

Target Product Profile: Therapeutics Part 1

A Target Product Profile provides a structure for the scientific, technical, clinical, and market information that is required to achieve a desired commercial outcome. It provides all stakeholders with a clear vision of the product objectives and helps guide research and development decisions. It is a dynamic strategic document that should be reviewed throughout the development process.

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	<i>Description</i>	<i>Example</i>		
Product Description	Brief description and/or current product name	CTSI-001		
Mechanism of Action (MOA)	The mechanism by which the product produces an effect on a living organism.	Blocks the interaction between		
Clinical Pharmacology	Pharmacokinetic information, distribution and pathways for transformation.	<ul style="list-style-type: none"> Intravenous (IV) administration of CTSI-001 to subjects was well tolerated in the ascending single-dose (0.002-10 mg/kg) and multiple-dose (0.5-5 mg/kg) studies. The pharmacokinetic profile is roughly linear at doses above 2 mg/kg and the mean half-life is around 28 days. Safety and PK profiles from the subcutaneous tolerability study are expected to be comparable to that seen in IV studies and PK/PD profile in treatment population will be supportive of monthly dosing regimen. 		
Indication	Target disease or manifestation of a disease and/or population.	Moderate to severe patients inadequately controlled on inhaled corticosteroids (ICS)		
Primary Efficacy Endpoints	The most important clinical outcome measure. Ideally should be easy to interpret and sensitive to treatment differences.	Optimistic: >50% exacerbation rate reduction vs. inhaled corticosteroids	Target: 50% exacerbation rate reduction vs. inhaled corticosteroids	Minimal: 35% exacerbation rate reduction vs. inhaled corticosteroids
Secondary Efficacy Endpoints	Additional criteria that may be met during a clinical trial, but that are not required to obtain a successful positive clinical trial result	Optimistic: <ul style="list-style-type: none"> Four (4) months asthma control measured by Asthma Control Questionnaire (ACQ) 	Target: <ul style="list-style-type: none"> Three (3) months asthma control measured by ACQ 	Minimal: <ul style="list-style-type: none"> Two (2) months asthma control measured by ACQ