July 29, 2021

Sigyn Therapeutics Announces Successful Completion of Animal Pilot Study

SAN DIEGO, CA, July 29, 2021 (GLOBE NEWSWIRE) -- via NewMediaWire -- Sigyn Therapeutics, Inc. (OTC Markets: **SIGY**), a medical technology company focused on the treatment of life-threatening inflammatory conditions, today announced the completion of a pilot animal study that validated the feasibility of a clinical protocol that resulted in the safe administration of Sigyn Therapy™ during six-hour treatment exposures. The pilot study represents the first-in-mammal use of Sigyn Therapy in a clinical setting.

Sigyn Therapy is a novel blood purification technology designed to overcome the limitations of previous drugs and devices to treat life-threatening inflammatory conditions, including sepsis. The annual U.S. market opportunity to treat these indications exceeds $20 billion.

Since December of 2020, the Company has completed a series of*in vitro* studies that validated the ability of Sigyn Therapy to deplete a broad-spectrum of therapeutic targets, including viral pathogens, bacterial endotoxin, relevant inflammatory cytokines (IL-6, IL-1b, TNF-a) and hepatic toxins (ammonia, bilirubin, and bile acid) from human blood plasma. The Company also completed a liposome study that modeled the capture of CytoVesicles that transport inflammatory cargos throughout the bloodstream. The Company believes Sigyn Therapy to be the first therapeutic strategy to address circulating CytoVesicles.

In the pilot animal study, an adult version of Sigyn Therapy was administered to two porcine (pig) subjects (each ~ 40 kilos) to evaluate the feasibility of a therapeutic protocol designed to support subsequent clinical studies. In the study, Sigyn Therapy was deployed on a standard dialysis hardware system and utilized conventional blood-tubing set configurations. There were no treatment complications, adverse events or observations of hemolysis during the six-hour treatment procedures. Additionally, hemodynamics, blood gases and lab values were maintained within normal limits for the duration of each treatment.

“Our recent *in vitro* studies demonstrated the ability of our technology to address a broad spectrum of inflammatory mediators, toxins and pathogenic sources of inflammation,” stated Jim Joyce, Chairman and CEO of Sigyn Therapeutics. “The successful completion of our pilot animal study is another critical step in our journey to translate the capabilities of Sigyn Therapy into a life-saving clinical product.”

Craig Roberts, Chief Technical Officer at Sigyn Therapeutics, added, “We are pleased with the results of our pilot study, which provides us with clinical evidence that our device can be safely used without complications or adverse events. This animal data, along with the results of our previous *in vitro* studies, gives us confidence as we pursue our goal of receiving FDA clearance to initiate human feasibility studies.”

Based on the pilot study results, the Company plans to treat up to eight additional porcine

subjects, whose treatment outcomes will be included in an Investigational Device Exemption (IDE) that Sigyn Therapeutics is drafting for submission to the United States Food and Drug Administration (FDA) to support the potential initiation of human clinical studies.

Note: Mr. Roberts and Mr. Joyce are the co-inventors of Sigyn Therapy and have extensive experience overseeing the development of blood purification therapies.

Mr. Roberts has invented life-saving technologies that include the Percutaneous Adult Extracorporeal Membrane Oxygenation (ECMO) system, which was licensed and subsequently sold to C.R. Bard. During the COVID-19 pandemic, ECMO has been broadly deployed to treat critically ill COVID-19 patients. Additionally, Mr. Roberts is the inventor of the IMPACT Blood Purification System, which received CE Mark clearance in the European Union and was subsequently registered in 32 countries and deployed to treat cytokine storm-related conditions, including sepsis, acute respiratory distress syndrome (ARDS), acute forms of liver failure and severe pneumonia. Beyond the development of therapeutic technologies, Mr. Roberts has administered more the 4,000 extracorporeal device procedures as a Clinical Perfusionist.

As the founder and former Chairman and CEO of Aethlon Medical, Mr. Joyce oversaw the development of the Aethlon Hemopurifier® from theoretical concept to clinical reality. The Hemopurifier® is a first-in-class blood purification technology that addresses a broad spectrum of life-threatening viruses and tumor-derived exosomes that promote the spread of cancer. Under Mr. Joyce's leadership, the Hemopurifier® became the first therapy to be awarded two FDA "Breakthrough Device" designations and was the first and only device to receive "Emergency Use Authorization" (EAU) clearance from both the FDA and Health Canada to treat Ebola virus. While at Aethlon, Time Magazine named the Hemopurifier® one of the "11 Most Remarkable Advances in Healthcare" and designated the device to its "Top 25 Best Inventions" award list.

About Sigyn Therapeutics

Sigyn Therapeutics™ is focused on significant unmet need in global health; the treatment of life-threatening inflammatory conditions that are precipitated by Cytokine Storm Syndrome. The annual market opportunity exceeds $20 billion.

Sigyn Therapy™ is a multifunctional blood purification technology designed to mitigate the Cytokine Storm that underlies Sepsis (the #1 cause of in-hospital deaths) and other high-mortality inflammatory disorders commonly induced by bacterial and viral pathogens. To overcome the limitations of previous therapies, Sigyn Therapy addresses the source of inflammation (viral pathogens, bacterial toxins) in concert with the broad-spectrum depletion of inflammatory cytokines from the bloodstream. Additionally, the device establishes a therapeutic strategy to target CytoVesicles that transport inflammatory cargos throughout the circulatory system.

Sigyn Therapy incorporates a formulation of adsorbent components that optimize the broad-spectrum elimination of therapeutic targets from the bloodstream without the risk of direct blood-cell interactions. 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 already located in hospitals and clinics worldwide. The Company has also completed studies that reinforce the potential

use of Sigyn Therapy to address acute and chronic liver indications, with an initial focus directed toward hepatic encephalopathy.

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.

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Source: Sigyn Therapeutics, Inc.