DRUG DEVELOPMENT TARGET PRODUCT PROFILE

Template

This template provides suggested considerations that may assist biopharmaceutical companies in their decisions as to whether to proceed with a drug development program (Program). This template is provided solely as a convenience aid, not as a decision-making tool. It does not necessarily include a comprehensive list of all of the information that may be useful to collect and evaluate in connection with any particular Program. In deciding whether to proceed with a Program, users of this template may find it necessary or beneficial to evaluate additional information not included in this template, exclude certain information included in this template, otherwise modify the approach suggested in this template and/or consult with others who are knowledgeable about their Program, as appropriate for the Program. This template is provided "as is" without any representations or warranties, express or implied.

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Asset Overview

Trademark: _____
Therapeutic Area: _____
Development Phase: _____

Generic Name: _____
Pharmacological/Chemical Class: _____

Project Code: _____
Order of Market Entry: _____
First Launch (MM/YY): _____

1. INDICATIONS AND USAGE

Target	Annotations
Comments	

2. DOSAGE AND ADMINISTRATION

Target	Annotations
Comments	

3. COMPARATOR PROFILE

Patent Life	
Date Approved:	
Date Generic Available:	
Indications	
Approved:	
In Development:	
Market Share (U.S.)	
Present:	
Future:	
Other Criteria	

4. TARGET BRAND POSITIONING:

Key Risk Decisions (examples)

- Early decisions on whether to proceed with a drug development program (go decisions) or to discontinue the program (no-go decisions) may be based on Phase I single agent or combination study data.
- The development strategy may be based on the need to pursue comparator trials.
- Reassessment of endpoint criteria for go/no-go decision may be required based on progress/status of competitors in development.

Indication(s) and Projected Launch Date:

_____

Target Population (Check all appropriate boxes):

Infants	Children	Adolescent	Adults	Elderly	Other _____	Men Only	Women Only
☐	☐	☐	☐	☐	☐ (Example: Special Populations)	☐	☐

5. ESSENTIAL TARGET PRODUCT PROFILE CLAIMS

Essential Messages/ Claims (Pharmacology, efficacy, safety or other)	Commercial Value of Additional Claims	Promotion or Publication Only	Study Design	Description/ Title	Essential Attributes for Registration	Competitor Data	Differential Competitive Advantages	Probability of Success/ Achievability
Phase I Efficacy								
		Promotion ☐ At Launch ☐ Post Launch **Publication** ☐ At Launch ☐ Post Launch	(Examples: Biomarker, Combo, Open Label, Basket, Adaptive)					**Claim is:** ☐ Achieved ☐ Not Achieved
Phase I Safety/ Tolerability								
		Promotion ☐ At Launch ☐ Post Launch **Publication** ☐ At Launch ☐ Post Launch	(Examples: SAD/MAD, DDI, PK, Food Effect, Special Populations)					**Claim is:** ☐ Achieved ☐ Not Achieved

5. ESSENTIAL TARGET PRODUCT PROFILE CLAIMS

Essential Messages/ Claims (Pharmacology, efficacy, safety or other)	Commercial Value of Additional Claims	Promotion or Publication Only	Study Design	Description/ Title	Essential Attributes for Registration	Competitor Data	Differential Competitive Advantages	Probability of Success/ Achievability
Phase II Efficacy								
		Promotion ☐ At Launch ☐ Post Launch **Publication** ☐ At Launch ☐ Post Launch	(Examples: Biomarker, Combo, Open Label, Basket, Adaptive)					**Claim is:** ☐ Achieved ☐ Not Achieved
Phase II Safety								
		Promotion ☐ At Launch ☐ Post Launch **Publication** ☐ At Launch ☐ Post Launch	(Examples: SAD/MAD, DDI, PK, Food Effect, Special Populations)					**Claim is:** ☐ Achieved ☐ Not Achieved
Phase III Efficacy								
		Promotion ☐ At Launch ☐ Post Launch **Publication** ☐ At Launch ☐ Post Launch	(Examples: Biomarker, Combo, Open Label, Basket, Adaptive)					**Claim is:** ☐ Achieved ☐ Not Achieved
Phase III Safety								
		Promotion ☐ At Launch ☐ Post Launch **Publication** ☐ At Launch ☐ Post Launch	(Examples: SAD/MAD, DDI, PK, Food Effect, Special Populations)					**Claim is:** ☐ Achieved ☐ Not Achieved

6. DEVELOPMENT DECISION POINTS BASED ON COMPARATORS

Endpoint	Comparator	Equivalence	Significant increase	Superior increase
Efficacy				
Safety				
Rapid Decision Point				

Go/No-go Decision Criteria:

- If there is **insufficient evidence** of increased efficacy vs comparator data (defined as meeting **none** of the significant activity thresholds for efficacy endpoint), this may indicate that a no-go decision is appropriate.
- In Phase I trials, if there is **some evidence of increased efficacy** vs. comparator data (defined as meeting or exceeding at least one significant activity threshold for one efficacy endpoint), proceeding with a controlled Phase II study may be appropriate. These results may be useful in deciding whether to begin Phase III studies.
- If there is **evidence of superior** efficacy vs. comparator historical information (defined as meeting all efficacy endpoints thresholds and at least one superior increase), it may be appropriate to accelerate development and begin Phase II-III controlled registration studies.
- If there is **some evidence of comparable or increased efficacy** vs. comparator data (defined as meeting or exceeding at least one significant activity threshold for one efficacy endpoint), and **superior safety or clinical benefit** it may be appropriate to begin a controlled Phase II study. These results may be useful in deciding whether to begin Phase III studies.

EXAMPLES OF SUGGESTED GO/NO-GO CRITERIA FOR EACH MILESTONE

Phase I

- Adequate safety and tolerability

Phase II Proof of Concept (PoC®)

- Efficacy threshold
- Comparable or better safety

Phase IIb

- Dose ranging

Comparable or better than adequate safety and efficacy

Phase III Registration Trials

- Efficacy
- Safety

Registration Decision Point (RDP)

- Totality of safety and efficacy data greater than or equal to standard of care

7. ADDITIONAL CLAIMS

Essential Messages/ Claims (Pharmacology, efficacy, safety or other)	Commercial Value of Additional Claims	Promotion or Publication Only	Study Design	Description/ Title	Essential Attributes for Registration	Competitor Data	Differential Competitive Advantages	Probability of Success/ Achievability
Japan Specific Claims								
		Promotion ☐ At Launch ☐ Post Launch **Publication** ☐ At Launch ☐ Post Launch	Incidence of Adverse Events (AEs) (Study Code To Be Determined)					**Existing data:** ☐ Increase Risk ☐ Decrease Risk ☐ Support Average Risk of Phase **Claim is:** ☐ Achieved ☐ Not Achieved
Safety / Tolerability								
Combination Therapy								
		Promotion ☐ At Launch ☐ Post Launch **Publication** ☐ At Launch ☐ Post Launch	Incidence of AEs Discontinuation Rate					**Existing data:** ☐ Increase Risk ☐ Decrease Risk ☐ Support Average Risk of Phase **Claim is:** ☐ Achieved ☐ Not Achieved

Essential Biomarker Claims						
Essential Messages/Claims (Pharmacology, efficacy, safety or other) (EU/USA)	Commercial Value of Additional Claims	**Promotion or Publication Only**	**Target Measures**	**Comparative Competitor Data/ Information**	**Differential Competitive Advantages**	**Probability of Success/ Achievability**
Life Cycle Management						
Pharmacology						
Other Profiling Messages/Claims (Pharmacology, efficacy, safety, convenience, pharmacoeconomics)	**Promotion or Publication Only**	**Target Measures**	**Comparative Competitor Data/ Information**	**Differential Competitive Advantages**	**Probability of Success/ Achievability**	

Dosage and Administration	
Pharmaceutical Form/Size:	
Colors:	
Route: oral/iv/sc/im administration	
Schedule/Duration: daily or weekly. Add food directive	

Unfavorable Profile Elements (e.g., teratogenicity, significant contraindications, inferiority data)

Special Technical Requirements (e.g., special packaging, delivery devices, required diagnostic tests, non-standard package sizes/configurations)
Shelf Life:
Primary and secondary packaging:

Special Marketing Requirements (e.g., need for co-promotion or co-marketing partner, or need to develop new market) • (Examples: Need to DIFFERENTIATE in a crowded market through distinct messaging) • (Examples: Health Economics dossier required to support premium pricing in the already difficult pricing/reimbursement/regulatory environment)

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