EMA Grants Myelo Therapeutics Orphan Drug Designation for Myelo001 as Treatment for Acute Radiation Syndrome

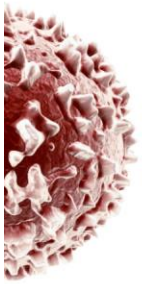
BERLIN, GERMANY, July 24th, 2019 – Myelo Therapeutics GmbH announced today that the European Medicines Agency (EMA) has granted an Orphan Drug Designation to its orally applied new chemical entity Myelo001 (Imidazolyl ethanamide pentandioic acid) for the treatment of Acute Radiation Syndrome (ARS). The positive EMA ruling follows the United States (US) Food and Drug Administration's (FDA) 2018 decision to award an Orphan Drug Designation to Myelo001 for the treatment of ARS.

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 accident or attack. It can lead to severe health consequences, including death. The European Union (EU) and the US government, amongst other countries, are encouraging the development of new drugs to prevent or treat ARS.

Myelo001 is a new, clinical-stage adjuvant cancer therapy for the treatment of chemotherapy- and radiotherapy-induced myelosuppression. Preclinical and clinical studies have shown that Myelo001 applied orally is effective in reducing hematopoietic symptoms caused by chemotherapy and radiation. Comprehensive chronic toxicology and safety studies, as well as clinical studies, have confirmed an excellent safety profile of Myelo001.

The EU orphan designation program provides incentives to companies that are developing therapies for diseases which affect fewer than 5 in 10,000 people within the territory of the EU. The benefits of achieving Orphan Drug Designation include scientific advice by EMA on study protocols, regulatory fee reductions and waivers, as well as access to EU grants for drug development. Upon marketing approval, Myelo001 will benefit from 10 years of market exclusivity for the ARS indication within the EU's territory.

Therapies for ARS qualify as medical countermeasures (MCMs), which may be used in the event of a potential public health emergency caused by a biological, chemical, or radiological/nuclear material. MCMs are purchased and stockpiled by the EU through its Joint Procurement Agreement for MCMs, the US Department of Health and Human Services and US Department of Defense, as well as various other foreign governments and militaries.



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About Myelo Therapeutics

Myelo Therapeutics is a pharmaceutical company based in Berlin and Dresden, 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 yet been approved by the European Medicines Agency and Food and Drug Administration.