

## EMERGING COMPANY PROFILE

# MYELO: PREVENTING NEUTROPENIA

BY LAUREN MARTZ, STAFF WRITER

**Myelo Therapeutics GmbH** is developing a small molecule that could provide a cheaper and safer alternative to standard of care G-CSF to prevent and to treat chemotherapy-induced neutropenia.

Neutropenia is a decrease in levels of the neutrophil subset of white blood cells required to fight infection. It is caused by diseases or drugs, including chemotherapy, that impair neutrophil production in the bone marrow or destroy neutrophils in circulation.

"In general, chemotherapy-induced neutropenia resolves itself after treatment," co-Managing Director Till Erdmann said. "The problem is that during treatment, patients are susceptible to infections that could be deadly due to the immune suppression. Any problem like this can also be disruptive to the treatment, decreasing the efficacy of the anti-cancer therapy."

In the U.S. and Europe, granulocytic colony stimulating factor (G-CSF) is used prophylactically only in high risk patients and as a therapeutic once neutropenia is detected. It works by stimulating production of new neutrophils in the bone marrow.

According to Erdmann, G-CSF's high cost limits its use in low-and-moderate risk patients. He added that the biologic also has the potential for severe side effects, including splenic rupture, and causes severe bone pain in about 10% of patients due to the stimulating effect in bone marrow.

### MYELO THERAPEUTICS GMBH

Berlin, Germany

**Technology:** Small molecule to prevent and treat chemotherapy-induced neutropenia

**Disease focus:** Cancer, hematology

**Clinical status:** Preclinical

**Founded:** 2013 by Till Erdmann and Dirk Pleimes

**University collaborators:** Hannover Medical School

**Corporate partners:** Valenta Pharmaceuticals JSC

**Number of employees:** 5

**Funds raised:** Undisclosed

**Investors:** Investitionsbank Berlin (IBB), Eckert Life Science Accelerator (ELSA), Valenta Pharmaceuticals JSC

**Managing directors:** Till Erdmann, Dirk Pleimes

**Patents:** 3 issued covering Myelo001's substance and target indications of chemotherapy-induced neutropenia and chemotherapy-induced thrombocytopenia

Myelo was founded last year and acquired rights to its small molecule, now named Myelo001, from **Valenta Pharmaceuticals JSC**. Valenta already markets the compound in Russia to treat chemotherapy-induced neutropenia and as a broad-spectrum antiviral.

"We have now finished preclinical safety and animal proof-of-concept studies to comply with guidelines in the U.S. and Europe," Erdmann said. "Regulations are different from those in Russia, but the fact that the compound is approved in Russia does de-risk our development."

Myelo plans to begin clinical testing early next year.

Although the exact mechanism and target of Myelo001 are not yet known, Erdmann said the company does know it acts by differentiating early forms of granulocytic cell lines to promote maturation, protects hematopoietic cells from the myelosuppressive impact of chemotherapy and prevents apoptosis and degeneration of hematopoietic cells.

Erdmann said the oral therapeutic would be dosed daily beginning five or six days prior to the start of treatment with chemotherapies that can cause neutropenia. He added the molecule may have an improved safety profile, which may allow dosing in patients with different risk profiles.

Myelo believes that Myelo001's antiviral activity, a secondary mechanism of action, is another benefit over G-CSF and other therapeutics in development. In ferrets, Myelo001 accelerated clearance of influenza from the respiratory tract and partially restored activation of cellular antiviral pathways, according to the company. The findings are not yet published.

“The most recent market reports indicate that only about 2% of compounds in development for chemotherapy-induced neutropenia have a new mechanism of action. Therapeutics in development are almost exclusively biosimilars of G-CSF,” said Erdmann.

At least 11 G-CSF-based therapeutics are marketed for neutropenia, with at least 32 more in clinical and preclinical development. The only other marketed therapeutics are antibiotics indicated to prevent infection in neutropenia patients.

At least three biologics with alternative mechanisms are in development for chemotherapy-induced neutropenia. Two of these are in Phase II testing: Telintra ezatiostat hydrochloride, an IV peptidomimetic glutathione S-transferase inhibitor from **Telik Inc.**; and **PledPharma AB**'s PledOx calmangafodipir, an IV pyridoxyl ethyldiamine (PLED) analog.

**Welichem Biotech Inc.**'s WBI-2100 is an anti-angiogenic cancer therapeutic that may stimulate neutrophils. It is in preclinical testing. Erdmann thinks Myelo001's secondary anti-viral mechanism and lower cost of production are potential benefits over biologic candidates.

Myelo has licensed exclusive rights to the molecule for chemotherapy-induced neutropenia outside of the Commonwealth of Independent States (CIS) from Valenta. It also owns patents covering its use in chemotherapy-induced thrombocytopenia, but does not plan to pursue that indication in the next year.

According to Erdmann, Myelo has sufficient funding for preclinical and early clinical development from a series A round of an undisclosed amount. The company plans to develop Myelo001 in-house through the end of clinical proof of concept or Phase II testing and then partner the molecule. 

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#### COMPANIES AND INSTITUTIONS MENTIONED

**Myelo Therapeutics GmbH**, Berlin, Germany

**PledPharma AB**, Stockholm, Sweden

**Telik Inc.** (NASDAQ:TELK), Palo Alto, Calif.

**Valenta Pharmaceuticals JSC**, Moscow, Russia

**Welichem Biotech Inc.** (TSX-V:WBI), Burnaby, B.C.