08 January 2025

Protocol Number: ISA101b-HN-01-17
EudraCT Number: 2018-000789-13
Clinical Study Title: A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of Cemiplimab Versus the Combination of Cemiplimab With ISA101b in the Treatment of Subjects With HPV16-Positive Oropharyngeal Cancer (OPC)

Protocol Number: ISA101b-OPC-03-19
EudraCT Number: 2020-003652-32
Clinical Study Title: A Phase II Study of cemiplimab, an anti-PD-1 monoclonal antibody, and ISA101b vaccine in patients with recurrent/metastatic HPV16-positive Oropharyngeal Cancer (OPC) who have experienced disease progression with prior anti-PD-1 therapy

Sponsor: ISA Therapeutics BV, De Limes 7, 2342 DH Oegstgeest, The Netherlands

Subject: Posting Study Results in EudraCT database

To whom it may concern,

PSI CRO AG, acting for and on behalf of ISA Therapeutics B.V., hereby informs you that no results of ISA101b-HN-01-17 and ISA101b-OPC-03-19 clinical trials are available.

Both of the aforementioned studies were prematurely ended in April 2024 as per the Sponsor's decision dictated by an FDA opinion that there is no regulatory path forward for ISA101b approval based on ISA101b-HN-01-17 and ISA101b-OPC-03-19 study design and delays in the study timelines.
Moreover, since April 2024, the study Sponsor, ISA Therapeutics B.V., dissolved and does not exist any longer.

Due to the above, no Clinical Study Report has been developed for any of the studies and, hence, full posting of the studies' results in EudraCT database is not possible either. The related Competent Authorities have been informed accordingly.

PSI CRO AG, as the Contract Research Organization responsible for certain activities within the studies (though not responsible for posting the studies' results in EudraCT database) and respecting the *Joint Letter by the European Commission, EMA and HMA to Stakeholders Regarding the Requirements to Provide Results for Authorised Clinical Trials in EudraCT*, draws the conclusion that the above justification provided as a pdf document is the only possible way to meet the obligation of posting the studies' results in EudraCT database.