Press Release

POLYNEURON'S PN-1007 RECEIVES U.S. FDA ORPHAN DRUG DESIGNATION IN ANTI-MAG NEUROPATHY

Myelin Binding Data also Published in Journal of Neurochemistry

Basel, Switzerland, June 5, 2020 – Polyneuron Pharmaceuticals AG, a clinical stage developer of a new class of biodegradable glycopolymers for the treatment of autoimmune diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to PN-1007 (PPSGG) in the treatment of anti-MAG neuropathy, a disabling, chronic disorder of the peripheral nervous system. Orphan designation is granted to advance the development of safe and effective therapies for the treatment of rare diseases or conditions affecting fewer than 200,000 individuals in the U.S. Under the Orphan Drug Act, the FDA may provide grant funding toward clinical trial costs, tax credits, FDA user-fee benefits, and seven years of market exclusivity following marketing approval. PN-1007 received orphan drug designation from the European Medicines Agency in July 2017.

"Receiving orphan designation in the U.S. provides additional validation to the development of PN-1007 as a treatment for anti-MAG neuropathy. PN-1007 directly targets and eliminates the auto-antibodies that cause the disease, which we believe could prevent demyelination and protect the nerves," said Ruben Herrendorff, Ph.D., CEO and co-founder of Polyneuron. "Data published recently in the *Journal of Neurochemistry* supported this hypothesis by showing that PN-1007 was able to inhibit the binding of anti-MAG IgM antibodies to myelin of non-human primate nerves. We now look forward to evaluatung PN-1007 in patients when our phase I/IIa study in anti-MAG neuropathy starts later in 2020."

In the *Journal of Neurochemistry* paper, entitled "Selective inhibition of anti-MAG IgM autoantibody binding to myelin by an antigen specific glycopolymer", Polyneuron and collaborators found that PN-1007 selectively bound anti-MAG IgM autoantibodies and prevented the binding of patients' anti-MAG IgM antibodies to myelin of non-human primate sciatic nerves.

In a dose titration study in mice, intravenous administration of PN-1007 was able to efficiently remove all anti-MAG IgM antibodies, strongly supporting the anticipated effective dose range for the upcoming phase I/IIa study in patients.

The mechanism of anti-MAG IgM removal *in vivo* was further verified by comparing PN-1007 treatment with that of a $CD20^+$ B cell depleting monoclonal antibody. $CD20^+$ B cell depletion was found to not affect the anti-MAG IgM titers in the immunological mouse model whereas weekly treatment with PN-1007 abrogated the MAG binding within less than an hour from administration. Moreover, further studies supported the favourable safety profile of PN-1007 in mice and *ex vivo* with human leukocytes and B cells of anti-MAG

neuropathy patients. PN-1007 did not induce or lead to the release of murine and human cytokines and chemokines, and did not activate antibody-producing cells of patients *ex vivo*.

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 U.S. Food and Drug Administration and 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 Stücki Park in Basel, Switzerland. More information can be found at http://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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