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Milan, January 17, 2024

RE: EudraCT 2021-002476-39

Prospective study to evaluate the effects of Raloxifene therapy on SARS-CoV-2 immunity after COVID-19 vaccination

Dear Sir or Madam,

This letter is to confirm that the clinical trial RLX0121 with EudraCT number 2021-002476-39 to evaluate if raloxifene was able to stimulate the immunization against the SARS-CoV-2 was closed. Dompé farmaceutici s.p.a. (the Sponsor) ended the trial prematurely as it was assessed that the study was no longer feasible as the majority of target recruitment population had received the first dose of the SARS-CoV-2 vaccine.

No patients were enrolled on RLX0121.

The Sponsor notified the concerned Italian Ethics Committees and Competent Authority (AIFA) on 09 December 2021.

The Sponsor performed a diligent review of the study status to decide on the future of the study, and ultimately deciding to end it. If you have any questions or require additional information, please contact Sarah Fenlon at the following email: sarahjane.fenlon@dompe.com.

We ask that this letter is filed with the study record.

Kind regards,

DocuSigned by:

Sarah Jane Fenlon



Signer Name: Sarah Jane Fenlon
Signing Reason: I am the author of this document
Signing Time: 17-Jan-2024 | 2:09:26 PM CET

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Global Regulatory affairs Director - NETosis

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