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Minoryx Therapeutics initiated the treatment of AMN in advance

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The ADVANCE trial is the result of a successful collaboration between scientists, clinical experts and patient associations

Minoryx is a clinical stage biotech company leading the development of new therapies for X-ALD and other inborn errors of metabolism, a group of rare diseases of genetic origin with a high unmet medical need.

The company announces the initiation of treatment of the first two patients in the ADVANCE trial, a pivotal phase 2/3 clinical trial of MIN-102 for the treatment of adrenomyeloneuropathy (AMN).

The trial enrolls adult male patients affected by AMN, the most frequent phenotype of X-linked adrenoleukodystrophy (X-ALD).

The first patients were dosed at the Vall d'Hebron University Hospital (Barcelona, Spain) by Dr. Josep Gamez and at the Academic Medical Center (Amsterdam, The Netherlands) by Dr Marc Engelen.

Recruitment was also initiated at the Institute of Genomic Medicine and Rare Disorders (Budapest, Hungary) by Dr. Maria Molnar.

The ADVANCE trial will be initiated in several other European countries (United Kingdom, Germany, France, Italy and Poland) in the coming weeks and in the US by mid-2018.

The ADVANCE trial is a randomized, double-blind, placebo-controlled study with an open-label extension to determine the efficacy and safety of MIN-102.

Min 102 is a novel, orally bioavailable and selective PPAR gamma agonist with a superior profile for central nervous system-related diseases and promising in vivo efficacy.

The primary outcome is to evaluate the efficacy of MIN-102 on the progression of AMN in male patients, as determined by a motor function test.

The trial aims to enroll more than 100 patients and results are expected at the end of 2020.

The trial was designed based on input from Minoryx's scientific advisory board, comprised of internationally renowned EU

and US clinical experts in X-ALD.

Additional advice was also obtained from major patient advocacy groups.

The design and endpoints were finalized following regulatory interactions with the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).