

Target Product Profile – Gram-positive – Therapeutic Product

Variable	Minimal Requirement	Ideal Requirement
Product Indication	Oral treatment for Gram-positive infections including community-acquired bacterial pneumonia (CABP), wound and skin infections	Oral (step-down) treatment for Gram-positive infections including CABP, wound and skin infections as well as confirmed Gram-positive hospital-acquired bacterial pneumonia (HABP), bloodstream infections (BSI)/endocarditis, diabetic-foot ulcers (DFU) and skeletal/bone infections
Organisms Covered / <i>in vitro</i> activity	<i>S. aureus</i> (MR/MS), <i>S. pneumoniae</i> , <i>S. agalactiae</i> , <i>S. pyogenes</i> , with additional coverage of fastidious Gram-negatives including <i>H. influenzae</i> and <i>M. catarrhalis</i>	<i>S. aureus</i> (MR/MS), <i>S. pneumoniae</i> , <i>S. agalactiae</i> , <i>S. pyogenes</i> , <i>Enterococcus</i> spp. including MDR isolates, , with additional coverage of fastidious Gram-negatives including <i>H. influenzae</i> and <i>M. catarrhalis</i>
Patient Population	Non-hospitalized CABP and/or outpatient wound/skin infections	Includes hospitalized patients with multiple indications where step down would be beneficial to maintain treatment in an out-patient setting
Treatment Duration	Up to 10 days	7-10 days for acute infections (longer if targeting DFU/skeletal and bone infections)
Delivery Mode	Oral	Oral (or oral/IV)
Dosage Form	Tablets/capsules/sachets	Tablets/capsules/sachets
Regimen	QD, BID, or TID dosing	QD or BID dosing
Efficacy	Non-inferior to SOC (including beta-lactams, fluoroquinolones, macrolides, vancomycin)	Demonstrated advantage over SOC
Risk/Side Effects	Comparable to current therapies with SOC, 3-5X therapeutic index, minimal evidence of DDIs	Comparable to current therapies with SOC, >5X therapeutic index, no evidence of DDIs
Cost	Equivalent to current treatment regimens in HIC	COGs that are compatible with launch in LMICs
Specific Population Claims	Contraindicated in patients with renal impairment	No renal adjusted dosing required
Overall Value Proposition: Safe, effective and affordable oral therapy against infections caused primarily by Gram-positive organisms, including antibiotic-resistant strains, that could prevent hospitalization for uncomplicated infections.		