



**FDA Public Workshop on
Development of Non-Traditional Therapies for Bacterial Infections**

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Antibacterial Human Monoclonal Antibodies Under Clinical Development for Acute Pneumonia

	AR-301	AR-105	AR-101
Target	<i>S. aureus</i> α -toxin	<i>P. aeruginosa</i> alginate	<i>P. aeruginosa</i> LPS
Mechanism of Action	Anti-toxin	Opsonization	Opsonization
Source of mAb	Human B-cell	Human B-cell	Human B-cell
Development Stage	Phase 3 ready	Phase 2 (on-going)	Phase 2/3 ready
Clinical Study Design	Adjunctive treatment to SOC Abx	Adjunctive treatment to SOC Abx	Adjunctive treatment to SOC Abx
Primary Endpoint	Superiority in Clinical Cure	Superiority in Clinical Cure	Superiority in Clinical Cure
Study Population	VAP (adults)	VAP (adults)	VAP (adults)
Clinical Data Readout	2020	1H 2019	2022

Development Challenges

- Study Design and Clinical Endpoints
 - Ventilator Associated Pneumonia (VAP)
 - Clinical Cure vs All Cause Mortality
 - Definition of Clinical Cure
- Safety Database
 - Larger than efficacy requirements
 - Limited patient population
 - Drug safety profile



Development Challenges

- CMC
 - Comparability
- Communication with FDA
 - Feedback and timing
 - Open dialog

