Based on population pharmacokinetic analysis in patients with advanced malignancies, a fixed dose of cemiplimab (350 mg Q3W) was established

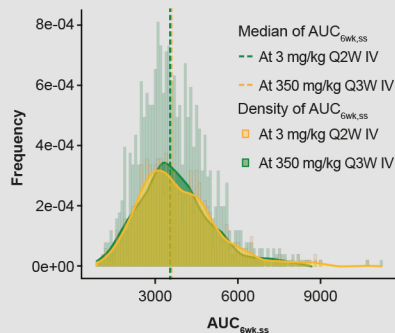## Build PopPK model for dose selection*

PK data from 505 patients (pooled)

Median body weight (range): **76.1 (30.9–156) kg**

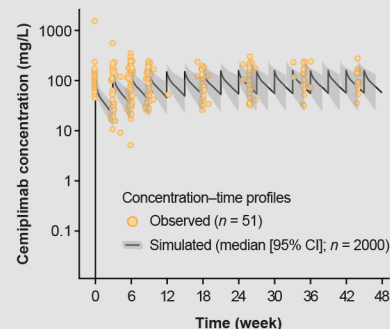*Baseline body weight significantly improved the model ($P < 0.01$).

A linear two-compartment model incorporating covariates was developed to compare cemiplimab exposure at 350 mg Q3W versus 3 mg/kg Q2W

Utilize PopPK M&S for dose selection

Median of $AUC_{6wk,ss}$
-- At 3 mg/kg Q2W IV
-- At 350 mg Q3W IV
Density of $AUC_{6wk,ss}$
■ At 3 mg/kg Q2W IV
■ At 350 mg Q3W IV

The distribution of cemiplimab $AUC_{6wk,ss}$ was similar at 350 mg Q3W and 3 mg/kg Q2W in advanced malignancies ($n = 2000$)

Confirm dose selection using observed data

Concentration–time profiles
○ Observed ($n = 51$)
— Simulated (median [95% CI]; $n = 2000$)

Overlay of individual observed ($n = 51$) and simulated ($n = 2000$) concentration–time profiles at 350 mg Q3W showed comparable cemiplimab exposure

$AUC_{6wk,ss}$, area under the cemiplimab concentration–time curve over 6 weeks at steady state; CI, confidence interval; IV, intravenously; M&S, modeling and simulations; PK, pharmacokinetic; PopPK, population pharmacokinetics; Q2W, every 2 weeks; Q3W, every 3 weeks.

Authors: Anne J. Paccaly, Michael R. Migden, Kyriakos P. Papadopoulos, Feng Yang, John D. Davis, Ronda K. Rippley, Israel Lowy, Matthew G. Fury, Elizabeth Stankevich, Danny Rischin.
Correspondence: anne.paccaly@regeneron.com

Adis