

September 3, 2025



Sigyn Therapeutics Announces Cardiovascular Disease Study

Future Study Could Lead to a Groundbreaking Approach to Reduce Major Adverse Cardiovascular Events

SAN DIEGO, CA. - September 3, 2025 ([NEWMEDIAWIRE](#)) - Sigyn Therapeutics, Inc. ("Sigyn" or the "Company") (OTCQB: SIGY), a developer of next-generation blood purification technologies, today announced plans to commence a multi-site clinical feasibility study of Sigyn Therapy(TM) in high-risk cardiovascular disease (CVD) subjects. According to the World Health Organization, CVD is the number one cause of death globally.

Sigyn Therapy(TM) is a first-in-class whole-blood adsorption technology designed for use on dialysis machines located in hospitals and clinics around the world. Specific to cardiovascular disease, Sigyn Therapy(TM) reduces the circulating presence of inflammatory molecules that promote CVD progression while simultaneously targeting cholesterol transporting lipoproteins that contribute to heart attacks, strokes, and other major adverse cardiovascular events (MACE).

The Company had previously reported that the protocol of its clinical feasibility study would enroll dialysis dependent end-stage renal disease (ESRD) patients with endotoxemia and concurrent inflammation. These are conditions that promote cardiovascular disease, which is the leading cause of ESRD patient deaths.

Based on insight from pre-clinical *invitro* studies, the Company is expanding its feasibility study protocol to quantify lipoprotein reduction resulting from the administration of Sigyn Therapy(TM). The successful completion of the Sigyn feasibility study would set the stage for a pivotal efficacy study necessary to pursue potential market clearance.

The use of an extracorporeal device to reduce lipoprotein(a) [Lp(a)] and low-density lipoprotein cholesterol [LDL-C] from the bloodstream is commercially known as lipoprotein apheresis (LA). LA is an established FDA-approved device precedent to treat cardiovascular disease. Published clinical studies of LA have reported 55% to 98% reductions in major adverse cardiovascular events (MACE) in treated patients.

While the clinical benefit of lipoprotein apheresis is well established, treatment access in the United States is limited to fewer than 60 specialized apheresis centers. Whereas Sigyn Therapy(TM) is deployed on dialysis machines located in approximately 7,500 U.S. dialysis clinics. Beyond its potential for broad commercialization, Sigyn Therapy(TM) can be conveniently administered to ESRD patients during their regularly scheduled dialysis treatments.

"Targeting the bloodstream reduction of Lp(a) and LDL-C while simultaneously suppressing dialysis-induced endotoxemia and inflammation introduces a broad-spectrum strategy to

extend ESRD patient lives by addressing multiple core drivers of cardiovascular disease," stated Jim Joyce, Sigyn Therapeutics' CEO and co-inventor of Sigyn Therapy(TM).

The Potential Value of Extending ESRD Patient Lives

In the United States, the dialysis industry generates annual revenues of approximately \$34 billion based on the administration of ~85 million dialysis treatments to more than 550,000 individuals with end-stage renal disease (ESRD). In the absence of an effective therapeutic intervention, most ESRD patients will die from cardiovascular disease. Based on reported dialysis treatment revenues, extending the lives of ESRD patients by just one month could increase top-line industry revenues by approximately \$2.8 billion. The primary revenue beneficiaries would be Fresenius Medical Care and Davita, Inc., who control 75% of the U.S. dialysis market based on public financial filings.

About Sigyn Therapeutics(TM)

Sigyn Therapeutics is a developer of next-generation blood purification technologies. **Sigyn Therapy(TM)** is a first-in-class whole-blood adsorption technology designed for use on dialysis machines located in hospitals and clinics around the world. Specific to cardiovascular disease, Sigyn Therapy(TM) reduces the circulating presence of inflammatory molecules that promote cardiovascular disease progression while simultaneously targeting cholesterol transporting lipoproteins that contribute to heart attacks, strokes, and other major adverse cardiovascular events.

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

CONTACT:

Sigyn Therapeutics, Inc.

Jim Joyce

CEO, Inventor

Email: jj@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, 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.

View the original release on www.newmediawire.com