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

BERLIN, GERMANY, September 25, 2018 – Myelo Therapeutics GmbH announced today that the US Food and Drug Administration (FDA) has granted an Orphan Drug Designation to its orally applied new chemical entity Myelo001 for the treatment of Acute Radiation Syndrome (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 US government is 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.

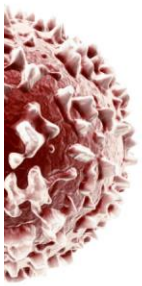
The US FDA Orphan Drug Designation program provides incentives to companies that are developing therapies for diseases which affect fewer than 200,000 people in the US. The benefits of achieving Orphan Drug Designation include close guidance by the FDA, which may accelerate the path to potential marketing approval, orphan drug research grants, tax credits, waivers of regulatory fees, as well as a 7-year market exclusivity upon marketing approval.

Therapies for ARS qualify as medical countermeasures (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 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. There is also a requirement to demonstrate the drug's safety in humans.

MCMs are purchased and stockpiled by the Department of Health and Human Services, the Department of Defense, and various foreign governments and militaries.

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies.

Upon approval, the FDA may award a priority review voucher (PRV) to sponsors of MCMs. A PRV allows for an expedited review process for a new drug application. A sponsor may also sell awarded PRVs to other drug companies. Past transactions of PRVs have resulted in market prices of up to USD 350 million.



Myelo Therapeutics GmbH
Kastanienallee 56 • 10119 Berlin, Germany
Phone: +49 (0) 170 9126 402 • HRB 149553 B - VAT-No./USt-ID: DE289451747
info@myelotherapeutics.com • www.myelotherapeutics.com

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.

Contact:

Myelo Therapeutics GmbH, Till Erdmann, Kastanienallee 56, 10119 Berlin, Germany. Phone: +49 (0) 170 9126 402, info@myelotherapeutics.com

The information included in this press release concerns a drug use that has not been approved by the Food and Drug Administration.