



TECHNICAL MEMO

RE: Shelf-Life extension of VIR-7831 Drug Product to 36-month

The shelf-life of VIR-7831 Drug Product (DP) was assessed using the following stability data available to date: 24-month time point data from analysis of VIR-7831 Gen 1 DP batches, 24-month time point data from analyses of the GMP Gen 2 WuXi DP batches, and 18-month and 12-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 36-month (from their current 30-month period from date of manufacture) see report *VQD-RPT-127382, version 4.0 VIR-7831 Drug Product Stability Trend Report*.

References:

VQD-RPT-127382, version 4.0 VIR-7831 Drug Product Stability Trend Report

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

Quality Control

Signature/Date: _____

Quality Assurance

Signature/Date: _____