# CO41863 (2019-004200-35) RESULTS SUMMARY DOCUMENT

8th October 2021

**Re: CO41863 (2019-004200-35) Clinical Trial**

To whom it may concern,

We would like to confirm that the Clinical Trial CO41863 (EudraCT: 2019-004200-35) was Terminated Early by the Sponsor (F. Hoffmann-La Roche Ltd).

Please find appended below, the withdrawal letter dated 2nd February 2021 containing the reason for this trial's termination.

As only 1 subject was enrolled in any of the participating countries/sites where this study was approved, minimal safety and exploratory efficacy data were collected for this study. No data was collected for all other outcome measures. To protect and maintain the privacy/confidentiality of this 1 subject and to prevent the risk of re-identification of them, no results data will be reported for this study.

Consequently, there are no trial results available for this study to be reported in the EudraCT database.

**RE: CO41863**

**A PHASE Ib/II, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY EVALUATING THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND EFFICACY OF VENETOCLAX IN COMBINATION WITH TRASTUZUMAB EMTANSINE IN PATIENTS WITH PREVIOUSLY TREATED HER2-POSITIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER**

**02 February 2021**

Dear CO41863 Study Investigators,

We are contacting you to provide an update on the enrollment pause that we issued in October 2020 following the Urgent Safety Measure Dear Investigator Letter (USM DIL).

This memo is a formal announcement by F. Hoffmann-La Roche, the Sponsor, of the decision to discontinue CO41863 study. The Sponsor's decision to discontinue the study is based on broader development and strategic prioritization. The Sponsor concludes there is no benefit-risk impact on the CO41863 study after additional evaluation of WO40181 (VERONICA) study results. Please note the following information:

- Currently, there are no patients on active treatment
- The patient currently in long-term follow-up will need to be withdrawn from study. Please document the final visit in the patient's chart.
- Your study monitor will reach out shortly to share expectations for any data collection and site closure as appropriate

Please submit a copy of this letter to the relevant institutional authorities (Ethics Committees/Institutional Review Board) to meet local regulations (as applicable). In addition, please file this correspondence in your investigator site file. Roche, or its designee, will provide notification to the Regulatory Authorities/Ethics Committees/Central IRBs of our close out plans.

If you have any questions related to this study, please do not hesitate to contact your local monitor. They will be able to advise you further.

We would like to thank you and your teams for the outstanding commitment and diligent work since the start of this study last year. The Roche team considers your effort to be a great collaborative effort for the entire solid tumor program. We hope to work with you again in the future.

Yours sincerely,

Ryan Lall
Global Studies Leader

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