



**Myelo Therapeutics' Phase II study of Myelo001 in Chemotherapy-induced Neutropenia is now fully recruited. Results are expected in the spring of 2018.**

Berlin/Dresden, October 4, 2017 – Myelo Therapeutics GmbH announced today that its Phase II MyeloConcept study of Myelo001 in Chemotherapy-induced Neutropenia has successfully completed recruitment. 137 patients have been randomized in the study.

The MyeloConcept study is a randomized, double-blind, placebo-controlled, parallel-design, multicenter study to investigate the efficacy of Myelo001 in reducing chemotherapy-induced neutropenia (CIN) in patients receiving adjuvant or neoadjuvant chemotherapy for the treatment of breast cancer – specifically its effects on the hematopoietic system, as well as its safety and pharmacokinetics. Myelo001 will be given once daily as a tablet. The treatment with Myelo001 starts 5 days prior to the first chemotherapy cycle and is continued consistently until the end of the chemotherapy cycle. The MyeloConcept study is being conducted at 23 study sites in Germany. Study results are expected during the first quarter of 2018.

The MyeloConcept study is being conducted jointly with two prominent oncology and gynaecology expert networks: *Arbeitsgemeinschaft Gynäkologische Onkologie—Breast* (AGO-B) [Working Group Gynaecological Oncology—Breast] and the study group and Central European Society for Anticancer Drug Research—EWIV (CESAR).

*“Myelo001 could be the first oral therapy for prevention of Chemotherapy-induced Neutropenia,”* says Prof. Dr. Dr. Frank Mayer, specialist for internal medicine with a focus on haematology/internal oncology from Friedrichshafen and principal investigator of the MyeloConcept study. *“It would be an important new therapy option with a novel mechanism of action, and could be an alternative to the exclusively injectable therapies available until now that are based on stimulating growth factors.”*

*“We are extremely pleased about the interest the study has received in the scientific community and the resulting successful completion of the recruiting phase. We plan to present the results of the study in the spring of 2018. The feedback in an FDA (U.S. Food and Drug Administration) advisory meeting in May 2017 regarding Myelo001’s preclinical and clinical data, as well as our development plan was positive. As such, we are confident that with a positive study result, our global development program can continue to advance swiftly towards phase 2b and 3 studies,”* said Dirk Pleimes, Managing Director and Chief Medical Officer of Myelo Therapeutics.



#### 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 in turn 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 of 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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