



# Innovative Therapeutics For Respiratory Health

Investor Presentation  
3Q-2022

# Forward Looking Statement



These forward-looking statements relate to future events or future financial performance of the Company. All such forward-looking statements involve risks and uncertainties and are not guaranties of future performance. An investment in the securities of Aridis is speculative in nature, involves a high degree of risk, and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment. These include many important factors that affect our ability to achieve our stated objectives including, but not limited to:

- \* The timing of regulatory submissions;
- \* Our ability to obtain and maintain regulatory approval of our existing product candidates and any other product candidates we may develop, and the labeling under any approval we may obtain;
- \* Approvals for clinical trials may be delayed or withheld by regulatory agencies;
- \* Pre-clinical and clinical studies will not be successful or confirm earlier results or meet expectations or meet regulatory requirements or meet performance thresholds for commercial success;
- \* The timing and costs of clinical trials, the timing and costs of other expenses;
- \* Our ability to obtain funding from third parties;
- \* Management and employee operations and execution risks;
- \* Loss of key personnel;
- \* Competition;
- \* Market acceptance of products;
- \* Intellectual property risks;
- \* Assumptions regarding the size of the available market, benefits of our products, product pricing, timing of product launches;
- \* The uncertainty of future financial results;
- \* Risks associated with this offering;
- \* Our ability to attract collaborators and partners;
- \* Our reliance on third party organizations.

We operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations.

We have filed a registration statement (including a prospectus) with the Securities and Exchange Commission ("SEC") for the offering to which this communication relates. Before you invest, you should read the prospectus in the registration statement and other documents we have filed with the SEC for more complete information about us and this offering. You may get these documents for free [by visiting EDGAR on the SEC web site at http://www.sec.gov](http://www.sec.gov). Alternatively, we, any underwriter, or any dealer participating in the offering will arrange to send you the prospectus if you request it from Cantor Fitzgerald & Co., Attention: Capital Markets, 499 Park Avenue, 6th Floor, New York, NY 10022; email: [prospectus@cantor.com](mailto:prospectus@cantor.com). This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

# Corporate Summary

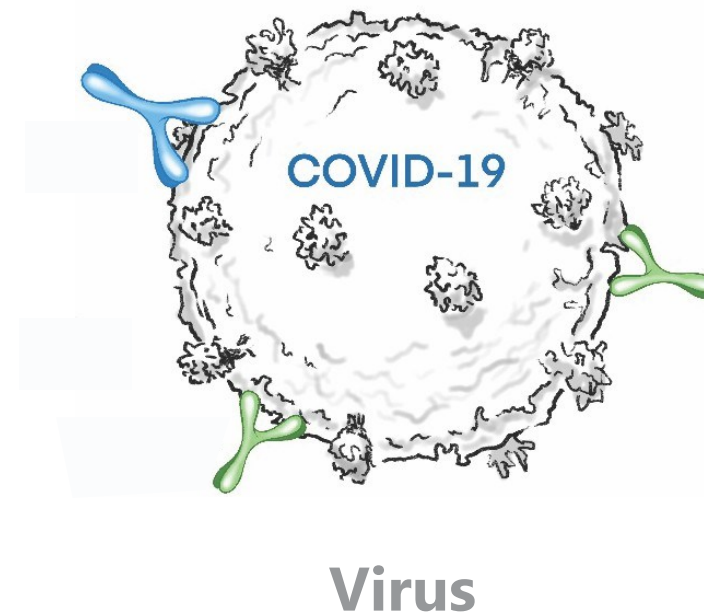
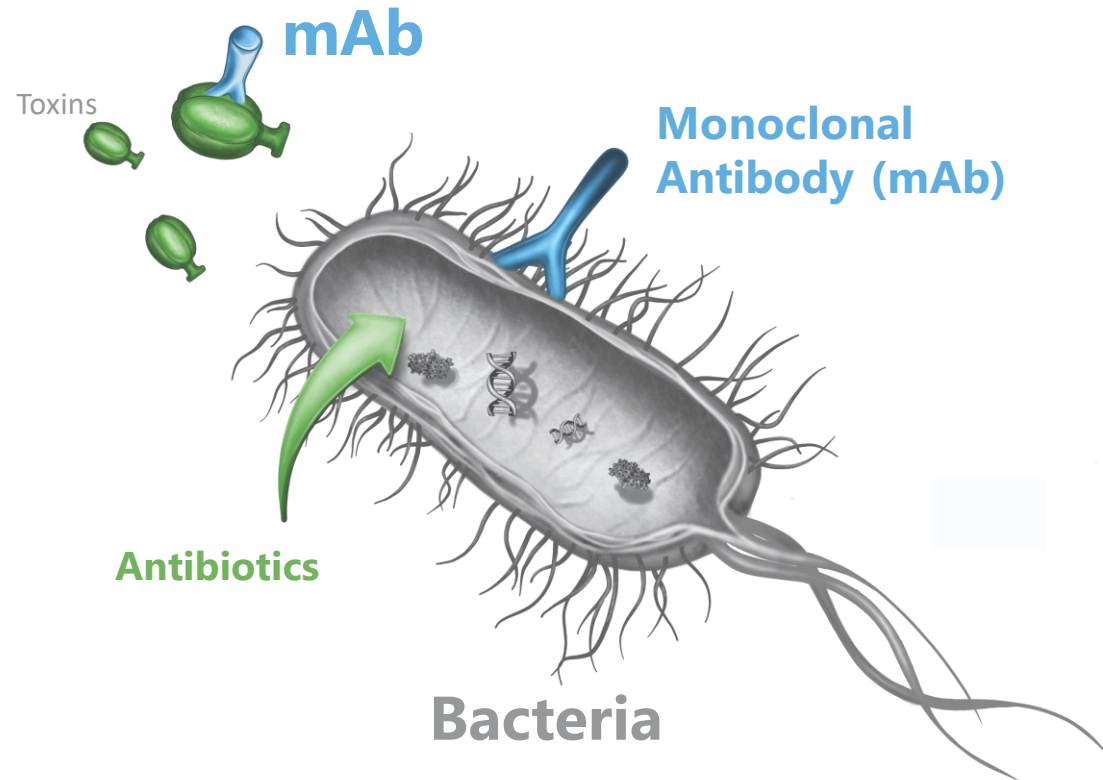
Late clinical stage company with two (2) Phase 3 assets

- First-in-Class & first-line treatment [AR-301] and prevention [AR-320] of acute pneumonia
- ~\$1 Billion market opportunities
- Strong Phase 2 clinical data in patients, supporting safety & efficacy

Clinical data readouts in AR-501 & AR-301 in 2H2022

Seasoned management team






# Employing Human Monoclonal Antibody for Infections



**Benefits of mAbs: Targeted, Durability of action, Predictable safety**

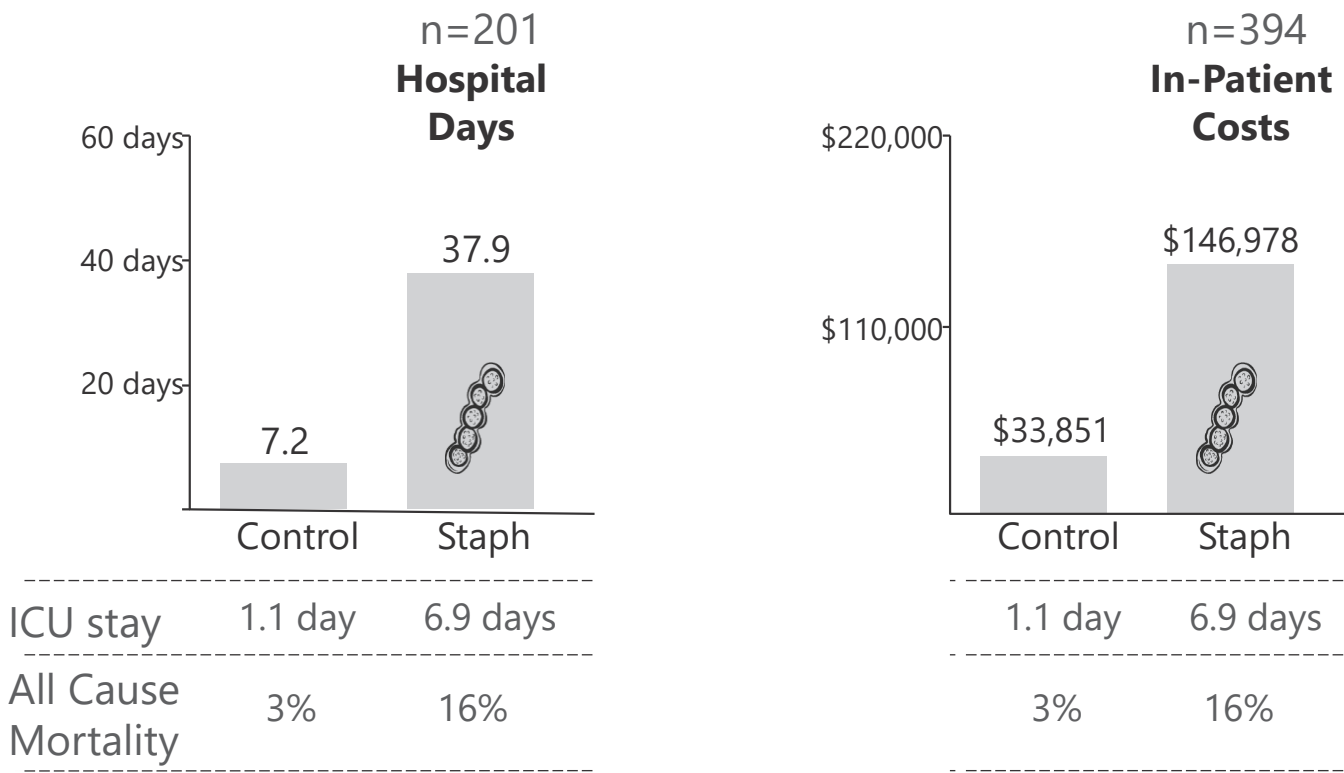
# Product Pipeline



Products	Targets	Pre-Clinical	IND	Phase 1	Phase 2	Phase 3	Next Milestone
AR-301 mAb (tosotoxumab)	Gram (+) Bacteria <i>S. aureus</i> $\alpha$ -toxin 	Pneumonia Treatment					Phase 3 data 2H2022
AR-320 mAb (suvratoxumab)	Gram (+) Bacteria <i>S. aureus</i> $\alpha$ -toxin 	Pneumonia Prevention					Phase 3 Interim Futility 2H23
AR-501 (Panaecin)	Gram (-) & (+) Iron Pathways 	Cystic Fibrosis					Phase 2a data 2H2022
AR-701 mAb	COVID-19 Virus Spike Protein 	COVID-19					Phase 1 1H2023
AR-401 mAb	Gram (-) Bacteria <i>A. baumannii</i> 	Bacteremia					tbd

# Healthcare Burden of *S. aureus* Bacterial Infections

~252,000 ICU patients  
US claims database (2018)\*



## Survey of 30 cases (median)

Hospital	44.4%
Pharmacy	21.0%
Laboratory	16.3%
Respiratory Treatment (Mech. ventilation)	9.3%
Radiology (+CT Scans)	3.3%
Cardiology	1.9%
Operating Room	1.4%
Diagnostics (Blood ECG)	1.9%
Pulmonary Diagnostic	0.4%
Orthopeadic	0.3%

Restrepo (2010) ICHE 31:509-515

\*Kyaw MH et al., 2015 BMC Health Serv Res. 15:241

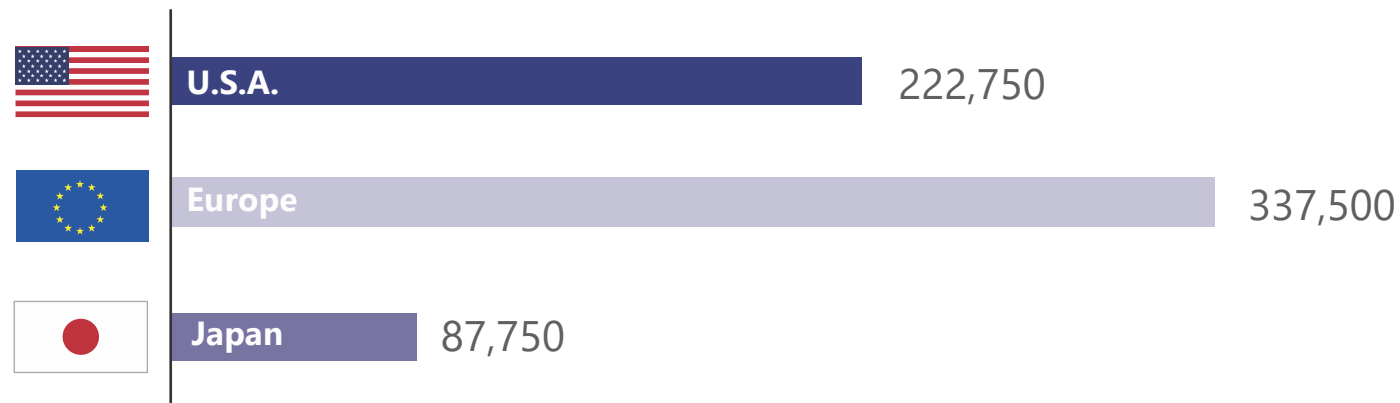
# \$6 Billion Market for *S. aureus* HAP/VAP

Estimated \$6 billion annual healthcare cost burden attributable to *S. aureus* nosocomial pneumonia<sup>3</sup>

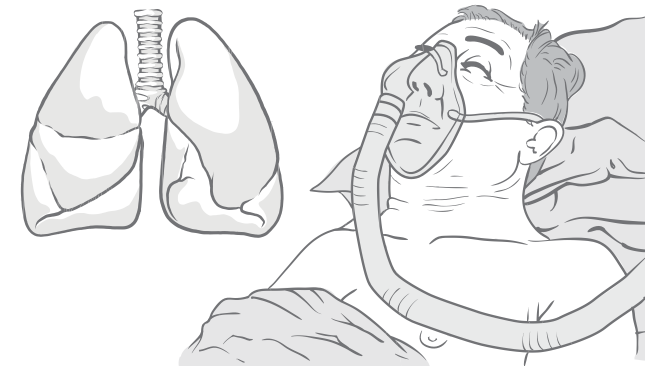
**AR-301 adressable patient population: 648,000<sup>1</sup>**



**Potential *S. aureus* HAP/VAP Patients by Market<sup>1</sup>**



**AR-320 adressable patient popl'n ~1.8 million<sup>2</sup>**



## \*Sources

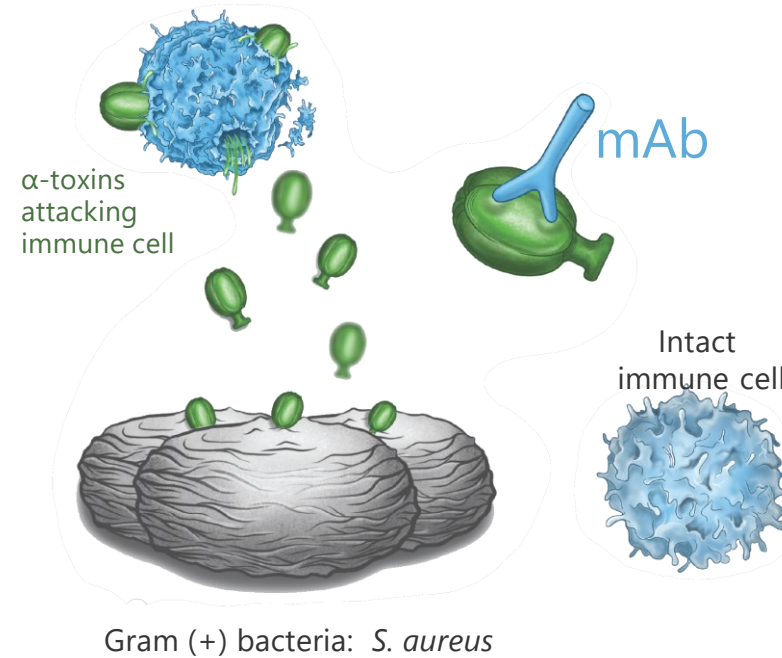
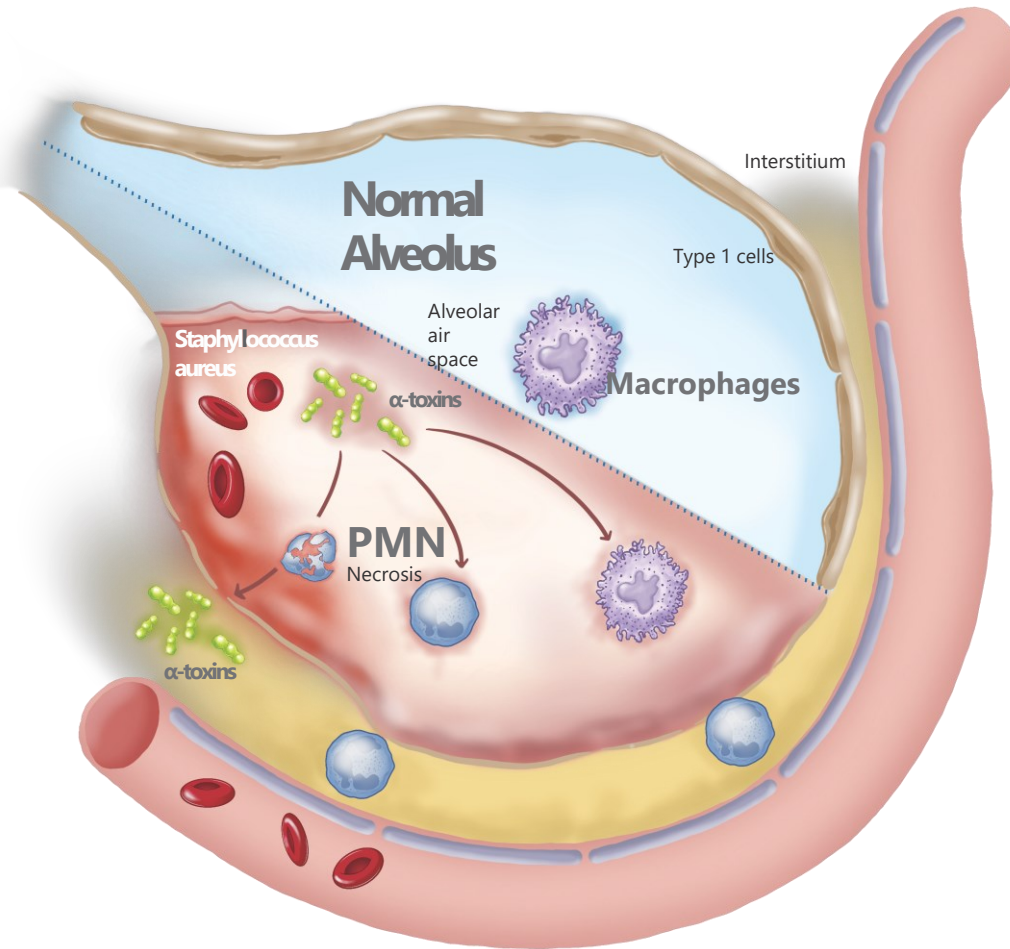
- 1 Paling FP, BMC Infect Dis. 2017;17(1):643
- 2 Francois, B. et al. Lancet Inf. Dis. 2021; [https://doi.org/10.1016/S1473-3099\(20\)30995-6](https://doi.org/10.1016/S1473-3099(20)30995-6)
- 3 Warren DK, Outcome and Attributable Cost of VAP among ICU patients in a suburban medical center, Critical Care Med 2003;31(5):1312-7.

Lifecycle opportunities include surgical site, skin/skin structure, UTI, and BSI infections due to *S. aureus*

# AR-301 & AR-320

## Mechanism of Action:

### Targets *S. aureus* $\alpha$ -Toxin



Anti-toxin monoclonal antibody approach is a proven MOA, e.g.

Commercialized:

C. Difficile mAb Bezotoxumab (MRK)  
Anthrax mAb Raxibacumab (GSK-EBSI)

## Host cells killed by $\alpha$ -toxins\*

Red blood cells	T-cells
Neutrophils	Pneumonocytes
Macrophages, Monocytes	Endothelial cells

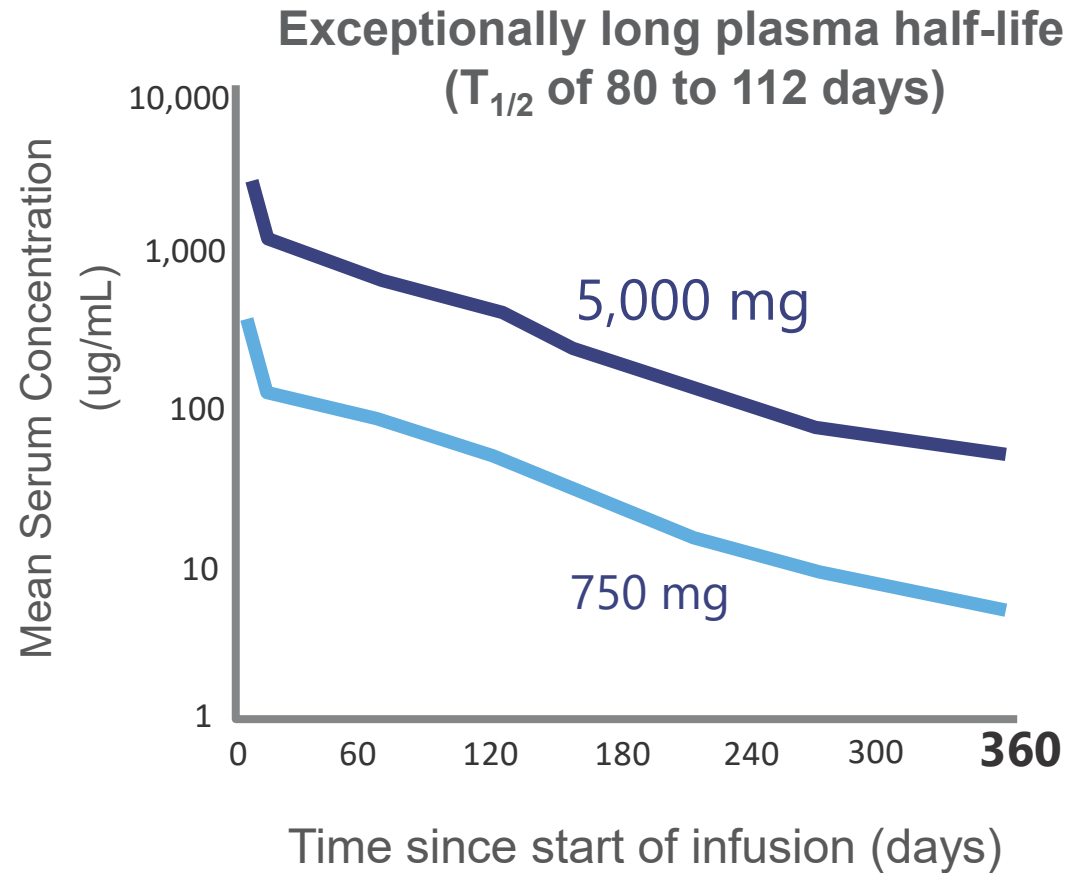
\*Toxins 2013, 5(6), 1140-1166



# **AR-320 (suvratoxumab)**

***Prevention of acute pneumonia in *S. aureus* colonized,  
mechanically ventilated ICU patients***

# AR-320: Favorable Phase 1 & 2 PK and Safety Data



## Phase 1 Healthy Adults (n=36)

Few adverse events (AEs) deemed related to AR-320

Suvratoxumab demonstrated a favorable safety

Half-life extension resulted in exceptionally long exposure, up to one (1) year post-dose

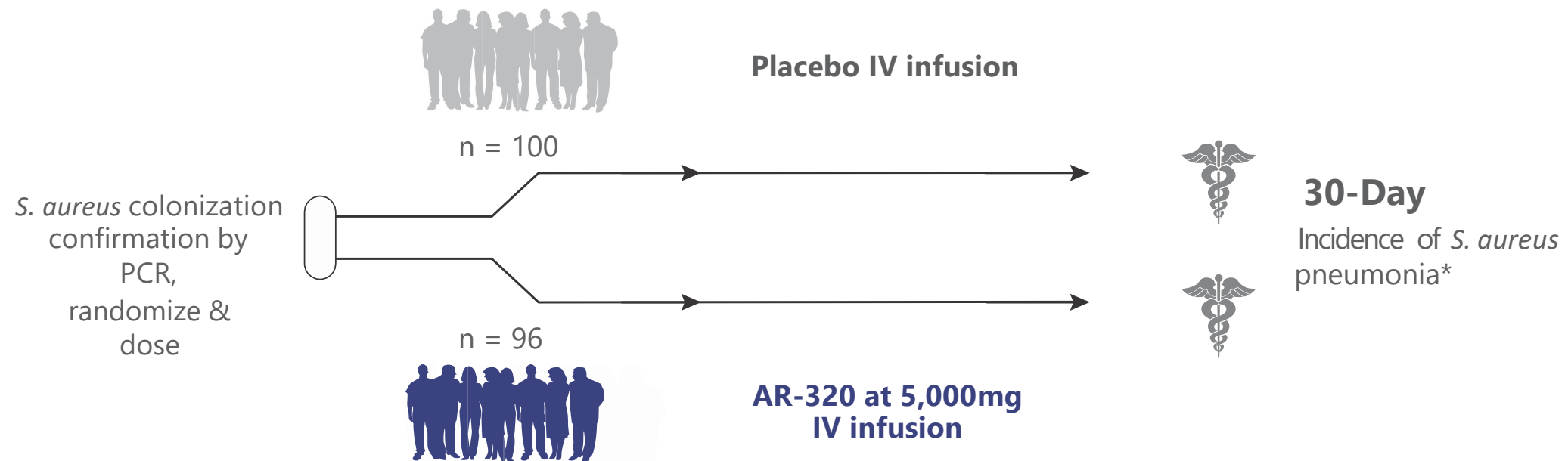
## Phase 2 ICU *S. aureus* Colonized Patients (n=196)

Adverse events (AEs), SAEs, deaths were balanced between Placebo and AR-320

Suvratoxumab demonstrated a favorable safety, PK, and ADA profile

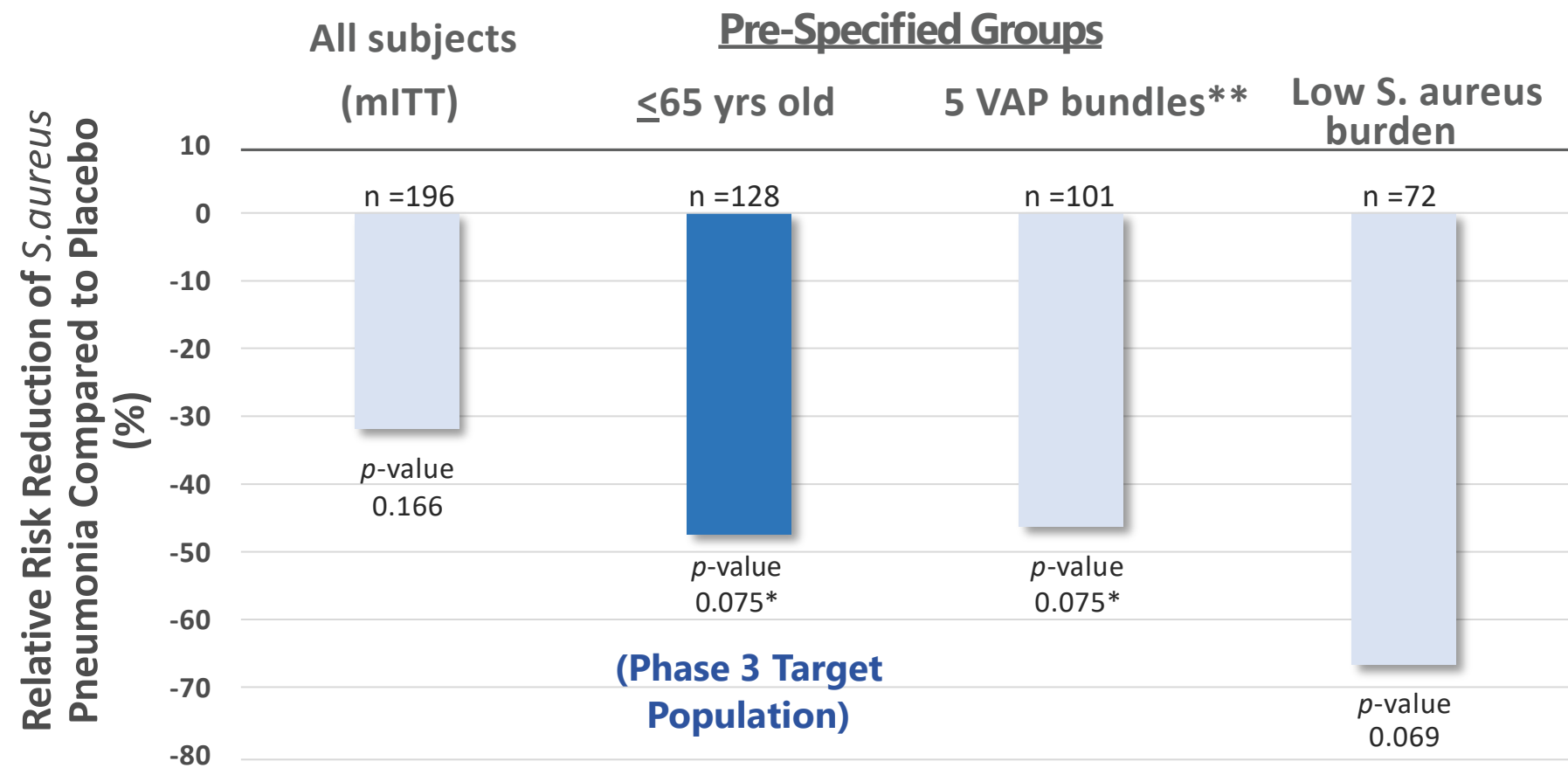
# AR-320: Phase 2 'SAATELLITE' Study Completed

- Randomized, double blinded, placebo-controlled Phase 2 study in 50 EU & US clinical sites  
(conducted by AstraZeneca & EU IMI's COMBACTE Consortium)
- Patient population: Intubated ICU patients colonized with *S. aureus* bacteria but did not yet have pneumonia
- Primary endpoint: Incidence of *S. aureus* pneumonia\* within 30 days post-IV dose (FDA & EMA-negotiated endpoint)



\*Adjudicated by panel of VAP experts & radiologists who are blinded to the treatment assignment

# AR-320 Phase 2: Attained Statistical Significance ( ≤ 65yrs old)



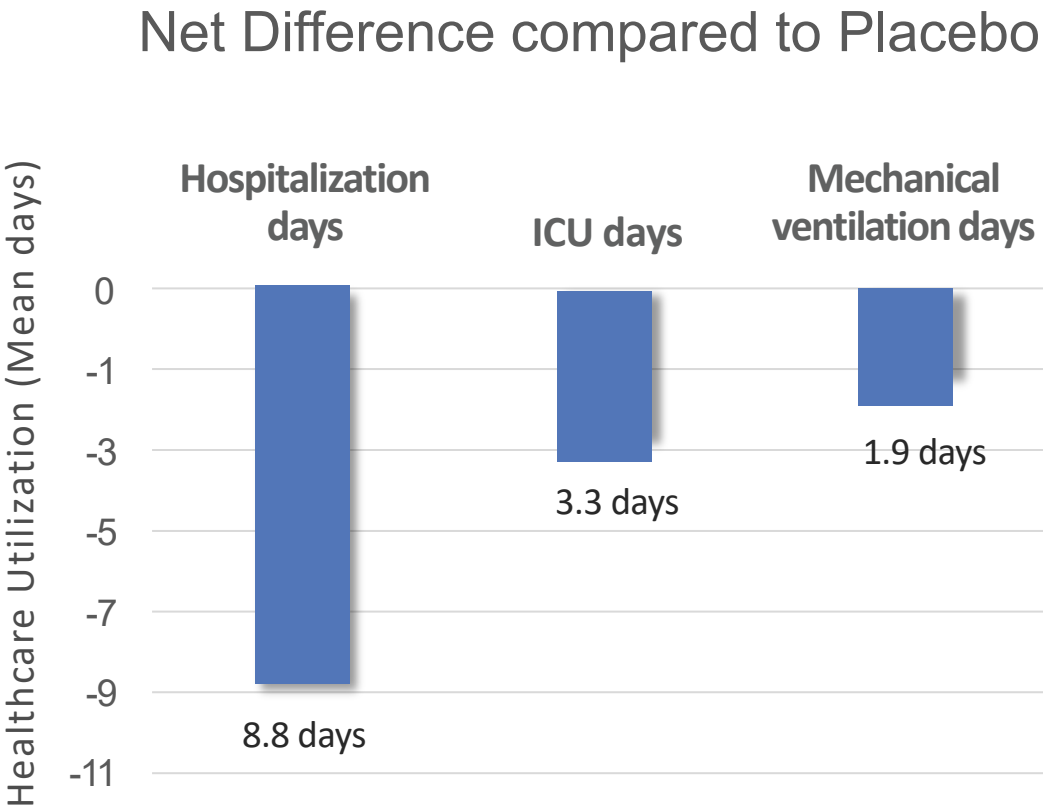
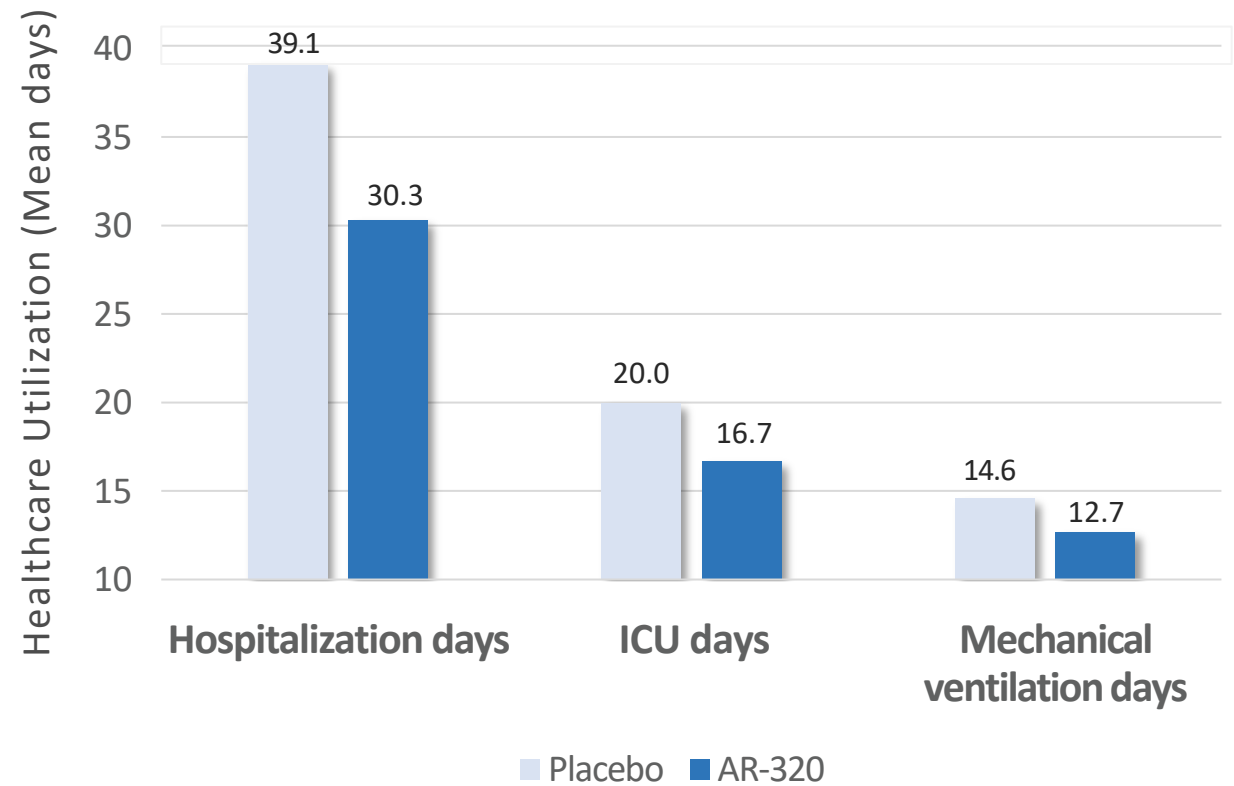
\*p-value < 0.10 is statistically significant per agreement with FDA & EMA, and allowed per FDA Guidance for VAP indication (see FDA Guidance for HAP/VAP, 2013)

\*\*5 VAP Bundles is a clinical outcome improvement assessment (elevation of the head of the bed, daily 'sedation vacation' & daily assessment of readiness to extubate, etc.)

See Francois, B. et al. 2021 Lancet Infectious Diseases

'mITT' is microbiological confirmed intend to treat population

# AR-320 Phase 2: Pharmacoeconomic outcomes for the Phase 3 target population ( $\leq 65$ yrs old)



# AR-320 Phase 3 'SAATELLITE-2' Trial Design

1-to-1 randomized, double-blind, placebo-controlled, single dose IV

Targeting 564 patients (12 to 65yrs old) colonized w/*S. aureus* (no VAP) across 200 sites in ~20 countries (U.S., EU, Asia)

S.a. colonization confirmation by PCR, randomize & dose

Evaluating the potential of AR-320 (5,000 mg) to prevent *S. aureus* pneumonia vs. placebo

Single confirmatory Phase 3 prior to BLA

Interim futility analysis in 2H2023 and final data readout in 1H2025



n = 282

Placebo buffer  
IV  
infusion

n = 282



**AR-320 at  
5,000mg  
IV  
infusion**



**30-Day**  
Incidence of all-cause pneumonia\*



\*n=564 translates to ~99% power to achieve  $p < 0.05$  for the primary endpoint of All-cause Pneumonia. For secondary endpoint of All-cause Pneumonia or Death, 564 translates to a power of 90%

# **AR-301 (tosatoxumab)**

***Treatment of *S. aureus* ventilator associated pneumonia***

# AR-301: Therapeutic Treatment of Acute Pneumonia

## Superiority Trial Design

Antibiotics alone



Standard  
of Care

**VS.**

Adjunct therapy



Standard  
of Care

+



**AR-301**

Allows for clear demonstration of differentiation & benefits

Provides necessary rationale for adoption as first-line treatment

With positive data, provides for value-based premium reimbursement



# AR-301 Phase 2a: Trial Recently Completed

Design

Randomized, double-blind, placebo-controlled, single ascending dose of AR-301  
31 sites across EU and U.S.

Patient Selection

48 patients with HAP or VAP caused by S. aureus

Groups

SOC [antibiotics alone] + Placebo

n=16

SOC + AR-301 (1 mg/kg )

n= 6

SOC + AR-301 (3 mg/kg)

n= 8

SOC + AR-301 (10 mg/kg)

n=10

SOC + AR-301 (20 mg/kg)

n= 8

Primary Endpoint

✓ Safety and pharmacokinetics

Secondary Endpoint

✓ Time to removal of ventilator (VAP patients)

✓ Microbiological cure

✓ Shorter time to eradication

✓ Days in ICU

✓ Hospitalization days

All-cause mortality

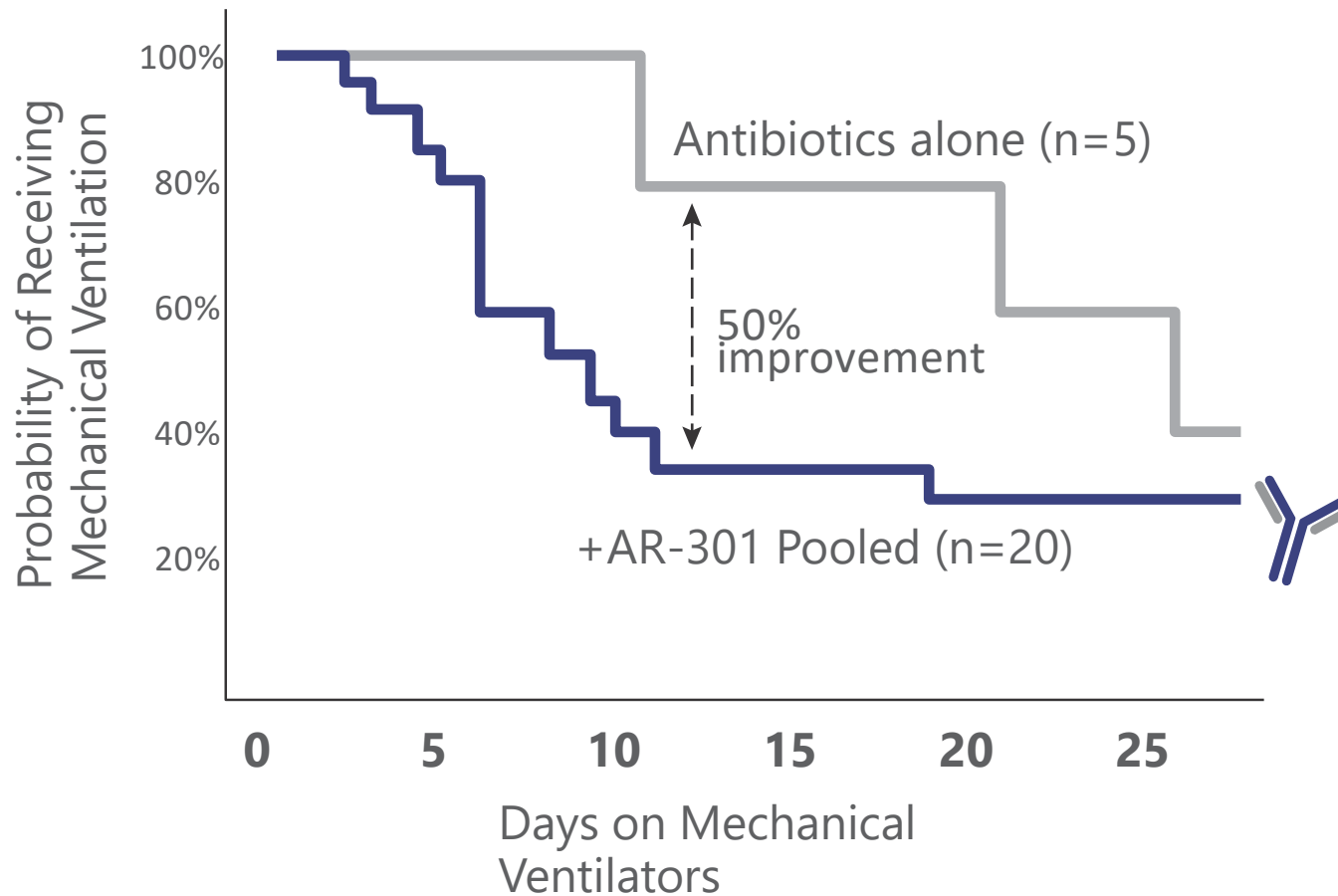
Clinical cure rate

✓ Data trend in favor of adjunctive treatment benefit

B. et al. 2018 Intensive Care Medicine

Francois, B. et al. 2018 Intensive Care Medicine

# AR-301 Phase 2 Efficacy: Time on Mech. Ventilation



## Phase 2

Aggregated AR-301 treated VAP groups exhibited lower probability of requiring mechanical ventilation vs. placebo.

# AR-301 Phase 3 (on-going): Trial Design

1-to-1 randomized, double-blind, placebo-controlled, single dose I.V.

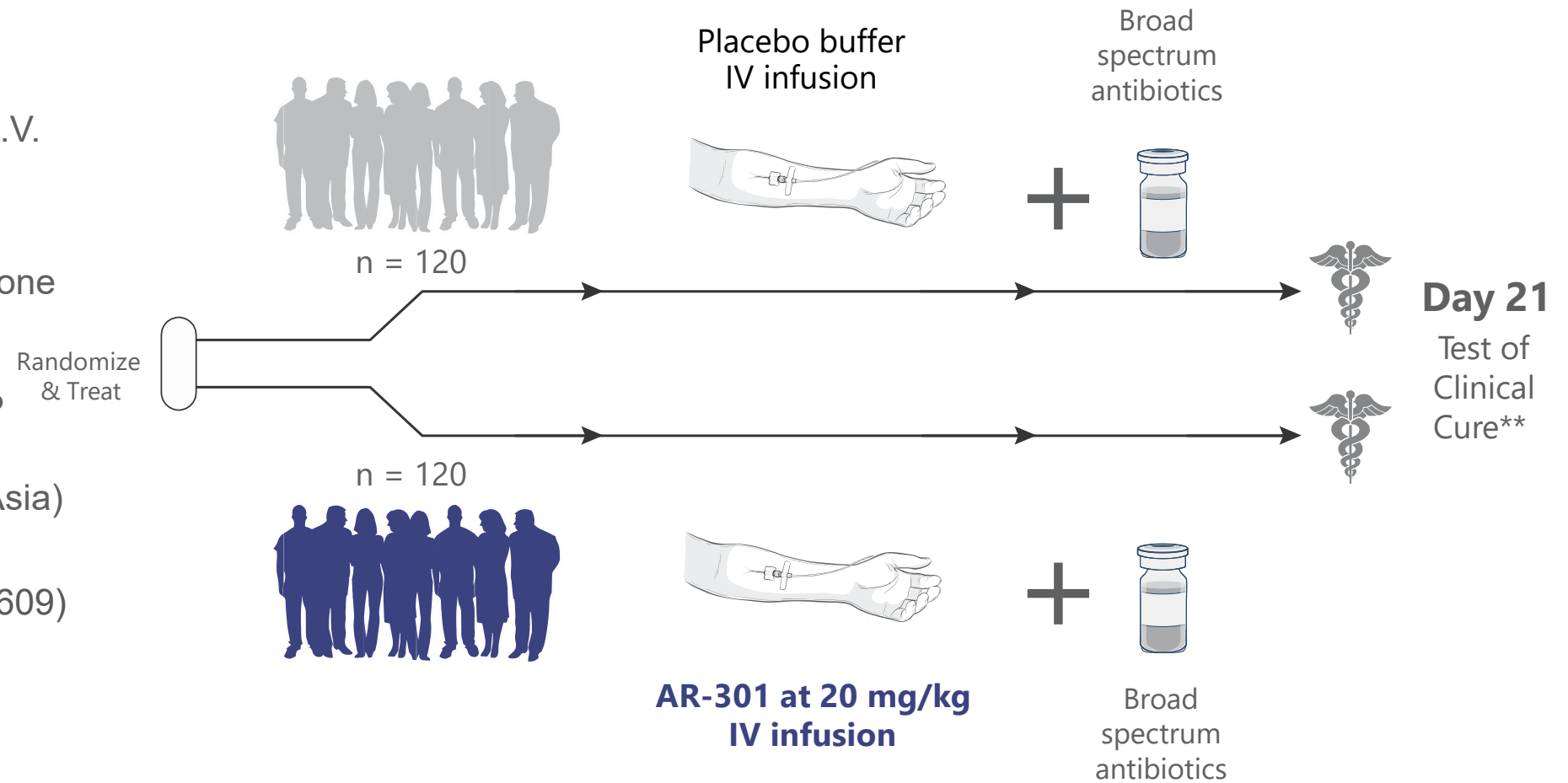
Evaluating the potential of adjunctive AR-301 (20 mg/kg) to SOC antibiotics vs. antibiotics alone

Targeting 240\* patients with VAP caused by *S. aureus* across 125 sites in 20 countries (U.S., EU, Asia)

(ClinicalTrials.gov ID NCT03027609)

Primary endpoint of clinical cure rate at day 21

Top-line data expected 2H2022



\*\*Sample size at 90% power ( $p < 0.05$ ) [20% absolute effect size]:  $n = 138$

\*Dependent on extent of COVID-19 related ICU utilization

# AR-301 Phase 3: Powering Calculation and Assumptions

## Primary Endpoint: Clinical Cure Rate

Study Power (p<0.05)	Control (SOC)	AR-301 + SOC	Absolute Difference	mITT per group	Total Enrolled
80%	75%	95%	20%	n = 55	n = 110
90%	75%	95%	20%	n = 69	n = 138

Phase 3 enrollment target = 240 patients\*  
 (i.e. over-powered versus n=138 patients to achieve superiority in primary endpoint)

\*Dependent on extent of COVID-19 related ICU utilization  
 'mITT' is microbiologically confirmed intent to treat population

# Covering Prevention and Treatment of *S.a.* HAP/VAP

## AR-320

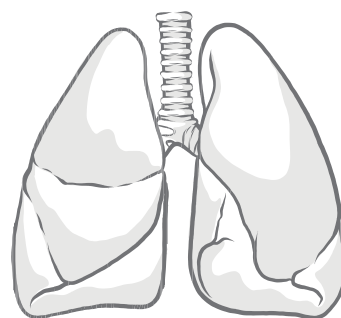
Suvratoxumab  
Prevention

Lung colonized, high risk but  
does not yet have VAP

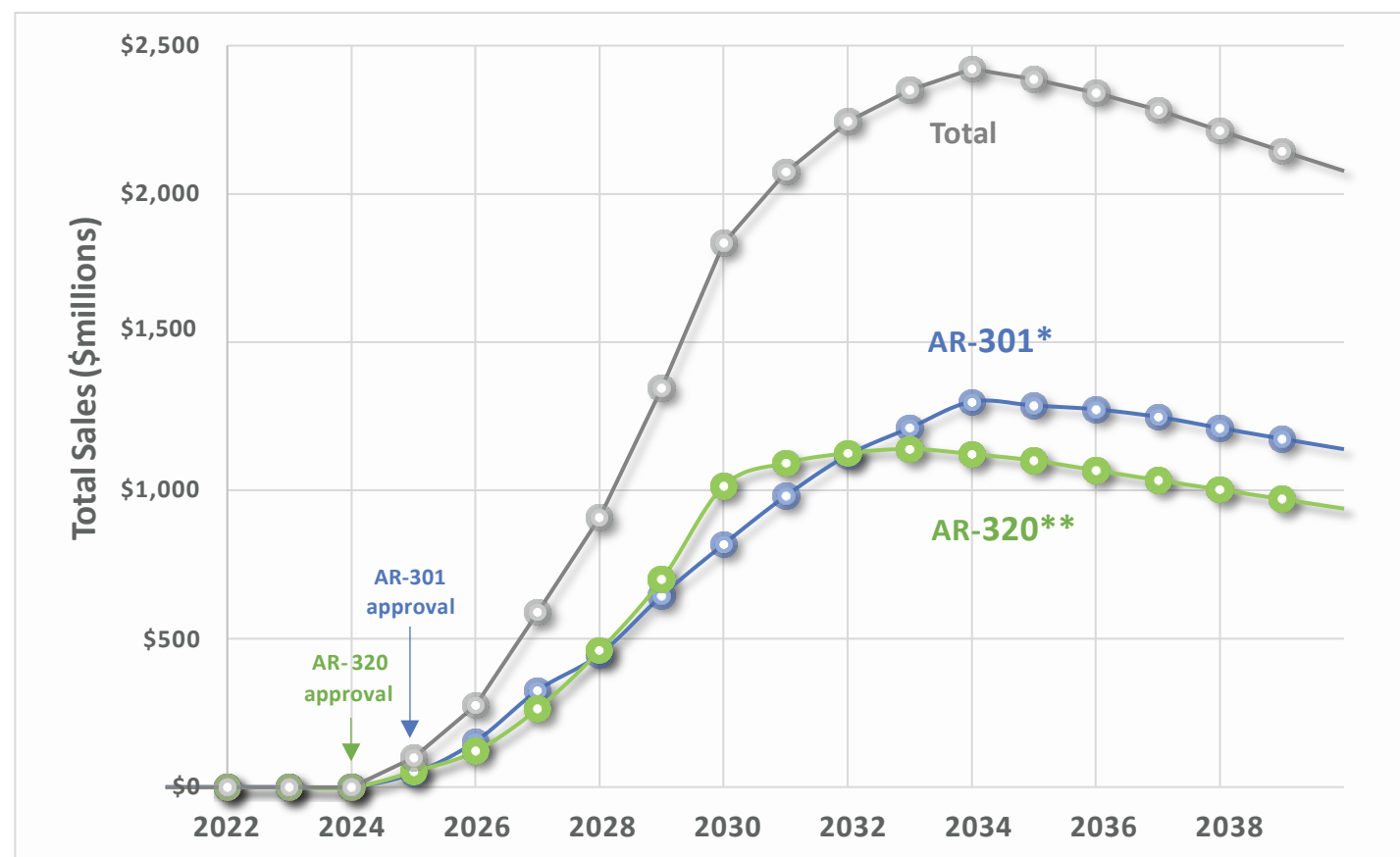
## AR-301

Tosatoxumab  
Treatment

Confirmed infection  
ventilator-assoc. pneumonia



Projecting \$1Bn+ market opportunity for each candidate



\*Assumptions: MRSA-only VAP, 60% adoption rate due to first-line, \$10,000 per regimen

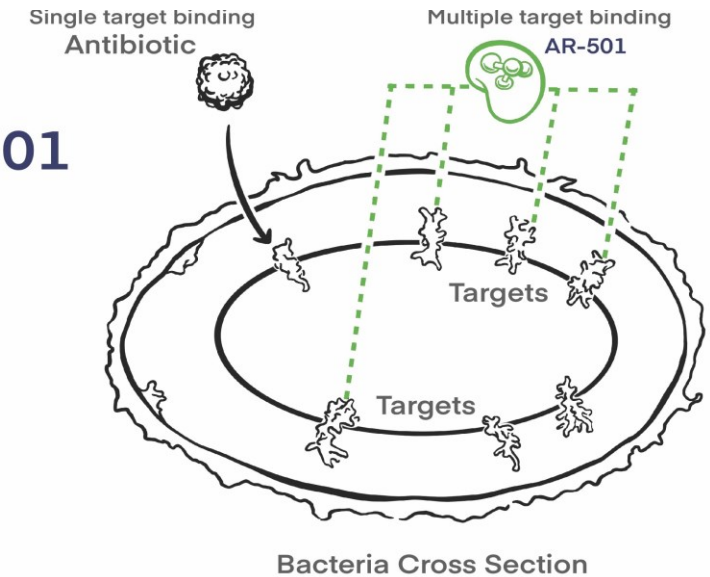
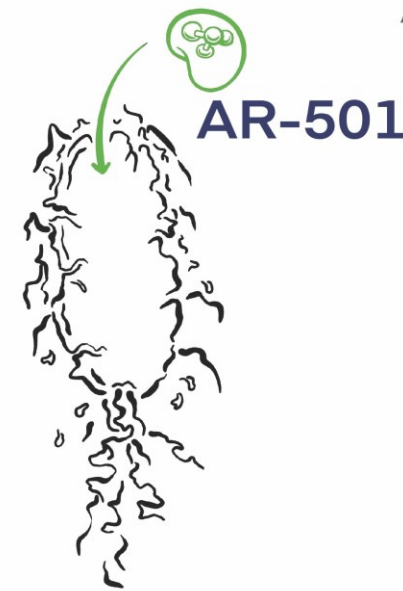
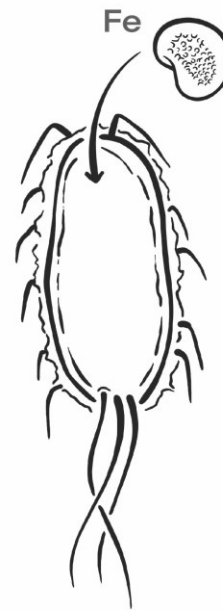
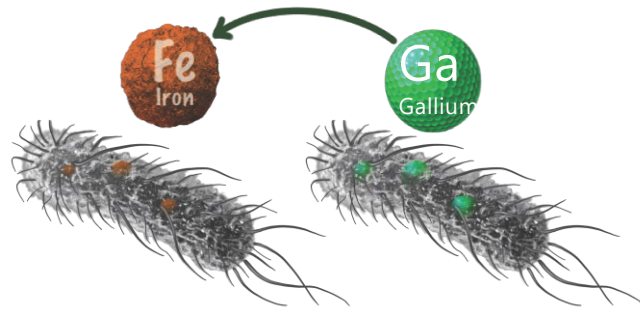
\*\*S. aureus colonized, intubated, without VAP symptoms, \$5,000 per regimen, 15% adoption rate

# AR-501: Novel Inhaled Non-Antibiotic

## Small Molecule Anti-infective

### Mechanism of Action

Iron (Fe) is necessary for bacterial metabolic functions. AR-501 (gallium, Ga) replaces Fe



AR-501 impairs multiple bacterial functions,  
while standard antibiotics inhibit single targets

# AR-501 Phase 1/2: Healthy & Cystic Fibrosis Patients

CF Foundation Funded

## Phase 1 Healthy Volunteers

Single Ascending Dose  **Done**

6 mg → 20 mg → 40 mg

18 patients  
**AR-501**

6 patients  
Placebo

Multiple Ascending Doses  **Done**

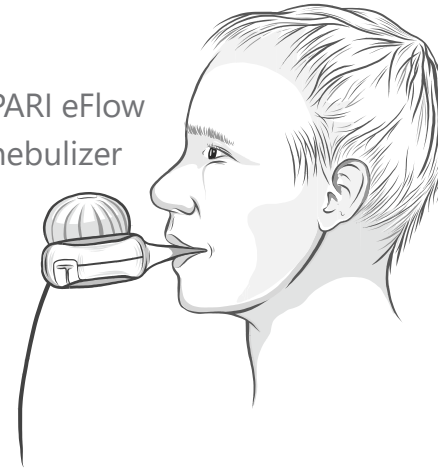
t = 0, 1, 2, 3, 4 weeks

6 mg → 20 mg → 40 mg

18 patients  
**AR-501**

6 patients  
Placebo

PARI eFlow  
nebulizer



**Primary Endpoint:**  
Safety and PK

**Secondary Endpoints:**

Lung function of CF patients (changes in FEV1)

Sputum bacteriology

## Phase 2 Cystic Fibrosis Patients (on-going)

Multiple Ascending Doses

t = 0, 1, 2 weeks

6 mg → 20 mg → 40 mg

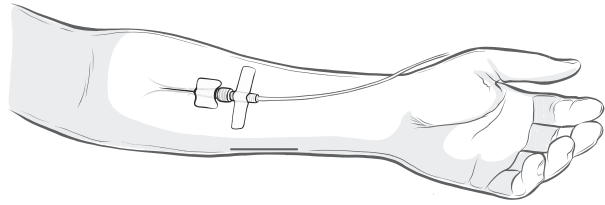
30 patients  
**AR-501**

15 patients  
Placebo

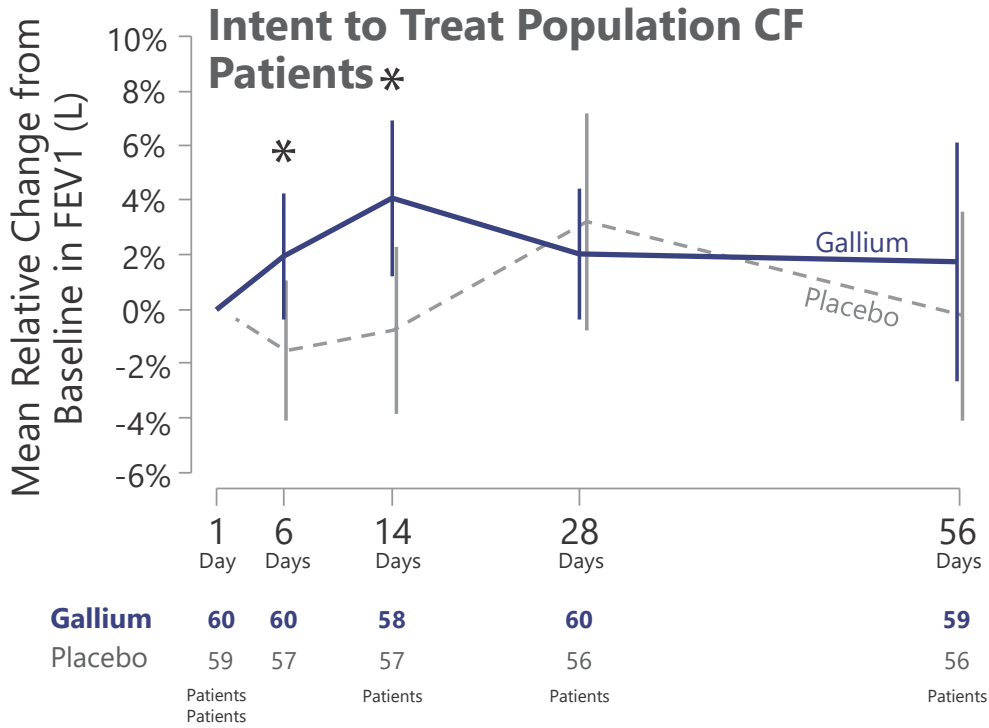
**Ph1 study results: AR-501 was well tolerated**

**Ph2a data readout: 2HQ22**

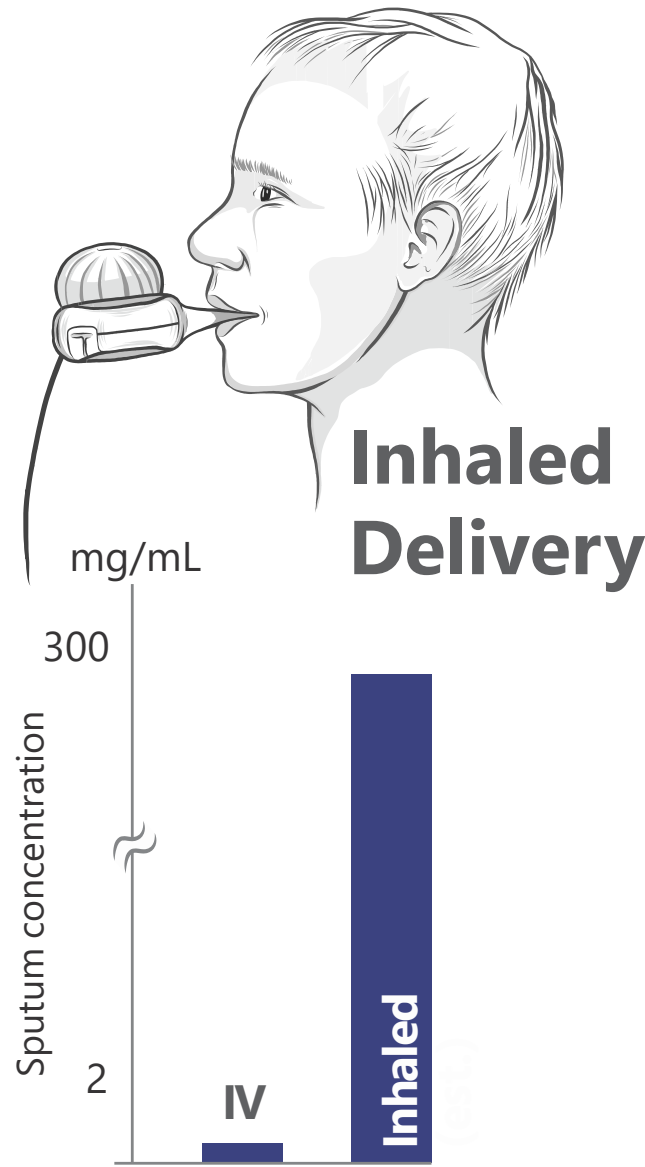
A single IV dose of gallium resulted in statistical significant improvement in lung infection



# Proxy Data: Safety & Efficacy of IV Gallium Demonstrated



Data from University of Washington: Goss, C. et al.  
2018 N. Am. Cystic Fibrosis Conference Abstract #307

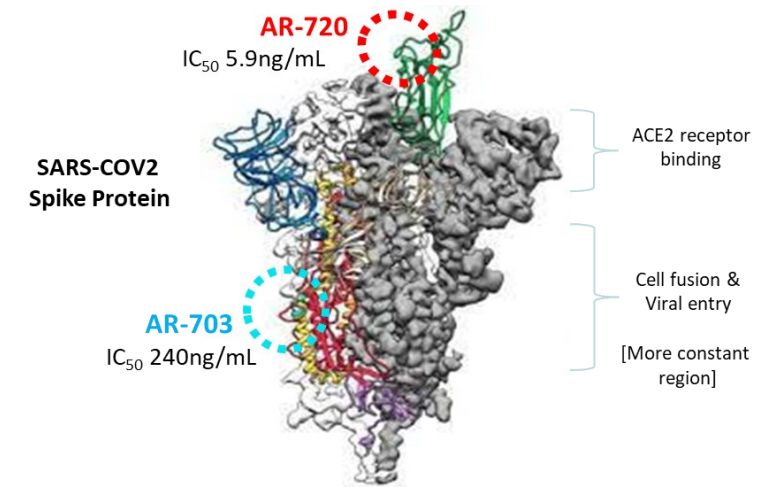


(\*estimate based on animal PK data)



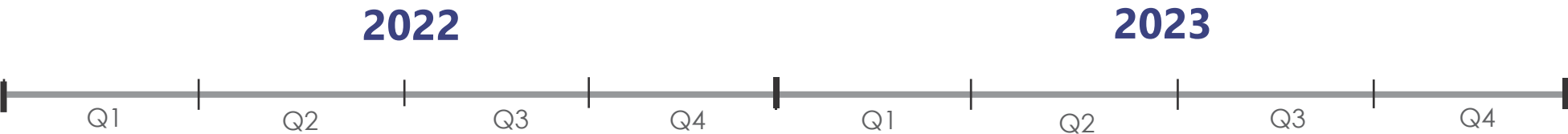
# AR-701: COVID-19 mAb Cocktail for I.M. & Inhalation

- Broad, pan-coronavirus cocktail utilizing dual mechanism of action
  - Effective against Omicron, more future-proof against SARS-COV2 variants
  - Effective against SARS, MERS, seasonal human coronaviruses
- Efficacious in ACE2 mice, hamster, and non-human primate SARS-CoV-2 virus challenge models
- Intramuscular and Inhaled formulation options
- Long-acting, mAbs are half-life extended
- Targeting non-hospitalized COVID population with self-administered, at-home treatment
- Phase 1 initiation in 1H2023



Self-administered  
inhaled formulation  
option

# Key Milestones: Multiple clinical data readouts in 2022



**AR-301**  
Toxin Blocker

Phase 3  
Data

**AR-320**  
Toxin Blocker

Phase 3  
Initiation

**AR-501**  
Cystic Fibrosis

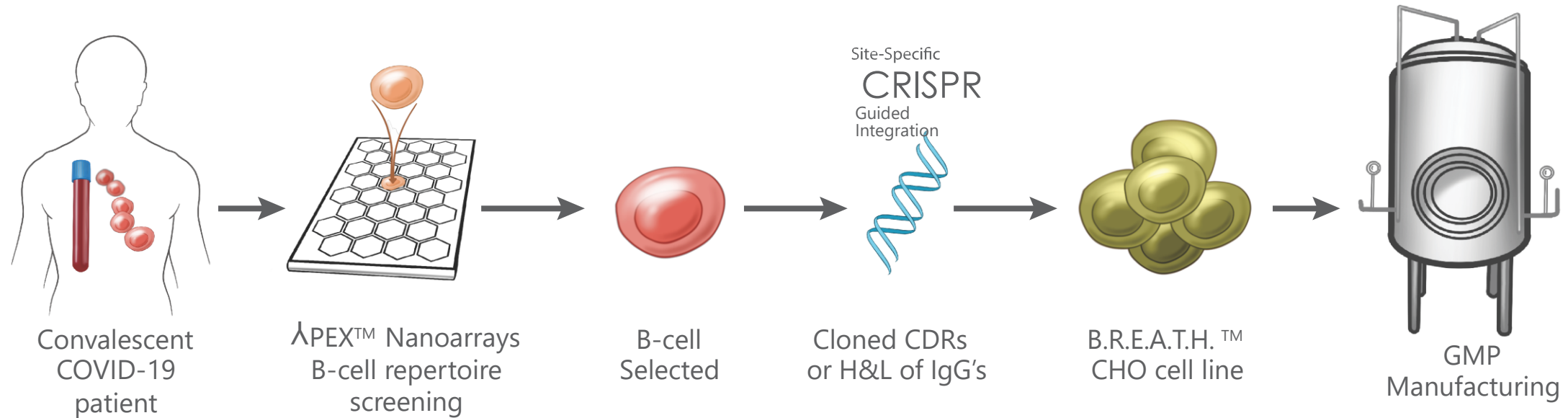
Phase 2a  
Data

Phase 2/3

**AR-701**  
COVID-19

Phase 1

# $\lambda$ PEX™ Monoclonal Antibody Discovery & Production Platform Technology



$\lambda$ PEX™

Discovery, Development, and Manuf.

12-15 months potential time saving

TRADITIONAL: Discovery, Development, and Manufacturing



Months

# Financial Information

As of 03/31/2021

▪ Cash & Cash Equivalents	\$12.5m
▪ Q4 Burn	\$ 5.7m
▪ Shares Authorized	100m
▪ Shares Outstanding	17,701,592

## Analyst Coverage

- HC Wainwright ( Vernon Bernadino)
- ROTH Capital (Jonathan Aschoff )
- Maxim Group (Jason MacCarthy)
- Northland Securities (Carl Byrnes)

# Senior Management

## **Vu Truong**

CEO, Director  
(Medimmune, Aviron)

## **Hasan Jafri**

Chief Medical Officer  
(AstraZeneca/Medimmune)

## **Fred Kurland**

Chief Financial Officer  
(XOMA, PDL, Aviron)

## **Franco Merckling**

SVP, Operations  
(Eli Lilly, Eisai, Merck)

## **Elizabeth Leininger**

VP, Regulatory & Quality  
(FDA, GSK, Chiron/Novartis)

## **Steve Chamow**

VP, Development  
(Genentech, Abgenix)

# Genentech



# AstraZeneca

The logo for Novartis, featuring a stylized orange and blue flame-like icon next to the word "NOVARTIS" in a blue, serif font.

# Board of Directors

## **Eric Patzer, Ph.D.**

Chairman  
(Co-Founder, Aridis)

## **Vu Truong, Ph.D.**

(CEO, Aridis)

## **Susan Windham-Bannister, Ph.D.**

(Assoc. Women in STEM, Mass. Life Sci. Ctr)

## **Robert Ruffolo, Ph.D., D.Sc.**

(Former President Wyeth/Pfizer)

## **Craig Gibbs, Ph.D., M.B.A.**

(Commercial Gilead; Genentech)

## **John Hamilton, M.B.A.**

(CFO, Depomed; BioMarin)



**Genentech**

