



## **Myelo Therapeutics treats first patient in Phase II study of Myelo001 in Chemotherapy-induced Neutropenia.**

Dresden, 7 April 2016 – Myelo Therapeutics GmbH announced today that the first patient has been successfully included and treated in the Phase II *MyeloConcept* 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 will be conducted at 18 study sites in Germany and plans to enrol 160 patients. Study results are expected in the first half of 2017.

The MyeloConcept study is being conducted jointly with two 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).

Myelo Therapeutics GmbH, Dresden and ABX-CRO advanced pharmaceutical services – Research Company GmbH, Dresden are financially supported by the Sächsische Aufbaubank (SAB) [Development Bank of Saxony] using funds from the European Regional Development Fund (ERDF) and the Free State of Saxony in the scope of a joint cooperation project to carry out research on Myelo001 for treating Chemotherapy-induced Neutropenia.

*“Neutropenia and associated complications, including febrile neutropenia, are important, dose-limiting toxicities in systemic chemotherapy,”* says Prof. Dr. Volker Möbus, head of the Steering Committee of the MyeloConcept study and chief physician of the Gynaecology and Obstetrics Clinic of the Frankfurt Höchst Clinic. *“We are pleased about the start of the MyeloConcept ‘Proof-of-Concept’ study, which is examining the safety and tolerance of Myelo001 for this critical side effect. The study is also making an important contribution to researching biomarkers of the hematopoietic changes caused by chemotherapeutic agents.”*

*“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. The treatment of the first patient in this study is an important milestone in global clinical development for this new small molecule.”*



*"Myelo001 offers a novel, orally applied treatment of chemotherapy-induced neutropenia and bone marrow suppression. New adjunct treatment options are needed for cancer patients to enable an optimal dose of chemotherapy and decrease the incidence of infections,"* states Dirk Pleimes, Managing Director and Chief Medical Officer of Myelo Therapeutics.

Till Erdmann, Managing Director of Myelo Therapeutics responsible for business development, adds: *"In less than three years after founding the company, we have brought our first development project from pre-clinical research to phase II. With a clear strategy, we are developing the new active substance Myelo001 targeting an indication with high unmet medical need and with no significant treatment innovation for over 20 years. The market for therapies to treat Chemotherapy-induced Neutropenia currently generates annual revenue worldwide of USD 7 billion."*

*"Myelo001 has already shown its potential in several indications, such as chemotherapy-induced neutropenia and radiotherapy-induced neutropenia. I am pleased that we are now starting clinical development in chemotherapy-induced neutropenia as a first step,"* says Dr. Vladimir Nebolsin, the medicinal chemist who first synthesized Myelo001.

*"We are very glad that Myelo Therapeutics has decided to establish itself in Saxony and is thus contributing to the development of the pharmaceutical scene here. The milestone that has now been reached in our joint research project with Myelo Therapeutics shows what can be achieved with a well-focused funding policy,"* says Dr. Andreas Kluge, General Manager of ABX-CRO GmbH. *"The interesting spectrum of efficacy of Myelo001 offers a number of other clinical development approaches which makes the project particularly interesting for us strategically."*

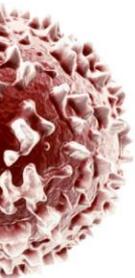
#### About Chemotherapy-induced Neutropenia (CIN):

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 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.

[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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### About ABX-CRO advanced pharmaceutical services – Research Company GmbH:

ABX-CRO, based in Dresden, is the largest independent pharmaceuticals contract research organisation in former East Germany. ABX-CRO offers comprehensive services in drug development, from procuring active ingredients to pre-clinical development to phase I-III clinical trials to approval. An emphasis is placed on studies in the field of oncology, neurosciences, and nuclear medicine.

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### About ERDF technology funding:

On the basis of the operational programmes of the Land of Saxony for the European Regional Development Fund (ERDF) and the European Social Fund (ESF) in the funding period 2014 to 2020, in accordance with the ERDF/ESF framework directive of 7 September 2015, the Free State of Saxony is granting subsidies for projects in the scope of implementing the European Union's structural policy with funding from the ERDF and/or ESF and complementary national budget funds. The intention is to boost the innovative capacity and thus competitive ability of Saxony's economy by supporting projects in the scope of the ERDF technology funding 2014 to 2020.