Nohla Receives EMA PRIME Designation for Dilanubicel (NLA101) to Treat Hematopoietic Stem Cell Transplant Patients

First Product to Achieve PRIME Designation for Hematopoietic Stem Cell Transplant Patients

Seattle -- (GlobeNewswire – June 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 the European Medicines Agency (EMA) has granted dilanubicel (NLA101) PRIority MEdicines (PRIME) designation for the treatment of patients receiving a Hematopoietic Stem Cell Transplant (HSCT). Nohla was granted Orphan Drug designation for dilanubicel in HSCT by the European Commission in January 2018.

The EMA PRIME program provides enhanced support for the development of medicines that target an unmet medical need and have clinical data demonstrating the potential for a major therapeutic advantage over existing treatments. The program is designed to speed up evaluation of potential treatments to reach patients more rapidly. Under the PRIME program, a marketing authorization application (MAA) for dilanubicel could be eligible for an accelerated regulatory assessment. Since its inception in 2016, only 21% of PRIME requests have been granted by the EMA.

“This designation is further validation that dilanubicel may represent a valuable therapeutic option and could address the high unmet medical need for patients undergoing a HSCT,” said Katie Fanning, President and CEO of Nohla. “We look forward to collaborating closely with the EMA to expedite the development of dilanubicel and potentially accelerate its availability to patients.”

The dilanubicel PRIME designation was supported by efficacy and safety data from a Phase 2 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 excellent long-term survival (86% vs. 66% in a concurrent 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 with chemotherapy-induced myelosuppression.

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 or on Twitter @nohlatx.

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