



## **Myelo Therapeutics conducts successful Pre-IND meeting with U.S. Food and Drug Administration (FDA) for Myelo001 and completes new financing round**

Berlin, June 20<sup>th</sup>, 2017 – Myelo Therapeutics GmbH announced that it successfully conducted a Pre-IND (Investigational New Drug) meeting with the FDA Center for Drug Evaluation and Research (CDER) on May 11<sup>th</sup>, 2017 for Myelo001, a novel, orally bioavailable small molecule to prevent myelosuppression caused by chemotherapy. Following the positive meeting with the FDA, the company closed a new financing round with its current investors on June 12<sup>th</sup>, 2017.

Myelo001 is currently being investigated in a randomized, double-blind, placebo-controlled, parallel-design, multicenter study in Germany regarding its efficacy and safety in reducing Chemotherapy-induced Neutropenia (CIN) in patients receiving adjuvant or neoadjuvant chemotherapy for the treatment of breast cancer. The completion of the study is expected in the fourth quarter of 2017.

A Pre-IND meeting provides an opportunity for communication between a sponsor and the FDA to discuss planned IND application content and to obtain regulatory advice on planned development activities. During the meeting, the FDA clarified the way forward for Myelo001 until New Drug Application (NDA) filing in the US. The comprehensive discussion included the target product profile (TPP) and R&D development plan for Myelo001 in Chemotherapy-induced Neutropenia until reaching US market authorization.

*"Following this positive meeting with the FDA, we are confident that our non-clinical data will be acceptable for an IND of Myelo001 for a first clinical trial in the US. This supports our strategy to expand our European clinical development program to the United States promptly and with a high likelihood of success,"* said Dirk Pleimes, Managing Director and Chief Medical Officer of Myelo Therapeutics.

Till Erdmann, Managing Director responsible for business development, declared, *"The FDA meeting confirms our assumptions for a time- and cost-efficient clinical development program to reach US market authorization of Myelo001 in Chemotherapy-induced Neutropenia. Myelo001 has the potential to be the first oral therapy in this indication, with superior safety and competitive efficacy compared to the current standard of care. If successful, Myelo001 is the first treatment innovation in more than two decades for patients at risk for one of the most frequent and most severe side effects of anticancer therapy, representing a market of USD 8 billion globally."*

Following the positive meeting with the FDA, Myelo Therapeutics closed a financing round to support further development activities for Myelo001 in Chemotherapy-induced Neutropenia. The funds raised will also expand research into the protective effects of Myelo001 against radiation, which could broaden the potential indication in supportive cancer care to Radiation-induced Myelosuppression.



#### About Chemotherapy-induced Neutropenia (CIN):

Cytotoxic chemotherapy frequently suppresses the hematopoietic system, impairing host protective mechanisms. Chemotherapy-induced Neutropenia (CIN), the most serious hematologic toxicity, is associated with the risk of life-threatening infections. As a consequence of such an infection it can become necessary to reduce the dosage of or delay chemotherapy, which may compromise treatment outcomes.

<http://www.ncbi.nlm.nih.gov/pubmed/14716755>

#### About Myelo001:

Myelo001 is a new, innovative adjuvant cancer therapy for the treatment for CIN. In preclinical and first clinical studies, Myelo001 has shown to be well tolerated and effective in reducing the risk of CIN in patients across various cancer types and chemotherapy regimens. In addition, Myelo001 possesses antiviral properties, an additional benefit in immunosuppressed patients treated with chemotherapy. Myelo001 is taken orally, starting treatment prior to chemotherapy.

<https://clinicaltrials.gov/ct2/show/NCT02692742>

[http://www.myelotherapeutics.com/news\\_files/Myelo001\\_Abstract\\_MASCC\\_2015.pdf](http://www.myelotherapeutics.com/news_files/Myelo001_Abstract_MASCC_2015.pdf)

#### About Myelo Therapeutics GmbH:

Myelo Therapeutics is a pharmaceutical company based in Berlin and Dresden, Germany, that is developing innovative treatments in areas of high unmet medical needs. For more information, visit [www.myelotherapeutics.com](http://www.myelotherapeutics.com).

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