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Sigyn Therapeutics CEO Note: 2021 Milestone Achievements / 2022 Clinical Progression / Images of Sigyn Therapy in Action

SAN DIEGO, Jan. 04, 2022 (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.

In the face of a pandemic that paused and shuttered numerous clinical research programs, we translated our vision for Sigyn Therapy from conceptual design to clinical application in 2021.

Milestone achievements in the past year establish Sigyn Therapy as an emergent strategy to address a wide-range of pathogen-related conditions that precipitate sepsis, the #1 cause of hospital deaths worldwide.

Building off preclinical observations first reported in December 2020, we initiated and completed five invitro blood purification studies in 2021. These studies validated the ability of Sigyn Therapy to address viral pathogens (including COVID-19), bacterial toxins and a broad-spectrum of inflammatory mediators that promote and fuel the advancement of sepsis.

Concurrent with these achievements, we established manufacturing procedures to support a final design of Sigyn Therapy that improved bloodstream turnover efficiency and expanded our capacity to extract therapeutic targets.

As a result, up to seven additional passes of a patient’s entire bloodstream can now be achieved during a single four-hour treatment. Regarding capacity, we incorporated an increased quantity of adsorbent components that now provide more than 200,000 square meters (~50 acres) of surface area on which to adsorb and bind bloodstream targets.

To demonstrate the feasibility and safety of our device, we initiated and successfully completed a pilot animal study in two porcine (pig) subjects that received six-hour administrations of Sigyn Therapy. Based on these results, we expanded our porcine studies and have now treated five subjects in an eight-subject study. The successful completion of this study will set the stage for the potential advancement of human clinical studies.

As referenced at the outset of this note, we advanced Sigyn Therapy from conceptual design to clinical application in 2021. In this regard, I am proud to share the following link, which provides access to images of Sigyn Therapy in clinical action during treatments administered

on the 10th and 14th of December.

https://tinyurl.com/Sigyn-Therapy-in-Action-Link

2022 – Clinical Progression

In 2022, we will navigate the next phase of our clinical endeavors. First and foremost, we have been drafting an Investigational Device Exemption (IDE) that we plan to submit to the United States Food and Drug Administration (FDA) upon completion of our porcine study. Our IDE submission will seek clearance from FDA to initiate first-in-human studies of Sigyn Therapy. Subsequent to our IDE submission, we will reveal clinical site locations and disclose our principal investigators.

Beyond this clinical objective, we plan to expand our board of directors, augment our senior management team, and establish a scientific advisory board with industry thought leaders. To leverage our status as a fully reporting public company, we are taking steps to comply with the requirements necessary to list our securities on a major exchange.

In our quest to address unmet needs in global health, we envisioned a medical technology that could overcome the limitations of previous blood purification therapies and perform functions that were beyond the reach of drugs. In 2022, we will continue our efforts to transform this vision into a reality.

Sincerely, 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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