TPP Summary

Product Goal	Current Standard of Care (Efficacy & Safety / Level of Generics)	
	Future Standard of Care (Efficacy & Safety / Level of Generics / development)	
Target Population Segment (inc sub-pop)	Approx Launch Year	

Unmet Medical Need

Physician Unmet Need	Patient Unmet Need	Unmet Need from Payer Perspective

Key Value Drivers

Clinical Differentiators	Impact on Reimb & Price (H/M/L)
Clinical Differentiator 1. Efficacy: eg 15% reduction in a composite endpoint in high-risk patients with documented CHD (incl. ACS) or CHD risk-equivalent disease with/without additional risk predictors on current standard clinical therapy. …	
Clinical Differentiator 2. ….	
Clinical Differentiator 3…..	
Economic Differentiators	
Economic Differentiator 1.	
Economic Differentiator 2.	
Pricing & Reimbursement Assumptions	
Future Pricing & Reimbursement Environment	
Price Range & Reimbursement Goal	
Other Assumptions (Technological Trends, Diagnostic Tests, Biomarkers)	
Key Considerations for a Minimum Acceptable Profile	

Global Peak Sales Value Range	e.g., £300-£700m

Key Questions to Consider in TPP Discussions

Product Goal	• A single sentence describing the strategic intent of this profile • What is it that is trying to be delivered
Target Patient Population	• Which specific subpopulations of this disease does the opportunity lie and the geographic strategies?
Current & Future Standard of Care (Products / Classes in Development)	• How high is the hurdle for a new entrant? - efficacy level of current gold standard - level of genericisation - future standard of care (~10 years forward) - may need to distinguish between payer and physician perspectives
Unmet Medical Need	• What is the unmet need that is seen by the physician and patient as well as the payer? • Have you any market research to underpin this?
Clinical Differentiators	• What clinical differentiators do you need to deliver in order to create medical value? • Need to be specific about which Efficacy parameters (depth, speed, sustainability) – with clarity on efficacy safety hurdles so that studies can be designed appropriately eg endpoints where appropriate • What other aspects drive incremental clinical differentiation Safety, tolerability, dosing
Economic Differentiators	• Aspects that drive value such as cost of illness, cost effectiveness, incremental value in sub-population) • Are there any Economic Differentiators that may deliver medical value (less time off work or less hospitalizations?
Reimbursement & Pricing	• What does the future pricing & reimbursement environment look like? • Have you delivered enough medical value? • What would someone pay for this increment? • If the molecule was successful in every way, what medical value would it have in the market place over what already exists? • Which elements of the TPP would drive a positive reimbursement? • Need to think about Price & Reimbursement in terms of (Current Standard of Care / Future Standard of Care/ New Assets /Across regions (US/EU/EMAP) • Reimbursement levels may change depending on the sub-segment of patients that is targeted
Other	• What Diagnostic Tests / Biomarkers would be needed to define sub-population segment? • What technological trends are affecting the delivery of a an asset to this market eg Biopharmaceutical?
Key Considerations for a Minimum Acceptable Profile	• What are the absolute requirements for a minimum acceptable profile eg must have Clinical differentiator 1 – but 2 & 3 would not have success in their own right • Please consider the trade-offs between the attributes that may go to produce a minimum acceptable profile – may need to refer to attributes not mentioned as key value drivers