Myelo Therapeutics GmbH Receives Additional NIAID Funding For Development of Myelo001 for Acute Radiation Syndrome

BERLIN, GERMANY, July 28th, 2022 - Myelo Therapeutics GmbH, a clinical-stage pharmaceutical company focused on developing medical countermeasures (MCMs) and therapies for cancer supportive care, announced that the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), extended their contract to advance the development of the new chemical entity Myelo001 to mitigate the acute radiation syndrome. The extension into year three of the three-year contract provides an additional $2 million USD to Myelo Therapeutics to develop clinical-stage Myelo001 as an oral formulation MCM for the treatment of Hematopoietic Acute Radiation Syndrome (H-ARS). Initially awarded in April 2020, the total contract is valued at up to $ 6.5 million over three years, extending until 2023.

The additional funds will advance the development of Myelo001 as a therapy for acute radiation syndrome in large animal models and towards an Investigational New Drug Application (IND) with the U.S. Food and Drug Administration (FDA) using the Animal Rule approval pathway." The candidate's MCM development program is funded in part by the Radiation and Nuclear Countermeasures Program (RNCP), NIAID, NIH, in the Department of Health, and Human Services (HHS), under Contract No. 75N93020C00005.

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/nuclear incident. A primary manifestation of ARS is the depletion of hematopoietic stem and progenitor cells, constituting one of the major causes of mortality. The development path follows the FDA Animal Rule and the European Medicines Agency (EMA) exceptional circumstances under which efficacy is established based on adequate and well-controlled studies in animal models, replacing efficacy trials in humans.

About Myelo001: Myelo001 is a clinical-stage, adjuvant cancer therapy for the treatment of chemotherapy- and radiotherapy-induced myelosuppression. Myelo001 is also under development as a MCM to treat Radiological threats under the category of Chemical, Biological, Radiological, and Nuclear (CBRN) threats. It is administered 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 in reducing hematopoietic symptoms caused by radiation and chemotherapy. Comprehensive chronic toxicology and safety studies, as well as clinical studies, have confirmed Myelo001's excellent safety profile.

About Myelo Therapeutics: Myelo Therapeutics GmbH is a pharmaceutical company based in Berlin, Germany, developing innovative medical countermeasure treatments against Chemical, Biological, Radiological, and Nuclear (CRBN) threats and Supportive Care therapies in Oncology and Nuclear Medicine. For more information, visit www.myelotherapeutics.com.

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The information included in this press release concerns a drug under development which has not been approved by the U.S. FDA or competent European authorities.