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Sigyn Therapeutics Reports Preliminary Results of Hepatic Encephalopathy Toxin Study

SAN DIEGO, July 13, 2021 (GLOBE NEWSWIRE) -- via NewMediaWire -- Sigyn Therapeutics, Inc. (OTCMarkets: SIGY), a medical technology company focused on the treatment of sepsis and other life-threatening inflammatory conditions, today announced the completion of an *invitro* blood purification study that validated the ability of Sigyn Therapy™ to eliminate bloodstream toxins associated with Hepatic Encephalopathy, a neurological disorder that occurs in individuals suffering from chronic forms of liver (hepatic) disease and acute liver failure.

Sigyn Therapy is a proprietary blood purification technology designed to deplete a broad-spectrum of pathogens, toxins and inflammatory targets from the bloodstream of treated patients.

Hepatic Encephalopathy (HE) is induced when toxins (normally removed by a healthy liver) accumulate in the bloodstream and then cross through the blood brain barrier. Severe cases of HE (grade 3 and 4) can cause serious, life-threatening complications that range from decreased consciousness to coma. 30-day mortality rates of 38% have been reported in cirrhotic patients suffering from grade 3 and 4 Hepatic Encephalopathy.

The goal of the hepatic toxin study was to collect supporting data that would expand the potential use of Sigyn Therapy to include chronic liver disease and acute liver failure indications, including HE.

In previously conducted studies, Sigyn Therapy was reported to deplete circulating pathogens, toxins and inflammatory cytokines that play a prominent role in acute life-threatening inflammatory conditions that underlie a $20 billion annual market opportunity.

In the hepatic toxin study, clinically relevant levels of ammonia, bilirubin and bile acids were spiked into 1000ml of human blood plasma and then circulated at through an adult version of Sigyn Therapy at normal treatment blood-flow rates. The study was conducted in triplicate over four-hour time periods.

In this disclosure, the Company is reporting on the*in vitro* removal of bilirubin by Sigyn Therapy. The depletion of bilirubin from human blood plasma was rapid, with an average reduction of 55% in one hour and 69.5% in four hours of treatment, with high levels of consistency among the triplicate studies. Data related to Ammonia and bile acid removal will be reported in a forthcoming disclosure.

Beyond the accumulation of hepatic toxins in the bloodstream, excessive inflammatory cytokine and endotoxin production contribute to increase the permeability of the blood brain

barrier in those suffering from HE. Thus, enabling the direct interaction of hepatic toxins with brain tissue. Among the most prominent HE related cytokines are tumor necrosis factor-α (TNF-α), interleukin 6 (IL-6) and interleukin 1 beta (IL-1b).

In previous studies, Sigyn Therapy demonstrated the simultaneous depletion of endotoxin, TNF-a, IL-6 and IL-1b from human blood plasma.

The data resulting 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) prior to year-end 2021.

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 is also conducting studies to evaluate the potential use of Sigyn Therapy to treat acute forms of liver failure, including 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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