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Sigyn Therapeutics™ Reports Simultaneous Clearance of Endotoxin and Inflammatory Cytokines From Human Blood Plasma

Sigyn Therapy™ is a Candidate to Treat Sepsis and Other Life-Threatening Inflammatory Conditions That Are Not Addressed with Approved Drugs

SAN DIEGO, Dec. 01, 2020 (GLOBE NEWSWIRE) -- via NewMediaWire -- Sigyn Therapeutics, Inc. (OTCMarkets: SIGY), a medical technology company focused on treating life-threatening inflammatory conditions, today announced the completion of an *in vitro* study that demonstrated the ability of Sigyn Therapy™ to clear both endotoxin and inflammatory cytokines from human blood plasma.

Sigyn Therapy is a novel blood purification technology designed to mitigate cytokine storm syndrome, which precipitates a wide-range of life-threatening conditions, including sepsis, the most common cause of hospital deaths. Virus induced cytokine storm syndrome is associated with high mortality and currently is a leading cause of SARS-CoV-2 (COVID-19) deaths. Sigyn Therapy is a single-use device designed for use on the established infrastructure of dialysis and CRRT machines located in hospitals and clinics worldwide.

In the *in vitro* study, Sigyn Therapy simultaneously reduced the presence of endotoxin and relevant pro-inflammatory cytokines, which included Interleukin-1 Beta (IL-1B), Interleukin-6 (IL-6) and Tumor Necrosis Factor alpha (TNF-a). Endotoxin (lipopolysaccharide or LPS) is a potent mediator implicated in the pathogenesis of sepsis and septic shock. The dysregulated over-production of IL-1B, IL-6 and TNF-a can lead to organ failure and cause death.

An objective of the study was to rebalance elevated cytokine levels and optimize the elimination of endotoxin from human blood plasma. The study was conducted in triplicate over four-hour time periods with a pediatric version of Sigyn Therapy. Average reduction of endotoxin load peaked at 83% during the studies. The average reduction of IL-1B was 69%, IL-6 reduction was 59% and TNF-a reduction was 57% during the four-hour studies. The resulting data will be incorporated into an Investigational Device Exemption (IDE) that Sigyn plans to submit to the United States Food and Drug Administration (FDA) in 2021.

“The simultaneous clearance of endotoxin and inflammatory cytokines is a significant milestone that reinforces the potential of Sigyn Therapy to overcome the limitations of industry pioneering devices that are currently deployed to treat life-threatening inflammatory conditions,” stated Jim Joyce, Chairman and CEO of Sigyn Therapeutics.

At present, the CytoSorb device from CytoSorbents Corporation and the Toraymyxin device

from Toray Industries are market cleared and broadly administered to treat a wide-range of life-threatening inflammatory conditions outside of the United States. In regards to mechanism, the Toraymyxin device has a high specificity to bind circulating endotoxin, but does not address inflammatory cytokines. Conversely, the CytoSorb device depletes inflammatory cytokines from circulation, but does not address endotoxin.

In addition to reporting the dual clearance of endotoxin and inflammatory cytokines, the Company further disclosed that it plans to evaluate the ability of Sigyn Therapy to address other inflammatory targets, including CytoVesicles that transport inflammatory cytokine cargos throughout the bloodstream. The Company believes that Sigyn Therapy is the first therapeutic candidate to target circulating CytoVesicles.

About Sigyn Therapeutics

Sigyn Therapeutics™ is a development-stage therapeutic technology company headquartered in San Diego, California USA. Our focus is directed toward a significant unmet need in global health; the treatment of life-threatening inflammatory conditions that are precipitated by Cytokine Storm Syndrome and not addressed with an approved therapy. Our mission is to save lives.

Sigyn Therapy™ is a novel blood purification technology designed to mitigate cytokine storm syndrome through the broad-spectrum depletion of inflammatory targets from the bloodstream. Cytokine storm syndrome is the hallmark of sepsis, which is the most common cause of in-hospital deaths and claims more lives each year than all forms of cancer combined. Virus induced cytokine storm (VICS) is associated with high mortality and is a leading cause of SARS-CoV-2 (COVID-19) deaths. Other therapeutic opportunities include, but are not limited to bacteria induced cytokine storm (BICS), acute respiratory distress syndrome (ARDS) and acute forms of liver failure, such as hepatic encephalopathy.

To learn more, visit www.SigynTherapeutics.com or www.SigynTherapy.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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