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Interim Results of a Phase I Study Investigating a Cord Blood-Derived Natural Killer Cell Therapy for Patients Hospitalized with COVID-19

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Introduction: In the setting of viral infections, including infection with SARS-CoV-2, lymphocyte exhaustion and lymphopenia are common. Patients with COVID-19 who develop lymphopenia, particularly low numbers of circulating natural killer (NK) cells, are at high risk for disease progression. Thus, strategies that overcome profound lymphopenia and restore innate immune function may reduce the severity of COVID-19. One approach is the direct infusion of an exogenous source of healthy, functional NK cells intended to boost the patient's immune system during the viral infection, enabling elimination of infected cells. "DVX201" is a cord blood-derived allogeneic NK cell therapy that is cryopreserved and intended for "off-the-shelf use" without HLA-matching.

Objective: The primary objective of this study is to investigate the safety and to identify the recommended phase II dose and/or the maximum tolerated dose (MTD) of DVX201 in patients hospitalized with COVID-19.

Methods: We are conducting an open-label, nonrandomized phase I safety and dose-finding (modified 3+3) study of DVX201 at three dose levels in patients hospitalized with COVID-19.

Adult patients with documented SARS-CoV-2 infection were eligible if they were admitted to the hospital, were receiving ≤ 6 L supplemental oxygen by low flow delivery, and did not have other evidence of cytokine storm based on levels of serum IL-6, C-reactive protein, and ferritin.

Results: To date, 9 patients have been enrolled: 3 subjects at each dose level. All dose levels have been well tolerated, with no dose-limiting toxicities, infusion toxicities, or cytokine release syndrome observed. All patients were discharged from the hospital at an average of 5 days post infusion. Blood samples were drawn for correlative studies including persistence of DVX201, pre- and post-infusion immune system characterization, and cytokine panels. Accrual is continuing at the MTD.

Discussion: This trial will serve as the proof of concept for the use of DVX201 as an anti-viral treatment for COVID-19. These results will inform the potential role of DVX201 for treatment of other life-threatening viral infections by harnessing NK cells' innate function to kill virally infected cells, regardless of the etiology of the infection.