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FDA Clears Mesoblast Remestemcel-L For Covid-19 Ards

Mesoblast says that the US Food and Drug Administration has cleared remestemcel-L to treat for use acute respiratory distress syndrome caused by coronavirus infection.

Mesoblast said that the FDA cleared an investigational new drug application to use intravenous infusions of the allogeneic mesenchymal stem cell formulation to treat patients with acute respiratory distress syndrome (ARDS) caused by Covdi-19.

Mesoblast chief medical officer Dr Fred Grossman said “the FDA clearance provides a pathway in the United States for use of remestemcel-L in patients with Covid-19 ARDS, where the prognosis is very dismal, under both expanded access compassionate use and in a planned randomized controlled trial”.

The company said that remestemcel-L was being developed for inflammatory conditions and was believed to counteract the inflammatory processes implicated in these diseases by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

A number of companies have said they were working to develop treatments for what is described as “a cytokine storm”.

Mesoblast said that remestemcel-L safety and efficacy had been evaluated in more than 1,100 patients in clinical trials, including its phase III trial for steroid-refractory acute graft versus host disease in children, a potentially fatal inflammatory condition due to a similar cytokine storm process as is seen in Covid-19 acute respiratory distress syndrome.

The company said that a post-hoc analysis of a randomized, placebo-controlled study in 60 patients with chronic obstructive pulmonary disease showed that remestemcel-L "significantly improved respiratory function in patients with the same elevated inflammatory biomarkers that are also observed in patients with Covid-19 [acute respiratory distress syndrome]," Mesoblast said.

The company said the outcomes provided the rationale for evaluating remestemcel-L in patients with COVID-19 acute respiratory distress syndrome.

Mesoblast was up 47 cents or 34.9 percent to $1.815 with 13.8 million shares traded.