PHASE 3 ENDPOINTS MET

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Safety, efficacy, and desired outcomes in humans demonstrated in pivotal trial.

Safety, efficacy, and desired outcomes in humans (full analysis) demonstrated.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Safety (includes clinical and laboratory abnormalities) profile of candidate aligns with TPP	Satisfactory safety profile using validated clinical endpoint assays and adequate statistical analyses: a) Safety signal detection (e.g., adverse events (AEs) which may includeserious adverse events (SAEs)) b) Fully characterized drug-drug interactions c) Management of any adverse events (reporting of the events to the applicableethical committees and regulatory agencies)	▪ Summary of Phase 3 clinical trial data
▪ Efficacy profile of candidate aligns with TPP	Clinical efficacy demonstrated using validated clinical endpoint assays and adequate statistical analyses: 1) Sufficient efficacy duration to achieve impact 2) Superiority ornon-inferiority datain comparative studies against licensed drug (or treatment) control (if applicable)	▪ Summary of Phase 3 clinical trial data
▪ Other TPP characteristics met	Assessment of whethercandidatemeets target product profile	▪ Use cTPP template