Innovative Product ExoFlo™ From Direct Biologics Fulfills Unmet but Urgent Medical Need in COVID-19 Treatment

Medical professionals report dramatic and consistent success in treating patients gravely ill with COVID-19-associated Acute Respiratory Distress Syndrome (ARDS)

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AUSTIN, Texas, January 28, 2021 (Newswire.com) - As intensive care units across the country fill to capacity, hospital beds are in dangerously short supply, and deaths from COVID-19 continue to spike, doctors from medical centers coast to coast are reporting on the remarkable healing properties of ExoFlo, an innovative life-saving therapy that leverages the anti-inflammatory and regenerative effects of bone-marrow derived mesenchymal stem cells, when used on their most seriously ill COVID-19 patients. The physicians note that utilizing ExoFlo, administered as a single IV infusion, is safe and efficacious and is saving lives on a consistent basis.

One of the product's earliest advocates, Dr. Vik Sengupta of New York, credits ExoFlo with saving his own life. He has since used it on many critically ill patients, eagerly shared it with colleagues, and coauthored, with his wife, Dr. Sascha Sengupta, a clinical safety trial conducted at Christ Hospital in Jersey City, N.J. as part of the therapy's FDA approval process. The safety data from this study has since set the stage for the FDA approval of ExoFlo for an Investigational New Drug (IND) application for COVID-19.

"The most common cause of death among critically ill COVID-19 patients is acute respiratory distress symptom, or ARDS, in which the lungs are badly damaged, scarred and fill with fluid," explained Dr. Sengupta. "This is essentially a result of the body reacting to a threat by overproducing cytokines and other mediators of inflammation that cause damage to the lungs and other tissues in the body in a phenomenon commonly known as the 'cytokine storm.'

"ExoFlo does two important things: it remediates the inflammation almost immediately by delivering miRNA that stop the inflammatory cascade, and it delivers growth factors that promote the regeneration of healthy lung tissue for a much speedier recovery."

ExoFlo is manufactured by Direct Biologics, a market-leading cGMP manufacturer of regenerative medical products based in Austin, Texas. ExoFlo has amazed doctors with its ability to fill an unmet but urgent medical need, saving the lives of patients experiencing COVID-19- associated Acute Respiratory Distress Syndrome. Time and again, patients were able to be discharged and returned to their families rather than deteriorating to an irreversible state.

"This product could not have come at a better time," noted Dr. Angel Lazo Jr. of New Jersey. "This product also opens the door to medical solutions for post-pandemic concerns, when there will be an urgent need to address COVID-19 survivors suffering from Post-Acute COVID Syndrome (PACS),

often referred to as long-hauler COVID, and to remediate compromised immune systems and likely lasting pulmonary scarring."

Dr. Sengupta recalls his first experience with ExoFlo: "We were all exhausted, working multiple shifts during the worst of the early days of the epidemic when the New York area was hit so hard. A friend asked me if I could help her elderly parents, both in their 80s and both very ill with COVID-19. The wife had been admitted to the hospital, and unfortunately, despite our best efforts, the hospital administration refused us permission to treat her with ExoFlo. The husband, who had been declining quickly and suffered from a fever, hypoxia, delirium, diarrhea, no sense of taste, and lack of appetite, became the first documented patient in medical history to be administered an exosome-based treatment for critical respiratory illness. He received ExoFlo at home without any adverse reactions and was out of bed and singing arias within two days. Sadly, and unbeknownst to him, his wife had died in the hospital."

This was a dramatic and eye-opening experience. "When I myself fell victim to COVID, I became seriously ill very fast," noted Dr. Sengupta. "I awoke in the middle of the night, struggling to breath and sinking into delirium, and checked my O2sat, immediately realizing I was going into respiratory failure. I called my wife. She left her shift at the hospital, rushed home, and administered ExoFlo. Within 24 hours my supplemental oxygenation requirement, fever, and respiratory symptoms significantly improved. And within five days of that single dose, I was almost fully recovered from the acute infection. I firmly believe that ExoFlo saved my life."

As word spreads within the medical community, increasing numbers of doctors have been astounded by the efficacy and safety of ExoFlo. Among those who have gone on record singing its praises are Dr. Iman Bar of Newport Beach, Calif., and Dr. Jack Mann of Flushing, N.Y.

"The COVID-19 pandemic has presented doctors with a heartbreaking learning curve," said Dr. Sengupta, who has since become Direct Biologic's chief medical officer. "For months we had no choice but to stand by while patients died despite our best efforts to save them. It's an incredible relief now to have ExoFlo in our arsenal of treatments."

ExoFlo is a biopharmaceutical grade regenerative medicine product that represents a meaningful therapy in the fight against the deadly lung inflammation caused by the COVID-19 virus. The new investigational drug uses extracellular vesicles and growth factor proteins isolated from human bone marrow mesenchymal stem cells (MSCs) to reduce inflammation and direct cellular communication capable of strengthening the body's defenses and advancing its healing processes.

ExoFlo is currently in a Phase II clinical trial that expands knowledge gleaned from a prospective, open-label study in which 17 out of 24 patients demonstrated resolution of their ARDS, exhibiting biomarker and oxygenation improvements within 48-72 hours following treatment with a single 15mL intravenous dose of ExoFlo. Since receiving FDA approval of an expanded access protocol in October 2020, ExoFlo is also being utilized by physicians around the country as part of single patient emergency or compassionate use protocol, commonly referred to as eIND.

About Direct Biologics

Direct Biologics, LLC, is headquartered in Austin, Texas, with a recently expanded R&D facility located at the University of California, and an Operations and Order Fulfillment Center located in St. Louis, Missouri. Direct Biologics is a market-leading innovator and cGMP manufacturer of regenerative medical products, including a robust line of extracellular vesicle-based biological products. The company was created to expand the science of regenerative healing by delivering cutting-edge biologic technologies. Direct Biologics' management team holds extensive collective

experience in biologics research, development, and commercialization, making the company a leader in the evolving, next generation segment of the biotherapeutics industry. Direct Biologics is dedicated to pursuing additional clinical applications of its extracellular vesicle biologic products through the FDA's investigational new drug application process.

For more information visit http://www.directbiologics.com.

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