



RESEARCH

Lead Chemical Series Selected	Lead Optimization Completed	IND-Enabling Studies Completed					
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PRODUCT STRATEGY

	Candidate Target Product Profile Expectations	Updated Candidate TPP	Updated Candidate TPP	Updated Candidate TPP		
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CHEMISTRY MANUFACTURING AND CONTROL DRUGS (CMC)

	CMC Development Plan In Place (Drugs)	CMC Development Plan Updated (Drugs)	CMC Development Plan Updated (Drugs)	CMC Development Plan Updated (Drugs)		
	Initial DS/DP Characterization Complete	DS/DP Characterized at Kilo-Scale	Full-scale DS/DP Manufacturing Process Optimized	Tech Transfer (DS, Analytical, DP & Packaging), Validation Completed		
				Full-Scale Post-Launch Manufacturing Strategy in Place	Full-Scale Post-Launch Manufacturing Strategy Updated	

CMC DRUG-DEVICE COMBINATION PRODUCT ADVANCED DRUG DELIVERY SYSTEM

	CMC Development Plan in Place (CP/ADDs)	CMC Development Plan in Place Updated (CP/ADDs)	CMC Development Plan in Place Updated (CP/ADDs)	CMC Development Plan in Place Updated (CP/ADDs)		
	Device Design and Development Plan Initiated	Device Design and Development Plan Updated	Device Design and Development Plan Updated			
User Needs and Acceptance	Human factors Study Plan Completed	Formative Human Factors Study	Summative Human Factors Study Completed		Complaint Handling Process Defined	
	Design History File Initiated	Design History File Updated	Design History File Updated	Design History File Closed	Pharmacovigilance Plan in Place	
Concepts Screening and Identification	Design Input Review	Design Output Review	Design Verification and Verification Reviews	Design Transfer Review		
		Design Risk Assessment		Supply Chain/Logistics Plan in Place		

REGULATORY

		End of Phase 1 Meeting Scheduled	End of Phase 2 Meeting Planned or Scheduled*	Pre-licensure Meeting Scheduled*	WHO PQ or First Local Registration	
	Pre-IND Meeting Scheduled* (Optional)	IND Submitted to Regulatory Agency				
	Regulatory Strategy and Plan in Place	Regulatory Strategy and Plan Updated	Regulatory Strategy and Plan Updated	Regulatory Strategy and Plan Updated		

CLINICAL

	Study Start-up Activities Initiated	Study Start-up Activities Initiated	Study Start-up Activities Initiated			
		Run Clinical Program Phase 1	Run Clinical Program Phase 2	Run Clinical Program Phase 3		
		Proof of Concept Obtained	Proof of Concept Obtained <small>* if not completed</small>			
	Clinical Development Plan in Place	Clinical Development Plan Updated	Clinical Development Plan Updated	Clinical Development Plan Updated		
		Phase 1 Endpoints Met		Phase 3 Endpoints Met		

DELIVERY

	Business Case	Business Case Updated		Coverage and Financial Tracker		Global Normative Guidance
	Deliverability Assessment	Deliverability Assessment Updated	Deliverability Assessment Updated			
			Launch Budget Prediction	Launch Budget Prediction Updated		Launch in First Country
	Strategic Demand Forecast	Strategic Demand Forecast Updated	Strategic Demand Forecast Updated	Strategic Demand Forecast Updated		50% Coverage Achieved
	COGS	COGS Updated	COGS Updated	COGS Updated		Target Market Share Achieved
	Cost-Effectiveness Analysis	Cost-Effectiveness Analysis Updated	Cost-Effectiveness Analysis Updated	Cost-Effectiveness Analysis Updated		

PARTNER MANAGEMENT

CMOs/CROs selected	Partner Selection Plan in Place	Commercial Partner Identified	Commercial Partner Identified <small>* if not completed</small>			
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GLOBAL ACCESS AGREEMENT

	Global Access Agreement Expectation	Global Access Agreement in Place	Global Access Agreement in Place	Global Access Agreement Updated		
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