Cellerant Announces Dosing of First Patient in Randomized Phase 2 Clinical Trial of CLT-008 in Acute Myeloid Leukemia Patients

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**SAN CARLOS, CA, USA I March 17, 2015 I** Cellerant Therapeutics Inc., a biotechnology company developing novel hematopoietic (blood forming) stem cell-based cellular and antibody therapies for blood disorders and cancer, announced that patient dosing has commenced in its multi-center, open-label, randomized controlled Phase 2 clinical trial of CLT-008, a first-in-class, allogeneic, cellular therapy, in de novo acute myeloid leukemia (AML) patients receiving induction chemotherapy.

"The initiation of this randomized study represents an important milestone for Cellerant and for AML patients receiving intensive chemotherapy," said Ram Mandalam, Ph.D., President and Chief Executive Officer of Cellerant Therapeutics. "Our Phase 1 study results showed favorable safety and signals of clinical activity with dose-dependent reductions in mucositis and febrile episodes in the CLT-008 treated groups. We believe CLT-008 has the potential to change the AML treatment paradigm by reducing the negative effects of chemotherapy and enabling optimal AML treatment that could positively impact patient outcomes."

"Elderly AML patients have a poor prognosis and are often at greatest risk for infections and infection-related morbidity and mortality," said John Galvin, M.D., principal investigator of this study at the Robert H. Lurie Cancer Center, Northwestern University. "These patients often suffer from severe neutropenia accompanied by opportunistic infections, leading to hospitalization and the use of advanced antimicrobial agents. CLT-008 has the potential to reduce these life-threatening infectious complications. This randomized, controlled Phase 2 trial should provide a clear understanding of CLT-008's efficacy and safety profile in this disease setting."

The Phase 2 trial is expected to enroll up to 140 de novo AML patients >= 55 years of age, randomized in 1:1 ratio to either Filgrastim alone or CLT-008 single infusion plus Filgrastim. The study will evaluate the effect of CLT-008 on the duration of febrile episodes and infections related to cytarabine-based induction chemotherapy. The primary endpoint will be the duration of febrile episodes from infusion of CLT-008 to day 28. Secondary endpoints will include incidence of infection, duration of antibiotic use, incidence of mucositis, duration of hospitalization, and hematologic recovery. The Phase 2 data will guide the design and choice of endpoints for the pivotal Phase 3 trial. Interim analysis is expected to take place after 50% of the patients are enrolled. Additional information on the clinical trial, including trial sites, can be found at [www.clinicaltrials.gov](http://www.globenewswire.com/newsroom/ctr?d=10125060&l=4&a=www.clinicaltrials.gov&u=http%3A%2F%2Fwww.clinicaltrials.gov%2F), Identifier #: [NCT02282215](http://www.globenewswire.com/newsroom/ctr?d=10125060&l=4&a=NCT02282215&u=https%3A%2F%2Fwww.clinicaltrials.gov%2Fct2%2Fshow%2FNCT02282215%3Fterm%3Dcellerant%26rank%3D1).

Cellerant has treated 75 patients in two Phase 1 dose escalation clinical trials with CLT-008. One trial tested CLT-008 in 45 leukemia patients following induction or consolidation chemotherapy. Several dose levels of CLT-008 were examined with or without Filgrastim. Data from the study show that CLT-008 was safe and well tolerated. Signals of clinical activity were observed with reductions in duration of fever (days in a febrile episode) and in the incidence of WHO Grade 2 mucositis in AML patients receiving induction therapy. Clinical data from this study were presented at the 2014 American Society of Hematology (ASH) Annual Meeting and Exposition in San Francisco on December 7, 2014.

Cellerant's CLT-008 development program, including this Phase 2 clinical trial in AML patients, and the nonclinical studies required for approval in treating Acute Radiation Syndrome, is funded under a United States Government contract awarded on September 1, 2010 and valued at up to $188 million with the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response of the Department of Health and Human Services. If licensed by the U.S. Food and Drug Administration (FDA), the federal government could buy CLT-008 for the Strategic National Stockpile under Project BioShield. Project BioShield is designed to accelerate the research, development, purchase and availability of effective medical countermeasures for the Strategic National Stockpile.

**About CLT-008**

CLT-008 is a unique, off-the-shelf, cryopreserved, cell-based therapy that contains human myeloid progenitor cells derived from adult hematopoietic stem cells that have the ability to mature into functional granulocytes and platelets in vivo. In nonclinical models, cryopreserved, allogeneic mouse myeloid progenitor cells have been shown to be highly effective in providing protection from lethal radiation, preventing infection, facilitating stem cell engraftment and improving overall survival. CLT-008 has the ability to proliferate and differentiate into myeloid effector cells to treat and reduce the life-threatening infectious complications due to intensive chemotherapy. Cellerant is developing CLT-008 as a treatment for severe neutropenia associated with chemotherapy in oncology patients, cord blood transplantation, and acute radiation exposure.

**About Cellerant Therapeutics**

Cellerant Therapeutics is a clinical stage biotechnology company focused on developing human stem cell and antibody therapies for oncology applications and blood-related disorders. Cellerant's lead product, CLT-008, is under evaluation in a multicenter, open-label, randomized, controlled Phase 2 clinical trial in patients with de novo AML. The Company also has a cancer stem cell antibody discovery program focused on therapies for acute myeloid leukemia, multiple myeloma and myelodysplastic syndrome.