

## 2.4 ADDENDUM TO THE NONCLINICAL OVERVIEW

This line extension formulation is a dispersion for injection that does not require dilution before use. It is presented in multi-dose dose vials, which are differing only in minor formulation change (use of tromethamine buffer and exclusion of sodium chloride and potassium chloride) and in the filling volume per vial.

As agreed in the Scientific Advice Meeting in March 2021 non-clinical bridging studies are not required, if analytical comparability of the pre-change and post-change quality attributes is shown and stability is sufficiently reassured.

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