Myelo Therapeutics Receives Additional NIAID Funding to Advance Development of Myelo001 for Acute Radiation Syndrome

BERLIN, GERMANY, June 4th, 2021 - Myelo Therapeutics GmbH, a clinical-stage pharmaceutical company focused on developing medical countermeasures (MCM) and therapies for cancer supportive care, announced today that the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, extended their contract to advance the development of the new chemical entity Myelo001. The extension into year two of the tree-year contract provides an additional $2 million to Myelo Therapeutics to develop clinical-stage Myelo001 as an oral formulation MCM for the treatment of Hematopoietic Acute Radiation Syndrome (H-ARS). The total contract, initially awarded in April 2020, is valued at up to $ 6.2 million over three years if all options are exercised.

The additional funds will advance the development of Myelo001 as an H-ARS monotherapy, and in polypharmacy regimens in laboratory models ranging from rodents to larger animals toward an Investigational New Drug Application (IND) with the U.S. Food and Drug Administration (FDA). The candidate MCM development program is funded in whole or in part by the Radiation and Nuclear Countermeasures Program (RNCP), NIAID, part of the National Institutes of Health (NIH), in the Department of Health, and Human Services (HHS), under Contract No. 75N93020C00005. Only a select number of companies are funded by the RNCP, based on a highly competitive application process.

Myelo Therapeutics GmbH will present a poster entitled “Imidazolyl ethanamide pentandioic acid (IEPA/Myelo001) for the treatment of radiation-induced myelosuppression” at the Multinational Association of Supportive Care in Cancer on June 24-26, 2021.

About Acute Radiation Syndrome: ARS, also known as radiation toxicity or radiation sickness, is an acute illness that presents after exposure of large portions of the body to high levels of radiation, like those that might be experienced during a radiological or nuclear incident. The primary manifestation of ARS is the depletion of hematopoietic stem and progenitor cells, constituting one of the major causes of mortality. The U.S. government encourages development of new drugs to treat bodily injuries resulting from ARS.

About Myelo001: Myelo001 is a clinical-stage, adjuvant cancer therapy for treatment of chemotherapy- and radiotherapy-induced myelosuppression. It is delivered as an oral tablet formulation and is stable at room temperature for at least three years. Preclinical and clinical studies have shown that Myelo001 has both prophylactic and therapeutic efficacy at reducing hematopoietic symptoms caused by radiation and chemotherapy. In irradiated mice and rabbits, Myelo001 reduced the nadir and accelerated recovery of neutrophils, lymphocytes, thrombocytes, and erythrocytes. In mice, treatment 24 hours post-total body irradiation resulted in increased survival, faster bone marrow recovery, and reduced body weight loss. Moreover, Myelo001 treatment prior to and after chemotherapy led to the accelerated recovery of blood cells in human subjects. Comprehensive chronic toxicology and safety studies, as well as clinical studies, have confirmed Myelo001’s excellent safety profile.

About Myelo Therapeutics: Myelo Therapeutics is a pharmaceutical company based in Berlin, Germany, that is developing innovative treatments in areas of high unmet medical needs, such as Chemotherapy-Induced Myelosuppression (CIM), Radiation-Induced Myelosuppression (RIM), and ARS. For more information, visit www.myelotherapeutics.com.

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The information included in this press release concerns a drug use that has not been approved by the U.S. FDA.