RESPONSE TO PREA NON-COMPLIANCE LETTER dated September 8, 2021

The Notification of Non-Compliance with the Pediatric Research Equity Act (PREA) from September 8, 2021, informed Octapharma about not having met the post-marketing requirement (PMR) of PREA for BL 125251/272 because of a missing pediatric assessment for PMR #1 which had been deferred until December 31, 2019.

Octapharma would like to clarify that the missing pediatric assessment for PMR #1 is a formal consequence of the fact that, in FDA's evaluation, the supplemental BLA based on the WIL-30 study did not contain the expected evidence of efficacy of Wilate in pediatric patients younger than 12 years of age with severe hemophilia A, as described in the Complete Response of August 6, 2021. In addition, the submission of the WIL-30 data was considered insufficient to address the PREA PMR referenced in the letter dated September 25, 2019, which granted approval for WILATE for adults and adolescents with hemophilia A for routine prophylaxis to reduce the frequency of bleeding episodes and on-demand treatment and control of bleeding episodes.

Octapharma plans to submit a revised pediatric study plan requesting for a waiver for studies in PTPs between 1 and < 12 years of age under IND 017181 by November 30, 2021. Specifically, a waiver will be requested based on point c) of Section 505B(a)(4)(A) of the Pediatric Research Equity Act:

(c) The product fails to represent a meaningful therapeutic benefit over existing therapies for pediatric patients **and** is unlikely to be used in a substantial number of all pediatric age groups or the pediatric age group(s) for which a waiver is being requested.

From Octapharma's perspective, this course of action is in line with the above referenced section since more than 10 therapeutic options are available for pediatric patients with hemophilia A and the use of plasma-derived products for patients with hemophilia A is dwindling.