



TECHNICAL MEMO

RE: Shelf Life extension of VIR-7831 Drug Product to 18-month

The shelf-life of VIR-7831 Drug Product was assessed using the following stability data available to date: 12-month time point data from analysis of VIR-7831 Gen 1 DP batches, 6-month time point data from analyses of the GMP Gen 2 WuXi DP batches, and 4-month time point data from analyses of the GMP Gen 2 Parma DP batches. The overall stability between VIR-7831 Gen 1 and Gen 2 WuXi and Parma DP batches has been deemed comparable (VQD-RPT-102561).

Data from the shelf-life assessment supports amending the expiry period for the Gen2 Parma drug product lots currently being used in ongoing clinical studies out to 18-month (from their current 12-month period from date of manufacture) see report *VQD-RPT-127382, version 1.0 VIR-7831 Drug Product Stability Trend*.

The 18-Month shelf life for VIR-7831 Drug Product was made effective in *VIR-7831 IMPD Version 4.6*.

References:

VQD-RPT-127382, version 1.0 VIR-7831 Drug Product Stability Trend

VQD-RPT-102561, Sotrovimab DP Comparability Report 2000L vs 6x2000L (v1.0)

VIR-7831 IMPD Version 4.6

Quality Control

Signature/Date: _____

Quality Assurance

Signature/Date: _____