Myelo Therapeutics Awarded NIH-NIAID Contract Valued up to $6 Million over 3 Years for Development of Myelo001 as Treatment for Acute Radiation Syndrome

BERLIN, GERMANY, May 11th, 2020 - Myelo Therapeutics GmbH, a clinical-stage pharmaceutical company focused on developing therapies for cancer supportive care and medical countermeasures (MCM), announced today that it has been awarded a 3-year development contract valued at up to $6 million, funded in whole or in part with Federal funds from the Radiation and Nuclear Countermeasures Program (RNCP), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (HHS), under Contract No. 75N93020C00005.

The objectives of the contract are to advance the development of the orally applied, clinical-stage new chemical entity Myelo001 as an MCM for the treatment of Hematopoietic Acute Radiation Syndrome (H-ARS). The contract consists of a one-year base period providing financial support of approximately $2 million, with two option periods of similar funding that would each extend the contract for an additional year.

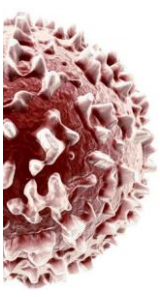
“Securing this highly competitive NIH-NIAID contract recognizes the relevance of an orally applied, safe, and easy-to-store therapy for H-ARS that may not only support neutrophils, but also lymphocytes and thrombocytes, thus ameliorating the immune response and hemostasis,” states Dirk Pleimes, MD, Managing Director and Chief Scientific Officer of Myelo Therapeutics. “We thank the NIAID for their support and look forward to collaborating closely with them as we advance this technology.”

ARS, also known as radiation toxicity or radiation sickness, is an acute illness that presents after exposure to high levels of radiation caused by a nuclear attack or accident. The primary manifestation of ARS is the depletion of hematopoietic stem cells, constituting one of the major causes of mortality. The U.S. government is encouraging the development of new drugs to prevent or treat ARS.

Myelo001 is a clinical-stage adjuvant cancer therapy for the treatment of chemotherapy- and radiotherapy-induced myelosuppression. It is delivered as an oral tablet formulation and is stable at room temperature for at least 3 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 chemotherapy led to a faster 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.

The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have both granted Myelo001 an Orphan Drug Designation for the treatment of Acute Radiation Syndrome (ARS).

Therapies for ARS qualify as MCMs, which are FDA-regulated products that may be used in the event of a potential public health emergency caused by a biological, chemical, or radiological/nuclear



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material. When developing MCMs for radiological and nuclear threats, it is not ethical or feasible to test a drug's efficacy by exposing human subjects to high levels of radiation. Given this, the FDA may grant approval based on well-controlled non-clinical studies, when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans. The nonclinical and clinical safety development program of Myelo001 will proceed in a manner similar to that of drugs developed under traditional regulatory pathways. MCMs are purchased and stockpiled by the Department of Health and Human Services, the Department of Defense, and various non-US governments and militaries.

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 Acute Radiation Syndrome (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 Food and Drug Administration.