

## **JadiCell for Treatment of COVID-19**

### *Background and Summary of Opportunity*

**Corporate Background:** Therapeutic Solutions International is a Biotechnology company dedicated to developing and commercializing novel therapies in the area of immunology and regenerative medicine. The Company is guided by internationally known scientists such as Francesco Marincola (Head of Cell Therapy for Gilead), Santosh Kesari (Brain and COVID-19 clinical trials expert) and Boris Reznik (Clinical trials expert).

**How do Stem Cells work for COVID-19?** Advanced COVID-19 kills based on stimulation of lung hyperinflammation. Patients that survive COVID-19 often have lung scarring which causes long term pulmonary deterioration. The mesenchymal family of stem cells, called mesenchymal stem cells (MSC), have previously been demonstrated to save lives of people with a severe inflammatory disease called graft versus host disease. Subsequent studies showed that MSC protect against patients with viral lung damage, as well as in COVID-19 patients. There are several companies attempting to use MSC for treatment of COVID-19, unfortunately none have passed Phase III trials to date.

**What is the JadiCell?** JadiCell is superior to other types of clinically used MSC, such as bone marrow, fat, and cord blood MSC based on its ability to produce higher levels of: a) anti-inflammatory cytokines such as IL-10, TGF-beta and IL-1RA; b) Proteins that stop death of lung cells such as EGF-1, CTNF, and KGF-1 and; c) Proteins that accelerate healing of damaged lung tissue such as HGF-1, FGF-2, and PDGF-1. The reason for these activities is related to the natural role these cells play in the body in preventing the mother's immune response from killing the fetus. It has been shown that JadiCells possess protein markers associated with stem cell potency that are not found on other stem cells.

**Preclinical Studies:** JadiCells have been shown to inhibit death, reduce cytokine storm, and preserve lung function in both the LPS and Poly (IC) induced models of COVID-19. Mechanisms of action have been elucidated and appear to be dependent on Fox-P3 and to some extent IL-10. In agreement with in vitro studies, the in vivo activities of JadiCells outperformed other stem cells.

**Clinical Translation:** JadiCells have been utilized in a variety of clinical trials including for Alzheimer's Disease and Type 1 Diabetes with no signs of adverse events. In 2020 Dr. Ricordi led the international team that successfully completed the first FDA approved controlled trial to treat the most severe cases of COVID-19 with stem cell infusions. The unprecedented results allowed for 100% patient survival at one month in subjects treated who were less than 85 years old, and 91% survival in subjects of all ages, compared to 42% survival in the control group. Numerous other patients have been treated with JadiCells for a variety of indications with no adverse events noted to date. Currently, the FDA approved a Phase III pivotal clinical trial for formal registration with the FDA.

**Emergency/Compassionate Uses:** Therapeutic Solutions International, Inc. has announced the preparation for filing an Emergency Use Authorization (EUA) to the FDA for JadiCells™ in treatment of COVID-19 associated lung injury. If you are a Physician or Hospital Administrator interested in obtaining JadiCells™ in treatment of COVID-19 lung failure under eIND, or Right to Try, please use this email contact for James Veltmeyer, M.D., Chief Medical Officer of the company at [jadicelltsoi@gmail.com](mailto:jadicelltsoi@gmail.com).

**Fees:** Unfortunately, JadiCells are not free, and we must charge \$20,000 per patient for just the cells. The fee for the cells must be prepaid by wire or cashier's check only and there are no returns and no refunds as this is a biological product that must be used once it ships from the manufacturing lab or destroyed if unused for any reason.