PHASE 1 ENDPOINTS MET

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Human safety and dose established.

Phase 1 endpoints met.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Initial safety and tolerability demonstrated (no gross clinical and laboratory abnormalities) relative to the TPP	Satisfactory safety profile using validated methods and adequate statistical analyses: a) Drug-related adverse events (AEs) which may include serious adverse events (SAEs) b) Management of any adverse events (reporting of the events to the applicable ethical committees and regulatory agencies)	▪ Summary of clinical safety data, AEs and SAEs
▪ Phase 1 safety, pharmacokinetics and biomarker data do not preclude the further development of the compound relative to the TPP	a) Validated bioanalytical measurements of drug candidate exposure and relevant biomarker concentrations b) Preliminary exposure-response relationships based on biomarker data	▪ Summary of clinical PK data, exposure, half-life and recommended Phase 2 dose with rationale