November 2, 2020

Sigyn Therapeutics (SIGY) CEO Note: Rethinking the Treatment of Sepsis and Other Life-Threatening Inflammatory Conditions

SAN DIEGO, CA, Nov. 02, 2020 (GLOBE NEWSWIRE) -- via NewMediaWire – Sigyn Therapeutics, Inc. (OTCMarkets: SIGY), today released the following note authored by its Chairman and CEO, Jim Joyce.

Dear Current and Candidate Shareholders,

We created Sigyn Therapy™ to address a significant unmet need in global health; the treatment of life-threatening inflammatory conditions that are precipitated by Cytokine Storm Syndrome (The Cytokine Storm). The intent of this communication (the first in a series) is to introduce and familiarize you with our technology and therapeutic opportunities, which include large market indications that remain beyond the reach of drug therapies.

Cytokine storm syndrome is characterized as a dysregulated response of the immune system, which can be induced by a wide-range of infectious and non-infectious conditions. Since the outset of the current pandemic, medical journals have widely reported cytokine storm syndrome to be a leading cause of death resulting from severe COVID-19 infections. A hallmark of the cytokine storm is an excessive or uncontrolled release of pro-inflammatory cytokines, which can induce multiple organ failure and result in death.

To recalibrate this dysregulated immune response, we designed Sigyn Therapy to deplete a broad-spectrum of inflammatory contributors from the bloodstream. The most prevalent condition associated with cytokine storm syndrome is sepsis. Earlier this year, the Journal Lancet reported that sepsis kills more people around the world than all forms of cancer combined. The Lancet reported that in 2017, there were 48.9 million cases of sepsis and 11 million deaths. In that same year, the journal reported an estimated 20.3 million sepsis cases and 2.9 million deaths were among children younger than 5 years old. In the United States, sepsis was reported to be the most common cause of in-hospital deaths and accounted for more than $24 billion in annual costs.

To date, more than 70 controlled human studies have been conducted to evaluate the safety and benefit of candidate drugs to treat sepsis. With one brief exception (Xigris from Eli Lilly), none of these studies resulted in an approved drug therapy. When considering the breadth of contributing inflammatory factors, sepsis is likely to remain an elusive target for therapeutic drug agents.

As a result of this therapeutic void, a significant opportunity for non-pharmaceutical blood purification devices has emerged. In this regard, I encourage you to learn about

CytoSorbents Corporation and Toray Industries, Inc. Both are publicly-traded organizations that we highly respect for the advancement of their respective CytoSorb and Toraymyxin devices. Each of these industry pioneering devices are market cleared and broadly deployed to treat a wide-range of inflammatory conditions outside of the U.S. They are being clinically evaluated in the U.S. as candidates to treat severe COVID-19 infection under FDA-awarded Emergency Use Authorizations.

In regards to mechanism of action, Toraymyxin has a high specificity to bind circulating endotoxin, which is reported to be a potent activator of cytokine storm syndrome. However, the Toraymyxin device does not address pro-inflammatory cytokines. Conversely, the CytoSorb device incorporates an adsorbent component that depletes pro-inflammatory cytokines from circulation, but does not address endotoxin.

We designed Sigyn Therapy to deplete the presence of both endotoxin and pro-inflammatory cytokines. To further optimize the potential of our therapeutic outcomes, we expanded Sigyn Therapy's mechanism to include the elimination of larger proteins that transport cytokines and other inflammatory cargos. We refer to these as CytoVesicles. To address this breadth of targets, we incorporate a cocktail of adsorbent components within Sigyn Therapy that each have unique binding and capture characteristics.

In the medical field, the term cocktail often refers to the simultaneous administration of multiple drugs with differing mechanisms of action. However, the dosing of multiple drugs is limited by toxicity and adverse events that may result from deleterious drug interactions. Sigyn Therapy is not constrained by such limitations as our cocktail of adsorbent components are not introduced into the body. As a result, we are able to incorporate a substantial dose of multiple adsorbents, each with differing mechanisms and capabilities to optimize the ability of Sigyn Therapy to calm the cytokine storm that underlies life-threatening inflammatory conditions.

Our therapeutic opportunities include, but are not limited to sepsis, virus induced Cytokine Storm (VICS), bacteria induced Cytokine Storm (BICS), acute respiratory distress syndrome (ARDS) and acute forms of liver failure, including hepatic encephalopathy.

To translate our therapeutic vision into a clinical reality, we are planning a series of studies whose outcomes will be included in an Investigational Device Exemption (IDE) that we intend to submit to FDA in 2021. At present, we are conducting an in vitro study designed to validate the ability of Sigyn Therapy to simultaneously reduce the presence of endotoxin and relevant pro-inflammatory cytokines from human blood plasma. In this study, our cytokine targets include interleukin-6 (IL-6), interleukin-1 (IL-1) and tumor necrosis factor alpha (TNF-a), which are each drug industry targets to treat COVID-19 infected individuals.

Roche, Sanofi, Regeneron and EUSA Pharma are evaluating anti-IL-6 drugs as COVID-19 treatment candidates. Additionally, SOBI is testing an IL-1 inhibitor and Amgen is evaluating the potential benefit of Enbrel to inhibit TNF-a in COVID-19 infected individuals. The prospect of aligning a therapeutic drug with a specific cytokine may be limited as researchers at Stanford and Yale have reported that cytokine profiles in those suffering from severe COVID-19 infection to be consistent with those previously observed in sepsis patients. We believe that a device with much broader capabilities will be required.

I look forward to keeping you updated on our endeavors to advance Sigyn Therapy.

Sincerely,

Jim Joyce
Chairman and CEO
Sigyn Therapeutics, Inc.

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) the outcome of any legal proceedings that may be instituted against Sigyn related to the merger agreement or the transaction. Further risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements are discussed in "Risk Factors" and elsewhere in the previous Reign Resources Corporation Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 and other reports filed with the SEC. 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.