the breadth of our therapeutic vision.”

In the past year, a series of *invitro* 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 COVID-19), hepatic toxins (ammonia, bile acid & bilirubin), cytovesicles that transport inflammatory cargos, and relevant proinflammatory cytokines (TNF-a, IL-1b, IL-6) that underlie the cytokine storm that precipitates sepsis.

About Sigyn Therapeutics™

Sigyn Therapeutics is a medical technology company focused on the treatment of pathogen-associated indications that precipitate sepsis, the #1 cause of hospital deaths worldwide. Sigyn Therapy™ is a dual-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.

The 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 the leading cause of death among infectious diseases, the leading cause of death in children under 5 years of age, and a catalyst for ~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, which eliminates their ability to interact with blood cells during treatment.

To learn more, visit www.SigynTherapeutics.com

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of Sigyn Therapeutics, Inc. (“Sigyn”) that involve substantial risks and uncertainties. All statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words “could,” “will,” “plan,” “intend,” “anticipate,” “approximate,” “expect,” “potential,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about Sigyn’s future financial performance, the impact of management changes, any proposed organizational restructuring, results of operations, capital resources to fund operations; statements about Sigyn’s expectations regarding the capitalization, resources and ownership structure of the combined company; statements about the potential benefits of the transaction; the expected completion and timing of the transaction and other information relating to the transaction; and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and

expectations disclosed in the forward-looking statements that Sigyn makes due to a number of important factors, including (i) the risk that the transaction may not be completed in a timely manner or at all, which may adversely affect Sigyn's business and the price of the common stock of Sigyn, (ii) the failure to satisfy of the conditions to the consummation of the transaction, (iii) the occurrence of any event, change or other circumstance that could give rise to the termination of the merger agreement, (iv) risks related to the ability to realize the anticipated benefits of the transaction, including the risk that the businesses will not be integrated successfully, (v) the effect of the announcement or pendency of the transaction on Sigyn's business relationships, operating results and business generally, (vi) risks that the proposed transaction disrupts current plans and operations, (vii) risks related to the combined entity's ability to up-list to a national securities exchange, (viii) risks related to the combined entity's access to existing capital and fundraising prospects to fund its ongoing operations, (ix) risks related to diverting management's attention from Sigyn's ongoing business operations, (x) other business effects, including the effects of industry, market, economic, political or regulatory conditions, future exchange and interest rates, and changes in tax and other laws, regulations, rates and policies, and (xi) risks related to an inability to manufacture Sigyn Therapy, risks related to the clinical advancement of Sigyn Therapy with regulatory agencies, and no assurance that Sigyn Therapy will be proven to be a safe and efficacious treatment for any condition. The forward-looking statements in this press release represent Sigyn's views as of the date of this press release. Sigyn anticipates that subsequent events and developments may cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing Sigyn's views as of any date subsequent to the date of this press release.

Media Contacts:

Russo Partners, LLC

David Schull
(212) 845-4271

David.Schull@russopartnersllc.com

Nic Johnson
(212) 845-4242

Nic.Johnson@russopartnersllc.com

Corporate Contact:

Jim Joyce
Chairman, CEO
619.353.0800 x301

jj@sigyntherapeutics.com



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