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Sigyn Therapeutics CEO Note: As Omicron Surges, Consider That the First Authorized COVID-19 Therapies Were Not Drugs or Vaccines

SAN DIEGO, Dec. 17, 2021 (GLOBE NEWSWIRE) -- via NewMediaWire -- Sigyn Therapeutics, Inc. (OTC Markets:"SIGY"), a medical technology company focused on the treatment of pathogen-related conditions that precipitate sepsis, today released the following note authored by its Chairman and CEO, Jim Joyce.

On March 24, 2020, the U.S. Department of Health and Human Services (HHS) declared that the emergence of COVID-19 justified the Emergency-Use Authorization (EUA) of drugs, biological products, and medical devices to combat the pandemic.

Within a month of the HHS declaration, The U.S. Food and Drug Administration (FDA) awarded an EUA to industry colleagues at Terumo BCT, ExThera Medical Corporation, CytoSorbents, Inc., and Baxter Healthcare Corporation. The therapeutic products from these organizations were not drug or biological agents, they were blood purification technologies.

In connection with these EUA awards, FDA published a statement that blood purification devices may be effective at treating certain patients with confirmed COVID-19 by reducing various pathogens, cytokines, and other inflammatory mediators from the bloodstream.

Consistent with FDA's statement, we have been advancing Sigyn Therapy, a dual-function blood purification technology that we created to address pathogen sources of life-threatening inflammation in concert with the broad-spectrum elimination of cytokines and other inflammatory mediators.

Beginning in December of 2020, we have reported results from a series of in vitro blood purification studies that validated the ability of Sigyn Therapy to extract a broad-spectrum of viral pathogens (including COVID-19), gram-negative and gram-positive bacterial toxins, hepatic toxins, cytovesicles and pro-inflammatory cytokines from human blood plasma.

Concurrent with our intent to participate in the emerging blood purification industry, COVID-19 has revealed the strengths and weaknesses of government preparedness initiatives that were in place at the outset of the pandemic.

In this regard, the development, clinical testing, market clearance, and global delivery of multiple vaccines that protect against severe COVID-19 infection is unprecedented. Less than one year after the HHS mandate, vaccines from Janssen, Moderna, and Pfizer-BioNTech were cleared under Emergency Use Authorization. Beyond the ongoing need to

protect against COVID-19, the business environment for protective vaccines should continue to be robust as a confluence of global warming, urban crowding and intercontinental travel are likely to fuel a continuance of future pandemics.

Inversely, 5.3 million COVID-19 deaths and the shutdown of global economies have exposed the futility of aligning post-exposure antiviral drugs with emerging pandemic threats. Especially if preventive messenger RNA (mRNA) vaccines can be delivered to the marketplace at a pace that precedes the development of a post-exposure antiviral drug. Between the EUA clearance of the blood purification and vaccine technologies referenced above, Remdesivir (Gilead Sciences, Inc.), a drug repurposed from the Ebola 2014 outbreak, was the sole antiviral to be cleared under EUA.

As a result, an increasing emphasis should be placed on blood purification technologies as post-exposure countermeasures to treat hospitalized patients with severe infections. In closing, consider that a properly designed blood purification device can perform functions that are beyond the reach of drugs and will have broad commercial applications beyond the treatment of pandemic viruses.

Have a Happy Holiday Season, Jim

About Sigyn Therapeutics™

Sigyn Therapeutics is a medical technology company focused on the treatment of pathogen-related conditions that precipitate sepsis, the #1 cause of hospital deaths worldwide. Sigyn Therapy™ is a dual-function blood purification technology that extracts pathogen sources of life-threatening inflammation in concert with the broad-spectrum elimination of inflammatory mediators from the bloodstream.

Beginning in December of 2020, a series of *invitro* blood purification studies have validated the ability of Sigyn Therapy to address endotoxin (gram-negative bacterial toxin), peptidoglycan and lipoteichoic acid (gram-positive bacterial toxins), viral pathogens (including COVID-19), hepatic toxins (ammonia, bile acid & bilirubin), cytovesicles that transport inflammatory cargos, and relevant proinflammatory cytokines (TNF-a, IL-1b, IL-6) that underlie the cytokine storm that precipitates sepsis.

Therapeutic opportunities for Sigyn Therapy include but are not limited to emerging bioterror and pandemic threats, drug-resistant pathogens, hepatic encephalopathy, and community-acquired pneumonia, which is a leading cause of death among infectious diseases, the leading cause of death in children under 5 years of age, and a catalyst for ~50% of sepsis and septic shock cases.

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 located in hospitals and clinics worldwide. Incorporated within Sigyn Therapy is a formulation of adsorbent components that provide more than 200,000 square meters (~50 acres) of surface area on which to adsorb and remove bloodstream targets. Unlike devices that concentrate therapeutic targets in the blood-path, Sigyn Therapy extracts targets from the bloodstream, which eliminates their ability to interact with blood cells during treatment.

To learn more, visit www.SigynTherapeutics.com

Cautionary Note Regarding Forward-Looking Statements

This information in this press release contains forward-looking statements of Sigyn Therapeutics, Inc. (“Sigyn”) that involve substantial risks and uncertainties. All statements contained in this summary are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that involve risks and uncertainties. Statements containing words such as "may," "believe," "anticipate," "expect," "intend," "plan," "project," "will," "projections," "estimate," "potentially" or similar expressions constitute forward-looking statements. Such forward-looking statements are subject to significant risks and uncertainties and actual results may differ materially from the results anticipated in the forward-looking statements. These forward-looking statements are based upon Sigyn's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Factors that may contribute to such differences may include, without limitation, the Company's ability to clinically advance Sigyn Therapy in human studies required for market clearance, the Company's ability to manufacture Sigyn Therapy, the Company's ability to raise capital resources, and other potential risks. The foregoing list of risks and uncertainties is illustrative but is not exhaustive. Additional factors that could cause results to differ materially from those anticipated in forward-looking statements can be found under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, and in the Company's other filings with the Securities and Exchange Commission, including its quarterly Reports on Form 10-Q. All forward-looking statements contained in this report speak only as of the date on which they were made. Except as may be required by law, the Company does not intend, nor does it undertake any duty, to update this information to reflect future events or circumstances.

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