Communication NISCI 2023

-"NISCI reports Topline Study Results"

- Pan-European NISCI Consortium completes phase II clinical trials to study Nogo-A Inhibition in acute spinal cord injury.

Zurich, Switzerland, July 5th, 2023 – A first ever, multicenter, multinational, placebo-controlled phase II trial utilizing a novel personalized prediction model to study **N**ogo-A **I**nhibition in acute **S**pinal **C**ord **I**njury (NISCI) has been successfully completed. The purpose of the NISCI trial was to reveal the best responder to an antibody therapy intended to improve hand and arm function.

"Preliminary review of pre-defined subgroups characterized by residual sensorimotor functions hint towards improved recovery profiles in patients receiving anti-Nogo compared to placebo. The increased extent of recovery was measured in clinically meaningful assessments, that were supported by preplanned neurophysiological and neuroimaging data. These data have also led to a better targeting of anti-Nogo's proposed mechanism of action and subsequent identification of responsive patients", according to Dr. Armin Curt, Chair of the SCI Center of the Balgrist University Hospital in Zurich, Switzerland.

The safety and tolerance of anti-Nogo was demonstrated with no relevant adverse events observed over 4 weeks of intrathecal dosing, including 168 days of follow-up. Individuals with acute cervical SCI were recruited within 4-28 days after their injury, and efficacy endpoints were changes in patient outcomes from baseline to five months post-baseline. Across the full cervical SCI patient cohort without distinguishing pre-defined subgroups, anti-Nogo compared to placebo, did not achieve statistically significant benefit for the prespecified primary efficacy endpoint.

"This significant body of work could not have been possible without the tremendous dedication and collaboration across 15 sites spanning 5 European countries," said Dr. Norbert Weidner, head of the SCI Center at the Heidelberg University Hospital. All participating sites would like to express that, "The commitment of participants, caregivers and research staff is deeply appreciated and acknowledged as critical to the successful completion of this trial."

The NISCI consortium will continue to advance the understanding of this anti-Nogo-A antibody therapy with particular focus on disseminating the totality of all study results and on further drug development for personalized treatment in acute SCI. The learnings from this NISCI trial will provide the basis of a next appropriately powered trial targeting selected patient subgroups who have the potential for significant improvement. According to Dr. Martin Schwab, Senior Scientific Advisor to the NISCI consortium, "the present results are very encouraging. Together with patient recovery data collected prospectively over two decades, the new data will guide the design and execution of future clinical trials in spinal cord and brain injury."

About the NISCI Study: The trial was approved by the National Ethics Committees and respective regulatory agencies for all participating trial sites. For more information, see ClinicalTrials.gov or SCITrialsfinder.net (NCT03935321).

This study was supported by, the European Union's Horizon 2020 research and innovation program (grant agreement number 681094); the Swiss State Secretariat for Education, Research and Innovation (SERI, contract number 15.0255); Wyss Zurich – University of Zurich and ETH Zurich: the Swiss Paraplegic Foundation; and the Wings for Life Foundation; and the International Foundation for Research in Paraplegia (IRP).

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