

# MedTech Stock Sigyn Therapeutics (OTC: \$SIGY) Reports Results of Pilot Study to Address Inflammatory CytoVesicles

*Sigyn Therapeutics, Inc. (OTCMarkets: SIGY) announced the results of an in vitro pilot study featuring Sigyn Therapy™ addressing CytoVesicles*



SAN DIEGO, CALIFORNIA, UNITED STATES, January 6, 2021

/EINPresswire.com/ -- Medical

Therapeutic technology stock news

from Investorideas.com Newswire - Sigyn Therapeutics, Inc. (OTCMarkets: SIGY) , a medical technology company whose focus is the treatment of life-threatening inflammatory conditions precipitated by Cytokine Storm Syndrome (the Cytokine Storm), today announced the results of an in vitro pilot study that successfully modeled the ability of Sigyn Therapy™ to address CytoVesicles that transport inflammatory cytokine cargos in the bloodstream.

Read the full news, featuring SIGN at

<https://www.investorideas.com/news/2021/biotech/01061SIGY-Inflammatory-CytoVesicles.asp>

Cytokine Storm Syndrome is an excessive response of the immune system that is induced by infectious and non-infectious conditions. A hallmark indicator of Cytokine Storm Syndrome is the excessive or uncontrolled release of pro-inflammatory cytokines, which can lead to multiple organ failure and cause death. The annual market opportunity to address Cytokine Storm related indications exceeds \$20 billion and includes sepsis, the most common cause of hospital deaths worldwide. Virus-induced Cytokine Storm Syndrome is a leading cause of death resulting from severe SARS-CoV-2 (COVID-19) infections.

Sigyn Therapy is a proprietary blood purification technology designed to overcome the limitations of previous drug and device candidates to treat acute inflammatory conditions. Incorporated within Sigyn Therapy is a cocktail of adsorbent components with unique binding and capture characteristics to optimize the broad-spectrum depletion of inflammatory targets from the bloodstream. These targets include pro-inflammatory cytokines, endotoxin and CytoVesicles (extracellular vesicles that transport inflammatory cytokine cargos) that participate in concert with freely circulating cytokines to further escalate the Cytokine Storm. CytoVesicles

are an important yet previously elusive target as they can be 20-60 times larger than cytokines themselves.

In the in vitro pilot study, 104nm liposomes were utilized as a model system to assess the ability of Sigyn Therapy's adsorbent components to deplete CytoVesicles from human blood plasma. After a two-hour interaction with Sigyn's adsorbent components, liposome concentrations in human blood plasma were reduced ~90%. Previously published studies have validated liposomes as a model for the isolation of extracellular vesicles from blood based on the similarity of their size and structural characteristics.

"When we designed Sigyn Therapy, we envisioned a device that could be broadly deployed by the medical community, yet also have expansive first-in-industry capabilities that offer to improve patient outcomes," stated Jim Joyce, Chairman and CEO of Sigyn Therapeutics. "When considering our previous report that Sigyn Therapy™ clears both endotoxin and inflammatory cytokines from human blood plasma, the observation from our CytoVesicle pilot study further reinforces the potential for our vision to become a therapeutic reality."

Sigyn Therapy is a single-use device designed for use on the established infrastructure of dialysis and CRRT machines already located in hospitals and clinics worldwide. On December 1, 2020, the Company reported the results of an in vitro study that validated the ability of Sigyn Therapy to simultaneously reduce the presence of endotoxin and relevant pro-inflammatory cytokines, which included Interleukin-1 Beta (IL-1B), Interleukin-6 (IL-6) and Tumor Necrosis Factor alpha (TNF-a). Endotoxin (lipopolysaccharide or LPS) is a potent mediator implicated in the pathogenesis of sepsis and septic shock. The dysregulated over-production of IL-1B, IL-6 and TNF-a can lead to organ failure and cause death.

An objective of the study was to rebalance elevated cytokine levels and optimize the elimination of endotoxin from human blood plasma. The study was conducted in triplicate over four-hour time periods with a pediatric version of Sigyn Therapy. Average reduction of endotoxin load peaked at 83% during the studies. The average reduction of IL-1B was 69%, IL-6 reduction was 59% and TNF-a reduction was 57% during the four-hour studies.

The resulting data from each of these studies will be incorporated into an Investigational Device Exemption (IDE) that Sigyn Therapeutics plans to submit to the United States Food and Drug Administration (FDA) in 2021.

About Sigyn Therapeutics

To learn more, visit [www.SigynTherapeutics.com](http://www.SigynTherapeutics.com) or [www.SigynTherapy.com](http://www.SigynTherapy.com)

Cautionary Note Regarding Forward-Looking Statements (Read the full release at <https://www.investorideas.com/news/2021/biotech/01061SIGY-Inflammatory-CytoVesicles.asp>)

This press release contains forward-looking statements of Sigyn Therapeutics, Inc. ("Sigyn") that

involve substantial risks and uncertainties.

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