



Press Release

POLYNEURON RECEIVES APPROVAL TO BEGIN CLINICAL STUDY WITH PN-1007 IN ANTI-MAG NEUROPATHY

Phase I/II study will begin before the end of 2020

Basel, Switzerland, April 27, 2020 – [Polyneuron Pharmaceuticals AG](#), a clinical stage company and developer of a new class of biodegradable glycopolymers for the treatment of autoimmune diseases, today announced that regulatory authorities in France, the Netherlands and the UK have approved the clinical trial application (CTA) for a phase I/IIa study of PN-1007 for the treatment of anti-MAG neuropathy, a disabling, chronic disorder of the peripheral nervous system. The study, called PN-1007-001, is scheduled to begin later this year and expects to deliver top-line safety, pharmacokinetic and biomarker data in the first half of 2021.

“The CTA approval in France, the Netherlands and the UK is a significant milestone both in terms of validating our Antibody-Catch™ approach as well as catapulting Polyneuron to the clinical stage. We anticipate similar CTA approvals in additional countries soon and look forward to starting the study later in 2020,” said Ruben Herrendorff, Ph.D., CEO and co-founder of Polyneuron. “The team is excited to move this first program into the clinic now and is working diligently on additional pipeline programs, in particular a second Antibody-Catch™ program as a potential treatment for multifocal motor neuropathy and severe subtypes of Guillain-Barré syndrome is under development.”

Study PN-1007-001 is an international, multicenter, ascending dose, first in-human study that will evaluate the safety, pharmacokinetics and preliminary efficacy of PN-1007 administration in patients with anti-MAG neuropathy. In the first open label part of the study, patients will receive single ascending doses of PN-1007. Safety, pharmacokinetics and the effect on anti-MAG autoantibodies will be evaluated. This will be followed by the placebo-controlled phase IIa part of the study, where patients will receive multiple doses of either PN-1007 or placebo over a more prolonged period. In this second part, on top of safety, pharmacokinetics and the effect of PN-1007 on the pathogenic anti-MAG antibodies, preliminary clinical efficacy will also be investigated. This multinational clinical study will be conducted in additional European countries, and regulatory submissions are currently ongoing.

About PN-1007

PN-1007 has been designed to target the IgM autoantibodies that cause anti-MAG neuropathy, a disabling chronic disorder of the peripheral nervous system that has no approved treatment. PN-1007 mimics the natural HNK-1 carbohydrate epitope found on

myelin of peripheral nerves and binds to the circulating disease-causing antibodies. By eliminating these pathogenic antibodies, PN-1007 may protect the integrity of the neuronal myelin sheaths of anti-MAG neuropathy patients. Polyneuron has obtained orphan drug designation from the European Medicines Agency for PN-1007 in anti-MAG neuropathy.

About Polyneuron Pharmaceuticals

Polyneuron Pharmaceuticals is pioneering a novel therapeutic approach for the effective and safe treatment of antibody-mediated immune diseases. The company's Antibody-Catch™ technology platform enables the chemical design of injectable glycopolymers that are able to selectively eliminate pathological (auto)antibodies, while leaving the rest of the immune system intact. Polyneuron was founded as a University of Basel, Department of Pharmaceutical Sciences, spin-off in 2014 by Dr. Ruben Herrendorff (CEO), Dr. Pascal Hänggi (CSO), Prof. Beat Ernst and Prof. Dr. med. Andreas J. Steck. The company is headquartered at the Stücker Park in Basel, Switzerland. More information can be found at www.polyneuron.com.

Disclaimer

This press release contains forward-looking statements which are based on current assumptions and forecasts of the Polyneuron management. Known and unknown risks, uncertainties, and other factors could lead to material differences between the forward-looking statements made here and the actual development, in particular Polyneuron's clinical trial timelines, financial situation, and performance. Readers are cautioned not to put undue reliance on forward-looking statements, which speak only of the date of this communication. Polyneuron disclaims any intention or obligation to update and revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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