Press Release
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Treeway announces positive data from two separate Phase I TW001 clinical trials

- Successful dose and confirmatory study solid platform for phase II/III trial in ALS patients

Rotterdam, The Netherlands, December 10th 2015 – Treeway, a biotech company developing therapies against amyotrophic lateral sclerosis (ALS), today announces the completion of two successful phase I trials with their lead compound TW001, a new more patient friendly oral formulation of the Japanese stroke and ALS therapy edaravone. Treeway, founded by two Dutch ALS patients, aims at speeding up ALS research in collaboration with academic and research centers around the globe.

TW001 was tested in both single and multiple dose phase I studies in healthy volunteers and in ALS patients. In the two Phase 1 clinical studies TW001 was shown to be safe and well tolerated and adequate exposure levels with the oral formulation were detected. Based on these trial data, the company is now aiming to start a pivotal phase 2/3 study in 2016. Earlier, Treeway obtained orphan drug designation for edaravone of ALS from both the FDA and EMA.

Inez de Greef, CEO of Treeway comments on the trial outcome:

“The positive results of our Phase I program are an important milestone for the development of TW001 for ALS. This outcome is not only represents a significant achievement for our company, but first offers important new patient friendly aspects to the treatment of ALS. We look forward to sustaining this momentum in the coming months, as preparations for the pivotal Phase II/III clinical study are now ongoing”.

Lead compound

TW001, Treeway’s lead compound, is an oral formulation of edaravone. Edaravone is a well-established free radical scavenger, which targets oxidative stress, a process that plays an important role in ALS. Intravenously administered edaravone has been shown to slow down disease progression in ALS patients in previous Japanese clinical trials.

Treeway has developed an oral formulation (TW001) to overcome the problems associated with intravenous administration. The reformulated drug allows for chronic daily use and its route of administration (oral) is patient friendly.

Currently, edaravone is marketed in Japan by Mitsubishi Tanabe as an intravenous formulation (Radicut®) for the indication stroke and ALS. The intravenous formulation of edaravone is administered to ALS patients via 1-hour infusions in a hospital setting. Drug holiday cycles are part of the treatment regimen (patients are treated 10 out of 28 days).
Note for the editor

About ALS
Amyotrophic Lateral Sclerosis, also known as Lou Gehrig’s Disease, is a relentless progressive neurodegenerative rare disease that causes muscle weakness, disability and eventually death. The average survival from diagnosis to death is three to four years. The disease most frequently occurs between the age of forty to sixty. The cause of ALS is not known in 90% of the cases. About 10% of cases is familial and several genetic mutations can be responsible for this. In Europe and the United States, the disease affects about two people per 100,000 per year. Currently, there are about 400,000 patients with ALS in the world. To date, there is no cure for ALS.

About Treeway
Treeway is a biotechnology company with a mission to develop therapies to cure ALS. It was founded in 2012 by two ALS patients and established strong patient empowerment within the target market. The management has wide expertise in drug development. The cohesive combination of approaches provides the highest successful treatment for ALS to the patient in an efficient manner.
For further questions about Treeway, please contact info@treeway.nl or www.treeway.nl