Target Product Profile –Therapeutic Product (Gram-Negative Lower Respiratory Infections)

Variable	Minimal Requirement	Ideal Requirement
Product Indication	Treatment for hospital-acquired bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) and associated bacteremias.	Treatment for hospital-acquired bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) and associated bacteremias. Preferred expansion to treatment for hospitalized community-acquired pneumonia (hCABP).
Organisms Covered	**Product must target** antibiotic-susceptible and -resistant isolates of *Pseudomonas aeruginosa* (incl. MDR). Enterobacterales spp. (incl. MDR, CRE, and ESBL-producing) and *Acinetobacter baumannii* (incl. CRAB) are considered a bonus.	**Product must target** antibiotic-susceptible and -resistant isolates of **either** *Pseudomonas aeruginosa* (incl. MDR) **or** Enterobacterales spp. (incl. MDR, CRE, and ESBL-producing). If *P. aeruginosa* is not covered, then *K. pneumoniae* must be among the covered Enterobacterales. Preferred additional coverage: antibiotic-susceptible and -resistant isolates of: A. baumannii (incl. CRAB); *Streptococcus pneumoniae* (incl. penicillin non-susceptible); *Staphylococcus aureus* (incl. MRSA); *Haemophilus influenzae* (incl. ampicillin-resistant); *Moraxella catarrhalis*; *Legionella spp.; Mycoplasma pneumoniae; Chlamydophila pneumoniae.*
Patient Population	Adults in a healthcare setting for the treatment of a confirmed serious Gram-negative infection.	Adults and children (>1 yr) in a healthcare setting for the treatment of a confirmed serious Gram-negative infection, with the possibility of early discharge with a PO step-down treatment
Treatment Duration	10 – 14 days	5 – 10 days
Delivery Mode	IV	Oral and IV
Dosage Form	Solution or powder for reconstitution	Tablet, capsule (oral), solution or powder for reconstitution (IV)
Regimen	Up to 3 doses/day	Up to 3 doses/day for IV treatment, then up to 2 doses/day for oral treatment
Efficacy	Equal to the standard of care for all targeted indications	Greater than or equal to the standard of care for all targeted indications
Risk/Side Effects	Manageable drug interactions; clean safety profile; minimum safety margin 3X over effective dose	Manageable drug interactions; clean safety profile; minimum safety margin >5X over effective dose
Stability	At least 3-month solid state stability at 4 °C	At least 3-month solid state stability at 4 °C and 25 °C
Cost	Equivalent to current treatment regimens in HICs	COGs that are compatible with launch in LMICs
Specific Population Claims		
Overall Value Proposition: Effective IV, Oral, or IV/Oral antibiotic active against antibiotic-resistant Gram-negative pathogens enabling timely transition from hospital to outpatient setting		

Target Product Profile – Therapeutic Product (Urinary Tract Infections)

Variable	Minimal Requirement	Ideal Requirement
Product Indication	Treatment of acute UTI or complicated UTI, including pyelonephritis and associated bacteremia	Treatment of acute UTI or complicated UTI, including pyelonephritis and associated bacteremia
Organisms Covered	*E. coli* and *K. pneumoniae* (including MDR, CRE, and ESBL-producing isolates)	*E. coli, K. pneumoniae,* other Enterobacterales, and *P. aeruginosa* (including MDR, CRE, and ESBL-producing isolates)
Patient Population	Acute UTI in adult women or men with and without signs or symptoms of infection beyond the bladder	Acute UTI in adult women or men with and without signs or symptoms of infection beyond the bladder
Treatment Duration	Up to 5 days for acute UTI confined to the bladder, and up to 10 days for pyelonephritis and complicated UTI	Up to 5 days for acute UTI confined to the bladder, and up to 10 days for pyelonephritis and complicated UTI
Delivery Mode	Oral, or IV/oral	Oral, or IV/oral
Dosage Form	Tablet, capsule (oral), solution or powder for reconstitution (IV)	Tablet, capsule (oral), solution or powder for reconstitution (IV)
Regimen	Up to 3 doses/day for IV treatment, then up to 2 doses/day for oral treatment	Up to 3 doses/day for IV treatment, then up to 2 doses/day for oral treatment
Efficacy	Non-inferior to SOC (e.g., nitrofurantoin, pivmecillinam, fosfomycin, trimethoprim-sulfamethoxazole, quinolones, BL-BLI therapies, and cefiderocol)	Non-inferior to SOC (e.g., nitrofurantoin, pivmecillinam, fosfomycin, trimethoprim-sulfamethoxazole, quinolones, BL-BLI therapies, and cefiderocol)
Risk/Side Effects	Comparable to current therapies with β-lactams, no toxicity signals in preclinical reproduction toxicity studies; minimum safety margin 3X over effective dose	Comparable to current therapies with β-lactams, no toxicity signals in preclinical reproduction toxicity studies; minimum safety margin >5X over effective dose
Stability	Heat stable, 3-year shelf life	Heat stable, 3-year shelf life
Cost	Equivalent to current treatment regimens	Equivalent to current treatment regimens
Population Claims	Contraindicated in pregnant women, catheterized patients and patients with comorbidities	Safe in pregnant women, catheterized patients and patients with comorbidities
Overall Value Proposition: Safe, effective and affordable therapy against hard-to-treat, antibiotic-resistant UTI infections in HIC and LMICs		

Target Product Profile – Therapeutic Product (Diarrheal Diseases)

Variable	Minimal Requirement	Ideal Requirement
Product Indication	Treatment for diarrhea	Treatment for diarrhea
Organisms Covered	Antibiotic-susceptible and -resistant isolates of *Shigella* spp. and *Salmonella* spp.	Antibiotic-susceptible and -resistant isolates of *Shigella* spp. and *Salmonella* spp., plus coverage of *Campylobacter jejuni* and diarrhea-causing *Escherichia coli* pathovars (Enterotoxigenic *E. coli*, Enteropathogenic *E. coli*, Enteroinvasive *E. coli*, Enteroaggregative *E. coli*, and/or Shiga toxin-producing *E. coli*)
Patient Population	Children (>6 months) and immunocompetent adults suffering from diarrhea	Children (>1 month) and both immunocompetent and immunocompromised adults, including pregnant women, suffering from diarrhea
Treatment Duration	5-7 days	1-3 days
Delivery Mode	Oral, tablet/capsules	Oral, liquid formulation and parenteral where oral administration is not possible
Dosage Form	Tablet or capsule (oral)	Tablet or capsule and liquid formulation for children (oral). Another parenteral dosage form that can be used in cases where oral dosing may not be feasible.
Regimen	Up to 3 doses/day	Daily dose
Efficacy	Equal to the standard of care for resolution of symptoms (diarrhea, fever)	Superior to standard of care for resolution of symptoms (diarrhea, fever), including a lower relapse rate
Risk/Side Effects	Safety profile equivalent to standard of care in target populations with safety margin >3X over effective dose; manageable drug-drug interactions	Safety profile equivalent to standard of care treatment in target populations with safety margin >5X over effective dose; manageable drug-drug interactions
Stability	At least 6-month solid state stability in ICH Zone IVb (30 °C and 75% relative humidity environment)	At least 12-month solid state stability in ICH Zone IVb (30 °C and 75% relative humidity environment)
Cost	COGs that are compatible with launch in UMICs	COGs that are compatible with launch in LMICs/LDCs
Population Claims		
Overall Value Proposition: Effective oral or oral/parenteral antibiotic active against antibiotic-resistant and antibiotic-susceptible Gram-negative pathogens, enabling safe treatment of diarrhea in vulnerable populations		