

Antibody Profile

The following table represents example categories to consider in describing your current results/status and desired results at the end funding period

Category	Parameters
Structure/Identity	Class and sub-class Light Chain Composition Amino acid (AA) sequence Carbohydrate content AA-sequence confirmed by peptide mapping 3D structure Epitope mapping
In vitro activity	Target binding: affinity/saturation Bioactivity/potency Stimulation of biological cascade Tissue Selectivity Selectivity/off-target effect to related target
In vivo activity (such as target engagement/proximal downstream effect or efficacy) Indicate dose and route of administration	Concentrations of testing agent in the serum and target tissue Brain penetration Serum half-life, AUC or other pharmacokinetic properties Optimize Dose Selection and Schedule ED50, Minimal effective dose, and Optimal effective dose Treatment duration optimization Treatment window optimization Interactions with standard of care Selectivity/off-target effect in vivo
Safety	Tolerability Antibodies to product Tumorigenesis Assess host immune response Tissue Cross-Reactivity Local reactogenicity Cardiovascular, respiratory, renal and CNS safety pharmacology studies if any
CMC	Master/Working Virus Bank Status Process development status Analytical Assays for release testing with specifications Scale-up feasibility Formulation needs/development Stability Analysis Potency assays (in vitro/in vivo) Delivery devices
GLP analytical method development/validation	Potency assays, assays for purity, pharmacokinetics and pharmacodynamics etc
Interactions with regulatory agencies	Pre-IND
Patent protection?	