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Development Stages in Scope
Drugs, Biologics and Vaccines

Hit-to-Lead (Lead Generation)
• Characterization of Preliminary Candidates(s) to further evaluate structure activity relationships
• Explore alternative chemical design across a number of lead series to improve on in vitro potency, selectivity, chemical stability and synthetic tractability cytotoxicity, other drug-like properties
• Demonstrate in vitro activity and potentially generate preliminary in vivo proof-of-concept efficacy data.

Lead Optimization
• Synthesize lead compounds from selected lead scaffolds - new analogs with improved potency, reduced off-target activities, and physiochemical/metabolic properties suggestive of reasonable *in vivo* pharmacokinetics
• Conduct non-GLP in vivo toxicity in accordance with the product's intended use.
• Initiate experiments to identify markers, correlates of protection (e.g., PK-PD), assays, and endpoints for further pre-clinical and clinical studies.
• Demonstrate in vivo activity and potential for efficacy consistent with the product's intended use (i.e. dose, schedule, duration, route of administration)
• Select candidate to progress into pre-clinical evaluation

Pre-Clinical (IND Enabling)
• Demonstrate acceptable Absorption, Distribution, Metabolism, and Elimination (ADME) characteristics and/or immune responses in non-GLP animal studies as necessary for IND filing.
• Conduct GLP non-clinical studies for toxicology, pharmacology, and immunogenicity (as appropriate).
• Continue development of animal models for efficacy and dose-ranging studies
• Develop a scalable and reproducible manufacturing process amenable to GMP. Manufacture GMP-compliant pilot lots.
• Initiate development of in-process assays and analytical methods for product characterization and release, including assessments of potency, purity, identity, strength, sterility, and quality as appropriate
• Prepare and submit Investigational New Drug (IND) package to FDA.

Phase 1
• Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) clinical trial(s) to determine the safety and pharmacokinetics of the clinical test article in healthy volunteers (in certain circumstances, patients).