

The Emergence of Blood Purification Devices to Treat Cardiovascular Disease

SAN DIEGO, CA - January 6, 2026 ([NEWMEDIAWIRE](#)) - Sigyn Therapeutics, Inc. ("Sigyn" or the "Company") (OTCQB: SIGY), a developer of dialysis-like therapies to address cardiovascular disease and cancer, today released a note authored by inventor and Chief Executive Officer, Jim Joyce. The note is entitled: *"The Emergence of Blood Purification Devices to Treat Cardiovascular Disease"* and it highlights attributes of CardioDialysis(TM) as compared to current blood purification technologies to treat cardiovascular disease.

Dear Readers,

For more than a century, cardiovascular disease has been the leading cause of death in the United States.

While single-target drugs have been a therapeutic focal point, cardiovascular disease is fueled by a multitude of circulating factors, including inflammatory and cholesterol targets that are not addressed with drug therapies.

While not broadly recognized, multi-target blood purification devices to lower LDL-cholesterol (LDL-C) and Lipoprotein(a) levels, otherwise known as Lipoprotein Apheresis, can reduce major adverse cardiovascular events (MACE) by 75-95% (American Heart Association). Whereas, LDL-C lowering statins, (e.g., Lipitor, Crestor), the leading class of drugs to treat cardiovascular disease, are limited to average MACE reductions of 25%.

When considering this variance between device and drug treatment benefit, Lipoprotein Apheresis provides compelling efficacy evidence that supports the clinical advancement of CardioDialysis.

As compared to Lipoprotein Apheresis, CardioDialysis addresses a wider range of cardiovascular disease targets and is supported by a vastly larger global delivery infrastructure.

In addition to targeting LDL-C and Lipoprotein(a), in vitro studies of CardioDialysis have demonstrated its ability to address a broad-spectrum of inflammatory factors that are also implicated in cardiovascular disease progression.

In regard to global delivery infrastructure, CardioDialysis is deployed for use on dialysis machines already located in hospitals and clinics around the world. This is an important strategic advantage as the delivery of Lipoprotein Apheresis is limited to plasma separation machines located in specialized apheresis centers.

To provide some perspective, there are more than 7,500 dialysis clinics in the United States, while geographical access to Lipoprotein Apheresis is limited to fewer than 60 apheresis

center locations. Globally, there are approximately 50,000 dialysis clinics, yet less than 800 apheresis center locations.

Regardless of distribution constraint, the demand for Lipoprotein Apheresis continues to grow. The global market for the therapy was estimated at \$300 million in 2024 and is projected to reach \$650 million in 2033. Thus, further supporting our rationale to clinically advance CardioDialysis.

Beyond our strategic distribution advantage, the deployment of CardioDialysis on dialysis machines provides an early clinical opportunity to address cardiovascular disease in end-stage renal disease (ESRD) patients who rely on kidney dialysis for survival.

Globally, more than four million ESRD patients receive approximately 640 million dialysis treatments each year. Once on dialysis, their median length of survival is 3-5 years.

Cardiovascular disease accounts for approximately 67% of ESRD patient deaths.

Unfortunately, drug therapies have not been found to improve survival or reduce cardiovascular events in this patient population. As a result, the treatment of cardiovascular disease in ESRD patients remains a significant unmet need in global health.

Unlike Lipoprotein Apheresis, CardioDialysis can be conveniently administered during regularly scheduled dialysis treatments to combat cardiovascular disease progression. Beyond providing potential patient benefit, CardioDialysis could have a significant impact on dialysis industry revenues. In the United States, there is an estimated 550,000 ESRD patients on dialysis. Extending the lives of these patients by just one month would boost top-line U.S. dialysis industry revenues by approximately \$2.8 billion. What if the lives of ESRD patients could be extended by years?

Our clinical plan to initially treat cardiovascular disease in ESRD patients is far more than a niche market opportunity. Consider that the \$300 million market for Lipoprotein Apheresis in 2024 was based on the treatment of approximately 5,500 individuals worldwide. That number is the equivalent of just 1% of the U.S. dialysis patient population and slightly more than 1/10th of one percent of the global population of ESRD patients on dialysis.

Now consider that a vast majority of ESRD dialysis patients suffer from cardiovascular disease; approximately two thirds will die from the condition; and drug therapies provide little if any benefit. Thus, further reinforcing the potential value of CardioDialysis.

Thank you for reading my note. If you have questions or comments, please reach out 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 lowering 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

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, 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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