Zachary Urlaub
Premier Research
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June 22nd, 2021

European Medicines Agency (EMA)
Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands

EudraCT number	Sponsor code	Title
2015-002072-24	15VR7	An Open-Label, Dose Finding, International Phase 2 Study with Once Monthly Subcutaneous Somavaratan (VRS-317) in Adult Growth Hormone Deficiency (GHD) Versartis International Trial in Adults with Long Acting Growth Hormone. The VITAL study

To whom it may concern,

It has been brought to our attention that the results for the trial above have not been posted in EudraCT. We have been informed that in case no results or only partial results are available, a PDF document justifying the missing/partial results for trial should be posted. In order to comply with the European Commission Guideline on results posting and as requested in the Joint Letter by the European Commission, EMA and HMA, please see justification below.

On March 04, 2015, Premier Research and Versartis, Inc effectively entered into a Master Service Agreement (MSA). Premier Research, the CRO, is engaged in the business of providing services related to the implementation and management of clinical development programs for the pharmaceutical, biotechnology, and medical device industries. And Versartis, Inc, being the Sponsor of the trial.

Per notification to Premier Research, in September 2017, Versartis announced that the VELOCITY Phase 3 clinical trial of Somavaratan in pediatric GHD did not meet its primary endpoint of non-inferiority. As a result, all ongoing clinical trials of Somavaratan were concluded as of the end of 2017 and the U.S. Investigational New Drug Application (IND) and all equivalent filings in foreign countries were withdrawn; this included the trial listed above, “The VITAL study”.

Moreover, on June 3rd, 2018, Versartis announced the signing of a merger agreement with Aravive which ultimately went into effect on October 16th, 2018. After this point, the combined company operated as Aravive, Inc. As a result of this merger, and that the Sponsor and not Premier was tasked with notifying the Health Authorities under the terms of the MSA, I cannot be sure if/when notification of premature closing was posted.

If useful, I can inform you that the Last Patient Last Visit (LPVL) in the UK occurred on September 12th, 2016, and the LPLV globally occurred on October 05th, 2016. However, while patients were dosed, no results are available.

Respectfully,

DocuSigned by:
Zachary Urlaub
Signer Name: Zachary Urlaub
Signing Reason: I am the author of this document
Signing Time: 23-Jun-2021 | 16:05:44 EDT
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