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Minoryx Therapeutics completes phase 2/3 clinical study of MIN-102

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Minoryx Therapeutics, a company specializing in the development of new drugs for orphan diseases, announces that it has completed patient randomization of its phase 2/3 clinical trial of MIN-102 for the treatment of adrenomyeloneuropathy (AMN). The trial enrolled adult male patients affected by AMN, the most frequent phenotype of X-linked adrenoleukodystrophy (X-ALD).

The ADVANCE trial is a randomized, double-blind, placebo-controlled study designed to determine the efficacy and safety of MIN-102 with an open-label extension for patients completing the double-blind part of the trial. The primary objective of the clinical trial is to evaluate the efficacy of MIN-102 on the progression of adrenomyeloneuropathy (AMN) in male patients, determined by a motor function test. Results of the study are expected at the end of 2020.

A total of 116 patients have been randomized in this study. 90 patients are being treated in Europe in a number of centers in Spain, France, Hungary, Germany, Italy, the United Kingdom and the Netherlands, while 26 are in the US in California, Maryland and Massachusetts. Enrolment was completed several months ahead of schedule.

“The strong interest in this AMN trial in the EU and US has resulted in exceeding the target enrolment ahead of schedule,” said Dr. Uwe Meya, chief medical officer of Minoryx. “We believe this highlights the very high unmet medical need in this area.”

MIN-102, the lead candidate in Minoryx’s pipeline, is a novel, orally bioavailable and selective PPAR gamma agonist with a superior profile for central nervous system-related diseases and good in-vivo efficacy. Phase 1 studies confirmed that MIN-102 is well tolerated and is able to cross the blood-brain barrier engaging the PPAR gamma in the CNS.

“On behalf of the company, I would like to take this opportunity to thank the patients and their families, the advocacy groups, and the caregivers and their staff for achieving this fast enrollment,” said Marc Martinell, CEO of Minoryx. “With the recent €21.3M Series B funding we are exploring the potential of MIN-102 in additional indications and plan to launch a new clinical study for a second orphan central nervous system indication.”