



TECHNICAL MEMO

RE: Clinical Shelf-Life extension of VIR-7831 Drug Product to 48-month

The shelf-life of VIR-7831 Drug Product (DP) was assessed using the following stability data available to date: 36-month time point data from analysis of VIR-7831 Gen 1 DP batch 202006002 and 202006004, 30-month time point data from analyses of the GMP Gen 2 WuXi DP batch 20209005 and 202010006, 24-month time point from the Gen 2 Parma manufactured batches, and Gen 1 DP lot 2275S200411Y. 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 clinical expiry period for the Gen 2 Parma drug product lots currently being used in ongoing clinical studies out to 48-months (from their current 36-month period from date of manufacture) see GSK stability trend report *VQD-RPT-127382, version 6.0 VIR-7831 Drug Product Stability Trend Report*.

References:

VQD-RPT-127382, version 6.0 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: _____