

NEUREVO GmbH received FDA approval for accelerated orphan drug development (ODD) for treatment of amyotrophic lateral sclerosis (ALS).

Munich, June 15, 2022. – NEUREVO GmbH, a biotechnology company dedicated to developing and commercializing next-generation treatments for serious neurodegenerative diseases, today announced that it has received FDA approval for accelerated orphan drug development in ALS.

"The FDA's positive decision acknowledges the strength of our data and the importance of novel treatment options using an innovative approach and a different Mode of Action to fight ALS. This is the second validation of our orphan drug development strategy which was already approved in November 2021 by Europe's EMA," commented the company's CSO and founder Dr. Francisco Pan-Montojo.

NEUREVO's proprietary patent-protected technology platform was recognized by several awards and strong support of governmental grants which were used to pave the standard regulatory pathway for IND enabling studies. To push programs further towards clinical development, management teamed up with Granzer Regulatory Affairs to create a convincing time- and capital-efficient orphan drug development (ODD) strategy.

With both EMA and FDA ODD approval in hand, NEUREVO now can clearly differentiate itself from competitors in the field and take advantage from its sharpened company profile. "We are now in a position to reach out to institutional US investors to support capital and syndicate formation and present NEUREVO's Preferred Series A Equity Financing Round as an interesting transatlantic investment opportunity", concluded Dr. Francisco Pan-Montojo.

About NEUREVO GmbH

NEUREVO GmbH is a German startup founded 2020 as a spin out of Ludwig-Maximilian-University (LMU), Munich and focuses on the development and commercialization of novel approaches to treat neurodegenerative diseases with a high unmet medical need (ALS, Frontotemporal Dementia (FTD), Alzheimer´s Disease, Parkinson Disease).

NEUREVO's products are based on patent-protected methods of treatment and formulation around glycolic acid and D-lactate which



prevent their toxicity, enhance their therapeutic effect, and unfold a significant potential to revolutionize neurological treatments.

NEUREVO is supported by several KOLs and a strong Scientific Advisory Board to continuously expand the range of neurodegenerative indication areas to build a highly focused franchise. Beyond its scalability to other neurological diseases, NEUREVO is able to apply its approach to CNS diseases with high unmet medical need that provide additional commercial upside. Further development is centered around data of preclinical and 1st-in-man studies that suggest a favorable safety profile.

About Amyotrophic Lateral Sclerosis (ALS)

ALS or Lou Gehrig's Disease is a neurodegenerative disease that results in the progressive loss of motor neurons that control voluntary muscles. Motor neuron loss continues until the ability of eat, speak, move, and finally the ability to breathe is lost. ALS eventually causes paralysis and early death, usually from respiratory failure.

In the field of neurodegenerative diseases, ALS and frontotemporal dementia (FTD) are considered to be part of a common disease spectrum because of genetic, clinical and pathological similarities. Until today there is no known cure for ALS, to date the goal of treatment is to improve symptoms. In 2014, a disease-specific promotional campaign (the "Ice Bucket Challenge") went viral on the Internet and increased public awareness of the condition.

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