AstroStem-V, FDA Clinical Trial for COVID-19 Patients with Pneumonia

LOS ANGELES , CALIFORNIA, UNITED STATES , October 12, 2020 /EINPresswire.com/ -- AstroStem-V, FDA Clinical Trial for COVID-19 Patients with Pneumonia

-FDA Phase 1/2a clinical trial for COVID-19 patients with pneumonia will be conducted in the Los Angeles area.
-Nature Cell, a leading biotechnology company of South Korea, has developed a stem cell therapy, AstroStem-V and obtained the approval for the FDA Phase 1/2a clinical trial.
-The company is in search of hospitals and principal investigators to conduct the FDA clinical trial in Southern California.

Nature Cell, a leading biotechnology company in South Korea and the parent company of Stemcellbio of Southern California, has developed AstroStem-V to treat COVID-19 patients with pneumonia and obtained the approval for the FDA Phase 1/2a clinical trial. AstroStem-V is a stem cell therapy based on same family allogenic adipose tissue-derived mesenchymal stem cells of parents, children, and siblings of COVID-19 patients. This FDA clinical trial is to explore the safety and efficacy of AstroStem-V. The stem cell therapy received the commercial clinical approval of IND from the FDA for COVID-19 indications. The following link is for further details to the NIH National Library of Medicine.
https://clinicaltrials.gov/ct2/show/NCT04527224

In April 2020, Nature Cell submitted to the FDA the protocol for the AstroStem-V clinical trial to administer stem cells from patients' parents, children, or siblings intravenously to COVID-19 patients with pneumonia. After completing consultation with the FDA and the data supplementation process, the IND was finally approved in August 2020. A total of 10 adults from age 19 to 80 with a diagnosis of pneumonia by radiologic examination with COVID-19 will be enrolled. AstroStem-V will be administered to the patient once and followed for 12 weeks to evaluate the safety and efficacy.

The safety will be monitored by evaluating 'treatment related adverse events' after the injection of AstroStem-V, and the efficacy will be monitored by evaluating the improvement of COVID-19 pneumonia by Oxygenation index (PaO2 / FiO2 ration), X-Ray or CT, and the duration of intensive care unit stay. In addition, molecular diagnostic tests will be used to evaluate the presence of COVID-19 virus.

Nature Cell and Stemcellbio are searching for hospitals and primary investigators in the Los Angeles area to conduct the AstroStem-V FDA clinical trial. Patient recruitment will begin in October 2020. Final results of the study are expected to be available in the first half of next year.

Lead researcher, Dr. Jeong-chan Ra expressed, “I think of it as Nature Cell’s act of community service to strive in saving lives.” He added, “I am delighted to be able to save the lives of Americans with Korean stem cell technology.”

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About Nature Cell
Nature Cell is a leading biotechnology company in South Korea. The Company develops stem cell therapies for rare diseases. In addition to AstroStem-V, the Company is conducting US FDA clinical trials for the following stem cell therapies.

JointStem – US FDA Phase 2b/3a clinical trial for Osteoarthritis, Knee
https://clinicaltrials.gov/ct2/show/NCT04368806?term=JointStem&draw=1&rank=2

AstroStem – US FDA Phase 2 clinical trial for Alzheimer’s Disease
https://clinicaltrials.gov/ct2/show/NCT04482413?term=Astrostem&draw=2&rank=1

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