



Nohla Therapeutics Initiates Global LAUNCH Phase 2 Trial of NLA101 in Patients with AML

LAUNCH Trial to Evaluate Safety and Efficacy of NLA101 to Reduce Rate of Infections Associated with Chemotherapy-induced Neutropenia

Seattle, Washington -- (GlobeNewswire – February 13, 2018) - Nohla Therapeutics Inc. (Nohla), a clinical stage biopharmaceutical company focused on the development of universal, off-the-shelf cell therapies to treat cancer and other critical diseases, today announced the initiation of its Phase 2 LAUNCH clinical trial. The open-label, multi-center, randomized, controlled, dose-finding LAUNCH trial will evaluate Nohla's lead product candidate, NLA101, in adult patients with acute myeloid leukemia (AML) who are at risk for myelosuppression after receiving high-dose chemotherapy.

The LAUNCH trial (NCT03301597) will enroll approximately 220 adult patients and will evaluate NLA101's ability to reduce the rate of \geq Grade 3 infections associated with chemotherapy-induced neutropenia, and identify the lowest effective cell dose of NLA101. Patients in the Phase 2 study will be randomized to one of three investigational treatment arms or a control arm. Patients randomized to an investigational treatment arm will be eligible to receive a single fixed dose of NLA101 after the first cycle of chemotherapy, and up to two additional identical NLA101 doses after subsequent cycles of chemotherapy. Additional information on this trial can be found at <https://clinicaltrials.gov/show/NCT03301597>. Funding for the LAUNCH trial is supported by a \$6.92 million grant from the California Institute for Regenerative Medicine.

"For patients receiving intensive chemotherapy, life-threatening infections are very common and typically lead to lengthy hospitalizations, increased reliance on supportive care, and delays or reductions in additional treatment," said Colleen Delaney, MD, Founder and Chief Medical Officer of Nohla. "We look forward to further clinical evaluation of NLA101 and the ability to reduce the rate of infections and toxicities associated with high-dose chemotherapy which could have a significant impact on clinical outcomes and patient quality of life."

"Although there have been improvements in therapeutic options for AML patients, they still face significant risk of infectious complications associated with chemotherapy-induced neutropenia," said Naval Daver, MD, Co-lead Investigator and Associate Professor at The University of Texas MD Anderson Cancer Center. "We are excited to participate in the LAUNCH trial as it will help determine NLA101's ability to provide a durable recovery that may reduce multiple regimen-related toxicities of chemotherapy while potentially improving the efficacy of the primary treatment."

About NLA101

NLA101 is a universal, off-the-shelf stem and progenitor cell therapy designed to provide short-term bone marrow function, while also providing long term immunologic benefits with the potential for improved survival. Over 125 infusions of NLA101 have been administered across four clinical trials since 2009.



About AML

AML is a type of cancer that begins in the bone marrow. The disease progresses rapidly, with an overproduction of abnormal myeloid cells taking over the bone marrow and interfering with the production of normal white blood cells, red blood cells, and platelets. The standard treatment for AML includes high-dose chemotherapy, which can lead to risk of myelosuppression in approximately 80% of patients. Induction and consolidation chemotherapy is frequently followed by allogeneic hematopoietic stem cell transplantation. The American Cancer Society estimates that there will be approximately 19,520 new cases of AML in the US in 2018.

About Nohla

Nohla Therapeutics is a clinical stage cell therapy company that's redefining clinical outcomes for patients with critical diseases by providing a short-term hematopoietic bridge to immune repair and healthy blood production with long-term immunologic benefits. Nohla's proven platform generates universal, off-the shelf therapies that enable improved clinical outcomes across a number of disease indications, with an initial focus on high-risk hematological malignancies. Nohla's lead candidate, NLA101, is an expanded progenitor cell therapy that provides the functional support of bone marrow in response to each patient's unique blood-production needs, without any requirement for HLA matching. The product has demonstrated the potential for robust efficacy in multiple clinical trials, while overcoming the broad safety and logistical risks of patient-customized cell therapies. More information is available at www.nohlatherapeutics.com or Twitter @nohlatx.

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