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Sigyn Therapeutics CEO Note: A Treatment Candidate to Address Bloodstream Pathogens, Deadly Toxins and Inflammatory Disease Targets

SAN DIEGO, CA, Aug. 10, 2021 (GLOBE NEWSWIRE) -- via NewMediaWire – Sigyn Therapeutics, Inc. (OTC Markets: **SIGY**), a medical technology company focused on the treatment of sepsis and other life-threatening inflammatory conditions, today released the following note authored by its Chairman and CEO, Jim Joyce.

Sigyn Therapeutics was founded on the belief that a properly designed medical device could address sepsis and other life-threatening inflammatory conditions that remain beyond the reach of drug therapies.

This belief is reflected through our development of Sigyn Therapy. Since December 2020, we reported results from a series of studies that have demonstrated first-in-industry capabilities of Sigyn Therapy to address pathogen sources of inflammation, deadly toxins and relevant inflammatory mediators.

Among the therapeutic targets validated were viral pathogens (including COVID-19), bacterial endotoxin, relevant inflammatory cytokines (IL-6, IL-1b, TNF-a) and hepatic toxins (ammonia, bilirubin, and bile acid). We also completed a study that modeled our ability to capture CytoVesicles that transport inflammatory cargos throughout the bloodstream.

Contributing to these expansive capabilities is a formulation of adsorbent components that are incorporated within Sigyn Therapy. Our adsorbent formulation provides more than 170,000 square meters of surface area on which to adsorb and remove bloodstream targets. This equates to more than 40 acres of surface adsorption area in each adult version of Sigyn Therapy.

Conversely, consider that the ~$340 million market value of our closest public comparable is driven by an adsorption device (market cleared to treat life-threatening inflammatory conditions outside the U.S.) with approximately one-fourth of our surface area capacity and based on an adsorbent bead component whose maximum pore size to eliminate inflammatory targets is reported to be 5 nanometers. Sigyn Therapy has been demonstrated to address inflammatory targets as well as pathogen sources of inflammation whose molecular size can exceed 100 nanometers in size.

Beyond our broad-spectrum capacity to remove bloodstream targets, we disclosed on July 29th, the completion of our first-in-mammal pilot study that demonstrated the safe administration of Sigyn Therapy during six-hour treatment exposures. In the coming months, we will continue to collect animal safety data, which will be included in an Investigational

Device Exemption (IDE) that we are drafting for submission to The United States Food and Drug Administration (FDA) to support the initiation of human clinical studies.

Sincerely, Jim

About Sigyn Therapeutics

Sigyn Therapeutics™ is focused on a 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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