



Source: FDA analysis of data from the Applicant’s 351(k) BLA submission

Figure 9.11 Pharmacokinetic profiles following 3 mg/kg single intravenous injection of bevacizumab in healthy subjects. (From <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566365.pdf>)

Table 9.5 Pharmacokinetic Parameter Evaluation of Bevacizumab Biosimilar

Comparison	Geometric Mean Ratio (90% CI)		
	C _{Max}	AUC _{0-t}	AUC _{0-inf}
ABP215 vs U.S.-Avastin	98.1 (93.7–102.8)	98.3 (94.0–102.9)	98.3 (94.0–102.9)
ABP215 vs EU-bevacizumab	102.9 (98.2–107.8)	95.6 (91.3–100.0)	95.6 (91.3–100.0)
U.S.-Avastin vs EU-bevacizumab	104.9 (100.1–109.9)	97.2 (92.8–101.7)	97.2 (92.8–101.7)

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Where a pharmacodynamic model is available, a direct comparison of treatment emergent adverse events is made by calculating the 95% confidence interval for the difference in proportions:

$$P1 - P2 \pm Z_{\alpha/2} * SE,$$

where SE is the pooled standard error of P1-P2, which is given by

$$SE = \sqrt{\frac{P1(1 - P1)}{N1} + \frac{P2(1 - P2)}{N2}}.$$