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Treatments for the Advancement of Life

Study Number: **TTP488-303**
EudraCT: **2017-004065-27**
Study Title: **Open Label Extension Study for Continued Safety and Efficacy Evaluation Of Azeliragon in Patients with Mild Alzheimer's Disease**
Status: **Terminated**

Study TTP488-303 was terminated prior to enrollment of any participants in the EEA. MHRA acknowledged the end of trial declaration received on 09 July 2018 and indicated requirement to only upload summary results to EudraCT.

On April 9, 2018, vTv Therapeutics announced that the results from Part A of the STEADFAST study (TTP488-301) did not meet either co-primary efficacy endpoint. As a result, vTv Therapeutics promptly discontinued clinical studies involving azeliragon, including the Open Label Extension study (TTP488-303) due to a lack of efficacy at the 5 mg azeliragon dose level. No subjects from the EEA were enrolled in Study TTP488-303 prior to discontinuation; therefore, this summary is provided to the EudraCT results database.

Enrollment Summary

Country	TTP488-303 participants enrolled
United Kingdom	0
Ireland	0
South Africa	0
Australia	0
New Zealand	0
United States	260
Canada	37
TOTAL: worldwide	297
TOTAL: EEA only	0

Safety Summary

	Total N=297
Number of subjects with at least one treatment-emergent adverse event	193 (65.0%)
Number of subjects with at least one treatment- emergent adverse event considered drug-related	23 (7.7%)
Number of subjects with at least one severe treatment-emergent adverse event	14 (4.7%)
Number of subjects with at least one treatment -emergent adverse event leading to study drug action: drug withdrawn	9 (3.0%)
Number of subjects with at least one serious treatment-emergent adverse event	25 (8.4%)