

Date	14 September 2022
EudraCT Number	2021-002193-63
Protocol Number	C-700-03
Protocol title	A Phase 3 Trial of Balstilimab versus Investigator Choice Chemotherapy in Patients with Recurrent Cervical Cancer after Platinum-Based Chemotherapy - BRAVA
Sponsor name of Vice-President of Regulatory	[REDACTED]
Email address of Vice-President of Regulatory	[REDACTED]
Sponsor Address	Agenus 3 Forbes Rd, Lexington, MA 02421 USA

Justification Letter for Missing Results for C-700-03

On the 22nd of October 2021, the sponsor (Agenus) took the decision to immediately discontinue an intended confirmatory phase 3 trial identified as C-700-03 (BRAVA). A formal communication was sent to all investigators to stop all activities at once and work on closing out the trial. The decision was also communicated to the health authorities and all applications withdrawn.

At the time of study discontinuation, 6 patients had signed an informed consent form, 2 in the US (Site 038) who were then considered as screen failures, and 4 in Armenia (Sites 415 and 416). No patients were dosed in the study before the trial was terminated on the 22nd of October 2021.

The reason of the trial termination and strategic decision to withdraw the Biologics License Application (BLA) for balstilimab for the treatment of patients with second line recurrent or metastatic cervical cancer was consequent to the full approval of pembrolizumab for the cervical cancer indication. Following pembrolizumab approval, balstilimab was no longer eligible for approval under the provisions for accelerated approval in the US; with the consequence being that the intended accelerated approval confirmatory study cited herein, would no longer need to be conducted.

The C-700-03 trial was recorded in the EudraCT database as “*prematurely ended*”. However, considering no patients were ever dosed and there’s no plan to restart the trial, the sponsor is hereby providing this letter to justify the missing results of this trial.

Sponsor Name/Title: [REDACTED], Vice President-Regulatory Affairs

[REDACTED]

Sponsor Signature

9/14/2022

Date