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Sigyn Therapeutics™ Discloses In-Vitro Viral Pathogen Study

Sigyn Therapy™ demonstrates the ability to address viral pathogens, including SARS-CoV-2 (COVID-19)

SAN DIEGO, April 21, 2021 (GLOBE NEWSWIRE) -- via [NewMediaWire](#) -- Sigyn Therapeutics, Inc. (OTCMarkets: SIGY), a medical technology company focused on the treatment of life-threatening inflammatory conditions precipitated by Cytokine Storm Syndrome (the Cytokine Storm), today disclosed initial in vitro study observations that demonstrated the ability of Sigyn Therapy™ to adsorb viral pathogens, including SARS-CoV-2 (COVID-19).

Cytokine Storm Syndrome is an excessive response of the immune system that is induced by infectious and non-infectious conditions. A hallmark indicator of Cytokine Storm Syndrome is the excessive or uncontrolled release of pro-inflammatory cytokines, which can lead to multiple organ failure and cause death. The annual market opportunity to address Cytokine Storm related indications exceeds \$20 billion and includes sepsis, the most common cause of hospital deaths worldwide. Virus-induced Cytokine Storm Syndrome is a leading cause of death resulting from severe SARS-CoV-2 (COVID-19) infections.

In the in vitro study, Sigyn reported the ability of the adsorbent components incorporated within Sigyn Therapy to address viral pathogens, including COVID-19. As the result of a two-hour exposure to Sigyn's adsorbent components, the presence of SARS-CoV-2 pseudotyped lentivirus was reduced by 68.8% from plasma. SARS-CoV-2 pseudotyped lentivirus is an established model previously utilized to study the development of antiviral drugs to treat COVID-19 and to assess the efficacy of vaccines against COVID-19 variants.

Sigyn Chairman and CEO, Jim Joyce stated: "While our first viral depletion observation may be compelling, we recognize this to be the first of several steps to validate viral depletion in combination with pro-inflammatory cytokine elimination as an effective strategy to mitigate virus-induced cytokine storms."

Sigyn Therapeutics further disclosed that it submitted a provisional patent application to the United States Patent and Trademark Office (USPTO) to protect this new discovery.

Sigyn Therapy is a proprietary blood purification technology designed to overcome the limitations of previous drug and device candidates to treat acute inflammatory conditions. Incorporated within Sigyn Therapy is a cocktail of adsorbent components with unique binding and capture characteristics to optimize the broad-spectrum depletion of inflammatory targets from the bloodstream. The single-use medical device is designed for use on the established infrastructure of dialysis and CRRT machines already located in hospitals and clinics worldwide.

Since December 1, 2020, the Company has reported results from several in vitro studies designed to validate the capability of Sigyn Therapy to address a broad-spectrum of inflammatory targets.

Included among these studies was the simultaneous capture 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 induce organ failure and cause death. An objective of this 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.

Sigyn Therapeutics has also reported the results of an in vitro pilot study that modeled the ability of Sigyn Therapy™ to address CytoVesicles that transport inflammatory cytokine cargos in the bloodstream. CytoVesicles (extracellular vesicles that transport inflammatory cytokine cargos) participate in concert with freely circulating cytokines to further escalate Cytokine Storm Syndrome. CytoVesicles have previously been an elusive target as they can be 20-60 times larger than cytokines themselves. In the in vitro pilot study, 104nm liposomes were utilized as a model system to assess the ability of Sigyn Therapy's adsorbent components to deplete CytoVesicles from human blood plasma. After a two-hour interaction with Sigyn's adsorbent components, liposome concentrations in human blood plasma were reduced ~90%. Previously published studies have validated liposomes as a model for the isolation of extracellular vesicles from blood based on the similarity of their size and structural characteristics.

The resulting data from each of these studies will be incorporated into an Investigational Device Exemption (IDE) that Sigyn Therapeutics plans to submit to the United States Food and Drug Administration (FDA) in 2021.

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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