



## **Nohla Therapeutics Receives FDA Fast Track Designation for Dilanubicel for Allogeneic Cord Blood Transplant Patients**

**Seattle -- (GlobeNewswire – August 6, 2018)** - Nohla Therapeutics, a leading developer of universal, off-the-shelf cell therapies for patients with hematologic malignancies and other critical diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to dilanubicel (NLA101) for patients with high-risk hematologic malignancies receiving an allogeneic cord blood transplant. Dilanubicel has already received PRIME designation from the European Medicines Agency, and Orphan Drug Designation from the FDA and European Commission.

The FDA Fast Track program is designed to facilitate the development and expedite review of drugs used to treat serious conditions and fill an unmet medical need. Fast Track designation provides Nohla with more frequent meetings and written communications with the FDA regarding dilanubicel's development, as well as eligibility for Accelerated Approval, Priority Review, and Rolling Review if the relevant criteria are met.

"FDA Fast Track designation represents another important regulatory milestone for dilanubicel as we continue to pursue accelerated development strategies in the US, Europe and Japan," said Katie Fanning, President and CEO of Nohla Therapeutics. "This designation by the FDA further reinforces the significance of dilanubicel's clinical results to date and its potential as an important treatment option for patients undergoing hematopoietic stem cell transplantation. We look forward to working with the FDA and other regulatory agencies after we receive top-line results from our randomized Phase 2b study in this patient population."

The FDA Fast Track designation was supported by efficacy and safety data from a dilanubicel Phase 2 single arm study in patients with hematologic malignancies who underwent a myeloablative cord blood transplant. The results of this study demonstrated that infusion of dilanubicel was safe and led to faster neutrophil and platelet recovery with improved long-term survival when compared to a separate control group. In addition, dilanubicel-treated patients experienced no severe acute Graft-versus-Host Disease (GVHD) and no transplant-related mortality.

### **About Dilanubicel**

The company's lead product candidate, dilanubicel, is currently under evaluation in two ongoing Phase 2 trials. A Phase 2b randomized trial (NCT01690520), has completed enrollment of 160 patients with hematologic malignancies undergoing a myeloablative allogeneic cord blood transplant with or without dilanubicel. In addition, the global Phase 2 LAUNCH trial (NCT03301597) is currently enrolling AML patients at risk for neutropenia after receiving intensive chemotherapy treatment.

Dilanubicel is a universal donor, off-the-shelf, ex vivo expanded hematopoietic stem and progenitor cell investigational product intended to provide rapid, transient hematopoiesis with long-term immunologic benefits. Unlike autologous or patient-specific allogeneic cell therapies, dilanubicel does not require Human Leukocyte Antigen (HLA) tissue matching. Intentionally developed to provide short-term, temporary bone marrow function until a patient's immune system recovers, dilanubicel may also induce long-term immunologic benefits with the potential for improved survival. Dilanubicel is manufactured ahead of time, cryopreserved, and intended for immediate off-the-shelf use.



### **About Nohla Therapeutics**

Nohla Therapeutics is a leading developer of off-the shelf cell therapies for patients with cancer and other critical diseases. Nohla's proprietary notch ligand technology platform serves as the foundation for its ongoing clinical, preclinical and discovery programs. The company's lead product candidate, dilanubicel, is currently under evaluation in two ongoing Phase 2 trials. Nohla is also pursuing multiple preclinical and discovery programs in the areas of immune tolerance and other diseases. More information is available at [www.nohlatherapeutics.com](http://www.nohlatherapeutics.com) or on Twitter @nohlatx.

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