CYNK-001 COVID-19 Clinical Trial

University of California, Irvine | UCLA-UCI Alpha Stem Cell Clinic

**Study Title:** A Phase I/II study of human placental hematopoietic stem cell derived natural killer cells (CYNK-001) for the treatment of adults with COVID-19

**Lead Investigator:** Leonid Groysman, MD

**Study Sponsor:** Celularity Inc.

What is the study?

The purpose of this study is to assess the safety of CYNK-001 and to test the effects of CYNK-001 on people with COVID-19. The study plans to find out the best dose of CYNK-001 and to find out if CYNK-001 improves or worsens the disease.

How long will my participation last?

Study participation will last approximately up to one year from the screening period.

How can I take part in this trial?

Approximately 86 subjects will participate across all sites. UC Irvine will enroll up to 10 subjects.

*Please note this may not be a complete list of eligibility criteria.*

**Main Inclusion Criteria**

* Adults, ≥ 18 years of age
* Confirmed positive for SARS-CoV-2 as measured by rRT-PCR.
* Subject is experiencing at least 2 of the 3 symptoms of the list below:
	+ a. Fever ≥ 38 C°
	+ b. Cough
	+ c. Positive disease-related chest x-ray
* Has mild to moderate pulmonary involvement as measured by chest radiograph presenting with lower respiratory tract infection.

**Main Exclusion Criteria**

* Not formally admitted to the hospital.
* Admitted to Intensive Care Unit / Pulmonary Acute Care Unit designated area with severe pulmonary pneumonia, ARDS or Sepsis.
* Pregnant women
* history of severe asthma and is presently on chronic medications or has a
* history of other symptomatic pulmonary disease.

How does it work?

CYNK-001 is an investigational product that is a liquid containing natural killer cells (NK cells) taken from human placenta cells. Natural Killer cells are a type of immune cell that can kill cancer cells in some cases. Laboratory tests have shown that CYNK-001 has the ability to specifically kill the tumor cells without killing normal healthy cells. Natural killer cells can also identify cells infected by some viruses.

CYNK-001 is made from human placental stem cells (cells that create different types of blood cells). These are gathered through the umbilical cord after the birth of healthy full-term babies. The gathered material is carefully screened.

Where is the study conducted?

At the University of California, Irvine Medical Center located in Orange, CA.

Will I be compensated?

Participants will not be compensated.

For more information, please contact:

**UC Irvine Alpha Stem Cell Clinic**

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