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Sigyn CEO Note: First-In-Industry Attributes of CardioDialysisTM to Treat Cardiovascular Disease

SAN DIEGO, CA - December 11, 2025 (NEWMEDIAWIRE) - Sigyn Therapeutics, Inc. ("Sigyn" or the "Company") (OTCQB: SIGY), a developer of dialysis-like therapies to address cardiovascular disease and cancer, today released the following note authored by inventor CEO, Jim Joyce.

Dear Readers,

Kidney dialysis sustains and extends the lives of approximately four million individuals with end-stage renal disease (ESRD). We are advancing CardioDialysisTM to extend the lives of individuals with cardiovascular disease, the leading cause of death worldwide.

A primary objective of cardiovascular disease therapies is to reduce the incidence of heart attacks, strokes, and other Major Adverse Cardiovascular Events (MACE). LDL-C reducing statins (Lipitor, Crestor, and Zocor), the leading class of drugs to treat cardiovascular disease are associated with ***25% reductions in MACE.***

Source Publication Link:

https://pmc.ncbi.nlm.nih.gov/articles/PMC12359277/

Whereas the American Heart Association (AHA) recently reported the use of blood purification to reduce LDL-C and Lipoprotein(a) levels (lipoprotein apheresis) is associated with ***75% to 95% reductions in MACE.***

Source Publication Link:

https://www.ahajournals.org/doi/10.1161/ATV.0000000000000177

When taking these factors into consideration, I want to highlight first-in-industry attributes of CardioDialysis that could expand the use of blood purification to treat cardiovascular disease and potentially allow for us to improve upon the MACE reductions reported by the American Heart Association.

Overcoming a Major Barrier for Treatment Adoption

As per the AHA report, blood purification to reduce circulating levels of LDL-C and Lipoprotein(a), otherwise known as lipoprotein apheresis, is an FDA-approved precedent proven to reduce MACE in those with cardiovascular disease. However, the broad adoption of lipoprotein apheresis is constrained by delivery infrastructure, with treatments being limited to approximately 60 specialized apheresis centers in the United States.

CardioDialysis is not constrained by delivery infrastructure as it is deployed for use on dialysis machines already located at more than 7,500 kidney dialysis clinics in the U.S. alone. Lipoprotein apheresis devices do not operate on dialysis machines.

Broad-Spectrum Clearance of Cardiovascular Disease Targets

Invitro blood purification studies have validated the ability of CardioDialysis to address a broad-spectrum of therapeutic targets, including inflammatory molecules that contribute to cardiovascular disease progression, yet are not addressed with market-approved therapies. To date, the clearance of twelve therapeutic targets (all below 200nm in diameter) from human blood plasma has been demonstrated. CardioDialysis has also been observed to be safe and well tolerated in porcine animal studies conducted at the University of Michigan.

Early Clinical & Commercialization Opportunity in Dialysis Patients

We have an early clinical and commercialization opportunity to treat cardiovascular disease in end-stage renal disease (ESRD) patients as CardioDialysis can be conveniently administered during regularly scheduled dialysis treatments.

The U.S. Renal Data System (USRDS) reports that cardiovascular disease accounts for 67% of ESRD patient deaths and its incidence is up to 20 times higher in ESRD patients as compared to the general population. As recently reported in the Journal Nature, drugs to treat cardiovascular disease have not reduced cardiovascular events in dialysis patients. Additionally, circulating levels of cholesterol-transporting lipoprotein(a), which is not addressed with an approved drug, are 2-4 times higher in ESRD dialysis patients as compared to the general population.

Beyond high mortality rates, cardiovascular disease is a substantial initial market opportunity, given an estimated 550,000 ESRD patients receive ~85 million dialysis treatments in the U.S. each year.

An Executable Clinical Strategy

Unless you have previously advanced an extracorporeal blood purification therapy through FDA's Center for Devices and Radiological Health (CDRH), you may not appreciate the elegance of our clinical strategy. Historically, human clinical studies of devices to treat life-threatening disease conditions often face the daunting challenge to identify and enroll subjects in a hospital intensive care unit (ICU) setting.

Whereas our clinical plan is to enroll ESRD patients to participate in a study conducted at their kidney dialysis clinic, with the administration of CardioDialysis occurring during their regularly scheduled dialysis treatments. This is an efficient yet executable clinical strategy that applies to both our human feasibility (safety) and pivotal efficacy study that will be required for market approval consideration. As a result, the time and cost to conduct our studies should be significantly reduced.

Strategic Value to the Dialysis Industry

When considering that cardiovascular disease is the leading cause of ESRD deaths, a reduction in MACE would be expected to extend ESRD patient lives. Based on average

annual per-patient revenues of $65,000, top-line dialysis industry revenues could be increased by $2.8 billion for each month that the lives of U.S. dialysis patients are extended. CardioDialysis also introduces a potential pathway for the dialysis industry to treat cardiovascular disease in the general population, which is the commercial focus of lipoprotein apheresis. In this regard, we envision the possibility that current "Kidney Dialysis Clinics" could be transformed into future "Renal and CardioDialysis Treatment Centers."

Thank you for reading my note. If you have questions or comments, please contact me at jj@sigyntherapeutics.com

Sincerely, Jim

About Sigyn Therapeutics(TM)

Sigyn Therapeutics is developing dialysis-like therapies to address cardiovascular disease and cancer. The Company's therapeutic candidates are designed to improve and extend the quality of patient lives, and their successful clinical advancement offers to provide strategic value to the dialysis and biopharmaceutical industry.

Sigyn CardioDialysis(TM) is a first-in-industry medical device to treat cardiovascular disease, the leading cause of death globally. CardioDialysis(TM) aims to reduce the circulating presence of inflammatory molecules that fuel cardiovascular disease progression while simultaneously lowing levels of cholesterol-transporting lipoproteins that contribute to heart attacks, strokes, and other Major Adverse Cardiovascular Events (MACE). Based on its broad-spectrum mechanism, CardioDialysis(TM) offers to reduce the incidence of MACE by overcoming the inherent limitations of single-target drugs.

The Company's development pipeline is comprised of ImmunePrep(TM) to optimize the delivery of immunotherapeutic antibodies to treat cancer; ChemoPrep(TM) to enhance the targeted delivery of chemotherapy; and ChemoPure(TM) to reduce the toxicity of chemotherapy.

To learn more about Sigyn Therapeutics, visit: www.SigynTherapeutics.com

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Cautionary Note Regarding Forward-Looking Statements

The 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, 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.