



# NEXT GENERATION RNA MEDICINES

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May 2026

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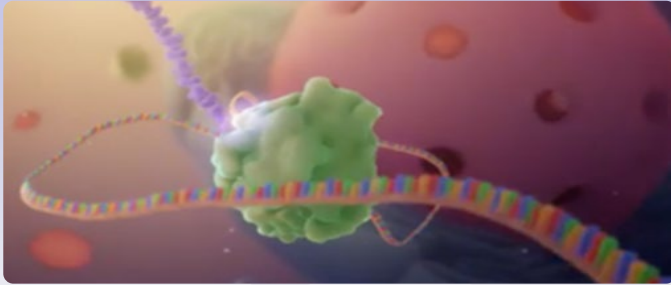
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# Arcturus Therapeutics



## STARR® mRNA Vaccines



### **KOSTAIVE®**

Approved in **Japan, UK, EU**

### **LUNAR-H5N1**

U.S. Pandemic Flu

### **PARTNERS**

**CSL meiji**



## Nasdaq: ARCT



**Headquarters:** San Diego, CA

**Employees:** 100

**Founded:** 2013

## mRNA Therapeutic Candidates



### **ARCT-810 (LUNAR-OTC)**

Ornithine Transcarbamylase Deficiency

### **ARCT-032 (LUNAR-CF)**

Cystic Fibrosis



# Proprietary mRNA Technologies Driving Therapeutic Programs

Broad Intellectual Property Portfolio



**500+**

Patents & Patent Applications



## mRNA Technology

- mRNA for protein replacement
- Self-amplifying mRNA technology (STARR®)



## LUNAR® Delivery

- Hepatocytes – **intravenous**
- Airway Cells – **inhaled**
- Myocytes – **intramuscular**





## Manufacturing Know-How

- Commercial end-to-end mRNA-LNP Manufacturing
- Scalable Process & Global Tech Transfer
- Proprietary Ionizable Lipid Design & Production
- Liquid and Lyophilized mRNA-LNP Drug Products

# Pipeline of Arcturus-Owned mRNA Therapeutic Candidates



Franchise	Candidate	Funded By	Indication	Global Prevalence	Upcoming Milestone
Respiratory	LUNAR <sup>®</sup> -CF (ARCT-032)	 CYSTIC FIBROSIS FOUNDATION <sup>®</sup>	Cystic Fibrosis	>100,000	12-Week Phase 2 Data Open Label Study <b>Ongoing</b>
Hepatic	LUNAR <sup>®</sup> -OTC (ARCT-810)	 ARCTURUS <sup>®</sup> therapeutics	Ornithine Transcarbamylase Deficiency (OTC)	>10,000	EOP2 Meeting <b>H2 2026</b>

**Each Arcturus-Owned Program Represents a Significant Commercial Opportunity**

# LUNAR-CF (ARCT-032)

Inhaled mRNA Therapeutic Candidate  
for Cystic Fibrosis

# ARCT-032 Background

- An inhaled mRNA therapeutic that can build new CFTR protein in the lung cells of individuals with CF is desired

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- Generally safe and well tolerated in Phase 2 studies after 28 daily treatments (up to 15 mg)

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- Arcturus initiated Phase 2 study in Q1 2026 enrolling up to ~20 people with CF over a period of 12 weeks

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- The Cystic Fibrosis Foundation has committed ~\$25 Million to ARCT-032

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- ARCT-032 received Rare Pediatric Disease Designation and Orphan Drug Designation from the U.S. FDA and Orphan Medicinal Product Designation from the European Commission (EC)



# Cystic Fibrosis

ARCT-032 Market Opportunity



## Cystic Fibrosis

- > **>100,000 worldwide prevalence**

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- > Caused by mutations in the CFTR gene, resulting in poor chloride transport and dehydrated, sticky mucus in the airways

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- > Chronic airway obstruction leads to infection and inflammation, which causes progressive airway damage and ultimately, respiratory failure



## Unmet Medical Need

- > Effective CFTR modulators are not approved for treatment of all people with CF

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- > Standard of care therapies do not prevent chronic, progressive loss of lung function that ultimately requires lung transplantation or leads to early death



## LUNAR-CF Aims to Restore CFTR Function

- > mRNA replacement therapy has the potential to produce wild-type CFTR in the lungs of CF patients, independent of genotype

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- > Functional CFTR protein can restore chloride efflux in the airways, reducing mucus accumulation and airway damage and minimizing the progressive respiratory impairment observed in people with CF

# Class I CF

ARCT-032 Initial Target Population



## Class I CF Patients

- > **~10,000 Class I CF patients globally**
- > Class I nonsense mutations result in no production of CFTR protein
- > **No treatment option available other than symptomatic care**
- > At risk of developing severe lung disease



## Unmet Medical Need

- > **Ineligibility for CFTR modulators is the greatest area of unmet need in CF**
- > Estimated 15% of people with Cystic Fibrosis are potential candidates for ARCT-032
- > 10% with ineligible Class I mutations
- > Up to 5% of patients with incomplete response or unacceptable side effects to CFTR modulators



## Potential Uptake

- > **Rapid adoption is expected** among people with CF who carry ineligible mutations or who are modulator intolerant due to the significant unmet need in this population
- > Those with incomplete response to CFTR modulators represent an important potential patient population

The ~10,000 Class I CF Patient Population Represents the Highest Unmet Need



# ARCT-032 Clinical Summary

## ➤ Phase 1 Study in Healthy Volunteers

- N = 32 across 4 ascending single-dose cohorts
- Safety, tolerability and PK data supported transition to Phase 1b study

## ➤ Phase 1b Study in Adults with Cystic Fibrosis

- N=7; Each CF participant received two administrations of ARCT-032
- Safety, tolerability and PK data supported transition to Phase 2 study

## ➤ Phase 2 Study in CF Participants who do not qualify for or benefit from CFTR modulator therapy

- Each participant received daily treatments of ARCT-032 over a period of 28 days
- Multiple ascending dose, open-label study
  - First cohort (N = 3; 5 mg) completed dosing
  - Second cohort (N = 6; 10 mg) completed dosing
  - Third cohort (N = 4; 15 mg) completed dosing
- Generally safe and well tolerated at all 3 dose levels (5mg, 10mg, 15mg)

## ➤ 12-Week Open Label Study Enrolling Up to 20 people with CF (U.S. and Abroad)

- Inhaled treatments of ARCT-032 over a period of 12 Weeks (starting dose = 10 mg)

**Objective:** Establish safety, tolerability, and efficacy, including assessment of lung function (ppFEV1 and LCI) in adults with Class I CF. Two validated quality-of-life outcome measures and changes in high-resolution computed tomography (HRCT) imaging will also be evaluated.



# ARCT-032 Phase 2 Interim Data

# Mucus Plug Reduction is Important

Arcturus evaluated mucus plug reduction after 28 days of treatment with ARCT-032

High-Resolution CT Scans were analyzed utilizing Thirona's FDA 510(k)-cleared AI Technology

Lung structure changes are an important predictor and precursor of lung function improvements

- Studies<sup>1</sup> have shown lung structural abnormalities in subjects with CF are associated with lower FEV1 lung function scores over the next 10 years of their life
- Mucus plugging are among the most predictive of lower FEV1 function
- Chest HRCT scans can provide an early readout of likely long-term success for CF patients

## Mucus Plug Reduction Interim Results

- No mucus plug reduction observed at the 5 mg dose level (first cohort)
- Significant mucus plug reductions observed at the 10 mg dose level (second cohort)
- Ongoing data collection and analysis in study cohorts 3 and 4, over 4 and 12 weeks, respectively

# Cohort 2: Mucus Reduction Summary

Subject Number	Dose (mg)	Number of Mucus Plugs % Change @ Day 28	Mucus Volume (mL) % Change @ Day 28
2	10	-38.5%	-67.4%
4	10	-34.9%	-27.5%
6	10	-28.5%	-29.5%
5	10	-9.1%	-6.1%
3	10	23.8%	9.1%
1	10	25.6%	60.9%

4 out of 6 participants in Cohort 2 exhibited Mucus Reduction (each received 10 mg ARCT-032 daily for 28d)

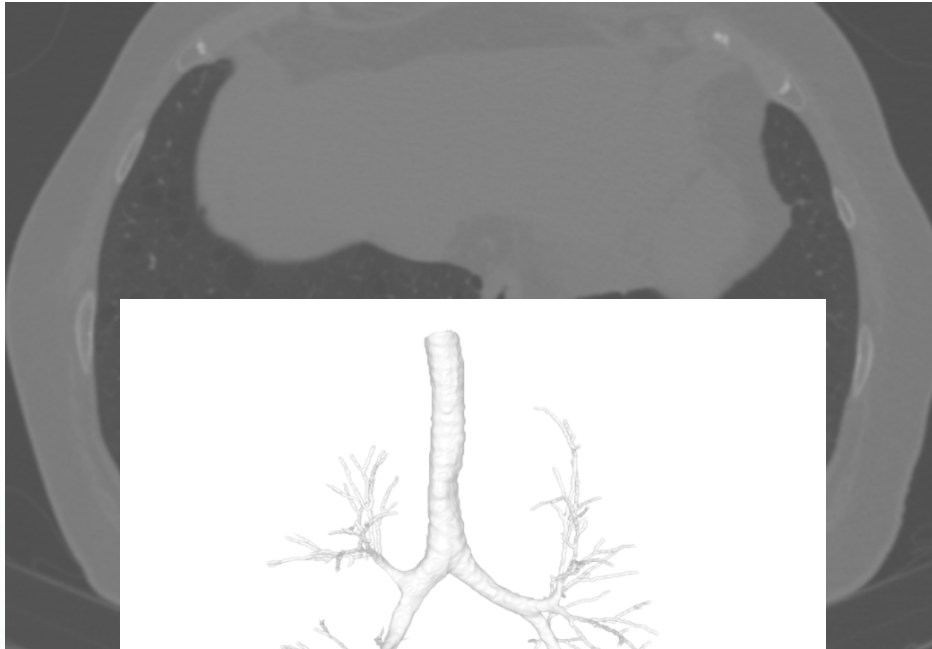
Averaging the four participants that exhibited Mucus Reduction (Patients 2, 4, 6, 5):

- 27.8% Reduction in Number of Mucus Plugs
- 32.6% Reduction in Mucus Volume

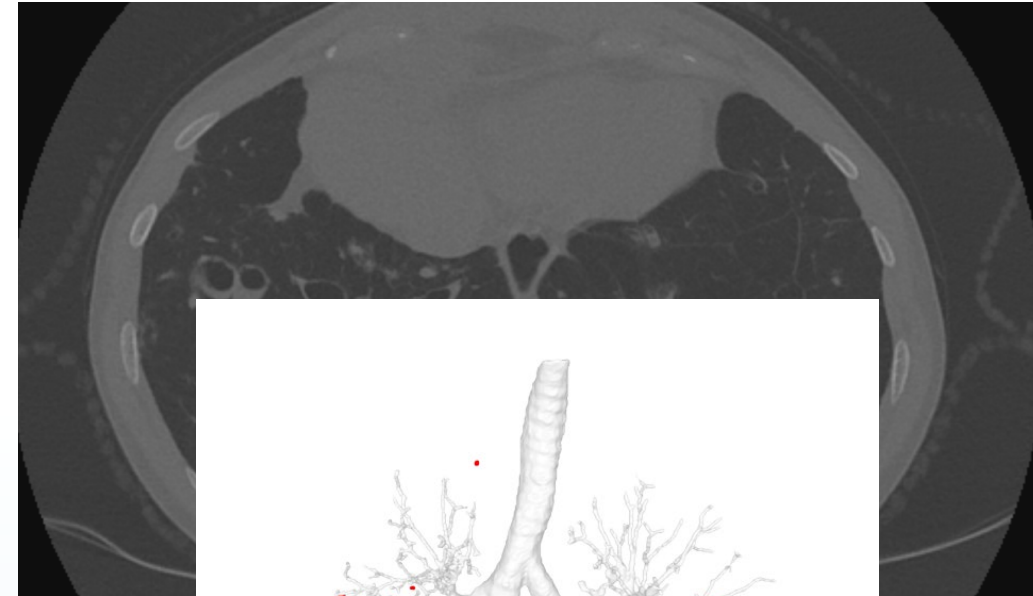
**After 28 daily doses (10 mg) of ARCT-032:  
Reduction of mucus plugs and mucus volume is encouraging**

# HRCT Imaging Background

## Example of Adult Healthy Lung



## Example of Adult Class I CF Lung

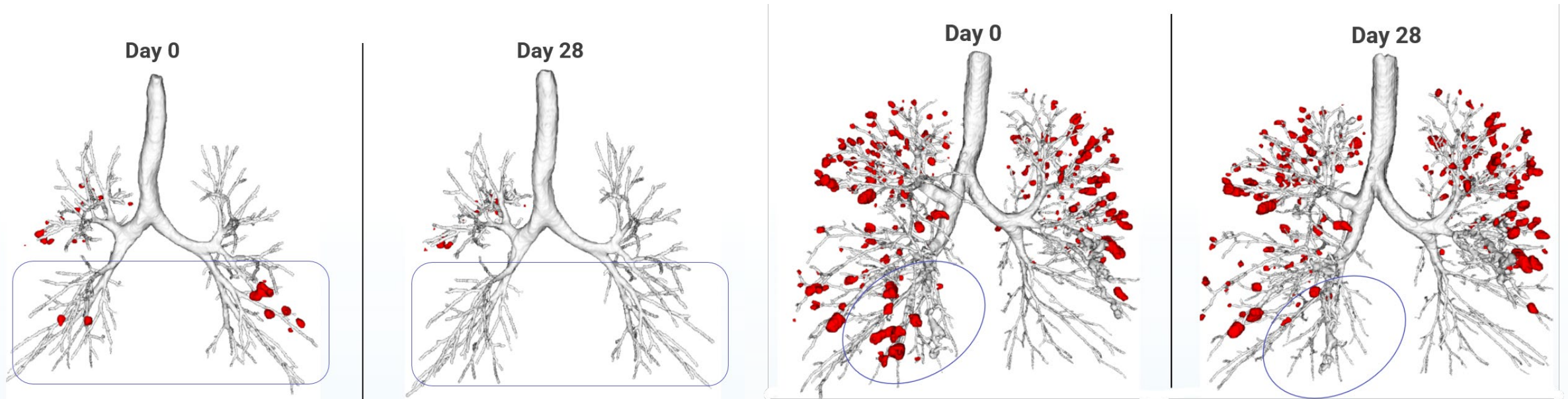


Mucus plugs are colored **red**

# HRCT Scans of Selected Class I CF Participants

Cohort 2: Patient 2

Cohort 2: Patient 5



**Reduction of mucus plugs after 28 days of treatment with ARCT-032**

# ARCT-032: Summary of Phase 2 Interim Data

- **ARCT-032 generally safe and well tolerated at all tested dose levels (up to 15 mg)**
- **Meaningful trends of clinical activity observed via high HRCT scans** – After 28 days of treatment with ARCT-032 (10 mg), 4 out of 6 Class I CF participants exhibited encouraging reduction in numbers of mucus plugs and mucus volume
- **Currently enrolling for cohort 4 (up to N = 20, starting dose 10 mg); open label study with longer duration (12 wks)**

<sup>1</sup>Reference <https://ir.arcturusrx.com/static-files/48940714-0106-400d-a4a9-15acb88da82e> for full Phase 2 interim data presentation

# LUNAR-OTC (ARCT-810)

Systemically Delivered mRNA for  
Ornithine Transcarbamylase (OTC) Deficiency

# Ornithine Transcarbamylase (OTC) Deficiency

ARCT-810 Market Opportunity



## The most common urea cycle disorder

- ~10,000 prevalence in U.S./ EU
- The urea cycle converts neurotoxic ammonia to water-soluble urea that can be excreted in urine
- Deficiency in OTC causes elevated blood ammonia, which can lead to **progressive neurological damage, coma, and death**



## Unmet Medical Need

- Present standard of care involves a strict diet (low protein, high fluid intake) plus ammonia scavengers
- Present standard of care does not effectively prevent life-threatening spikes of ammonia
- Severe OTC Deficiency patients are referred for liver transplant, currently the only cure



## LUNAR-OTC Aims to Restore Enzyme Function

- Establishing expression of OTC enzyme in the liver has the potential to restore urea cycle activity to detoxify ammonia, preventing neurological damage and potentially removing the need for liver transplantation

# ARCT-810 Clinical Summary

- **Phase 1 Study in Healthy Volunteers**
  - Completed dosing up to 0.4 mg/kg, total participants N = 24, generally safe and well tolerated

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- **Phase 1b Single Ascending Dose Study in OTCD Adults**
  - Completed enrollment and dosing of all cohorts (N=16)
  - Dose cohorts were 0.2, 0.3, 0.4 and 0.5 mg/kg; no serious or severe adverse events

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- **Phase 2 (UK & EU) Single and Multiple Ascending Dose, Placebo-controlled Study in OTCD Adolescents & Adults**
  - Completed enrollment of 8 participants at the 0.3 mg/kg dose level
  - Up to 6 bi-weekly doses for each participant with the following endpoints
    - Primary Endpoints: Safety and tolerability
    - Secondary Endpoints: PK and PD (ureagenesis assay, plasma ammonia: 24-hr profile and peak level)
    - Exploratory Endpoints: Plasma amino acids and OTC enzyme activity; urine orotic acid

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- **Phase 2 Ongoing Open Label Study (U.S.)**
  - Enrolling adults and adolescent participants with more severe disease
  - Multiple dose levels to be evaluated
  - Each participant is expected to receive five intravenous infusions administered over two months

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- **ARCT-810 received Orphan Drug Designation, Fast Track Designation & Rare Pediatric Disease Designation from the U.S. FDA and Orphan Medicinal Product Designation from the European Commission (EC)**

## Objectives

- Establish safety and tolerability in OTC deficient adolescents and adults
- Evaluate physiologic and biomarker responses – ammonia, glutamine and <sup>15</sup>N-ureagenesis

## European Phase 2 Study – Completed (N = 8; 6 ARCT-810 / 2 placebo)

- Randomized, placebo-controlled
- 0.3 mg/kg ARCT-810; up to six biweekly IV infusions
- Entry criteria: Study subjects with stable disease

## U.S. Phase 2 Study – Ongoing (up to N = 6)

- Open-label, multiple ascending dose study
- 0.3 mg/kg and 0.5 mg/kg; five biweekly IV infusions of ARCT-810
- Entry criteria: Study subjects with more severe disease
- More frequent and optimized physiologic and biomarker timepoints
- Includes <sup>15</sup>N-ureagenesis assay

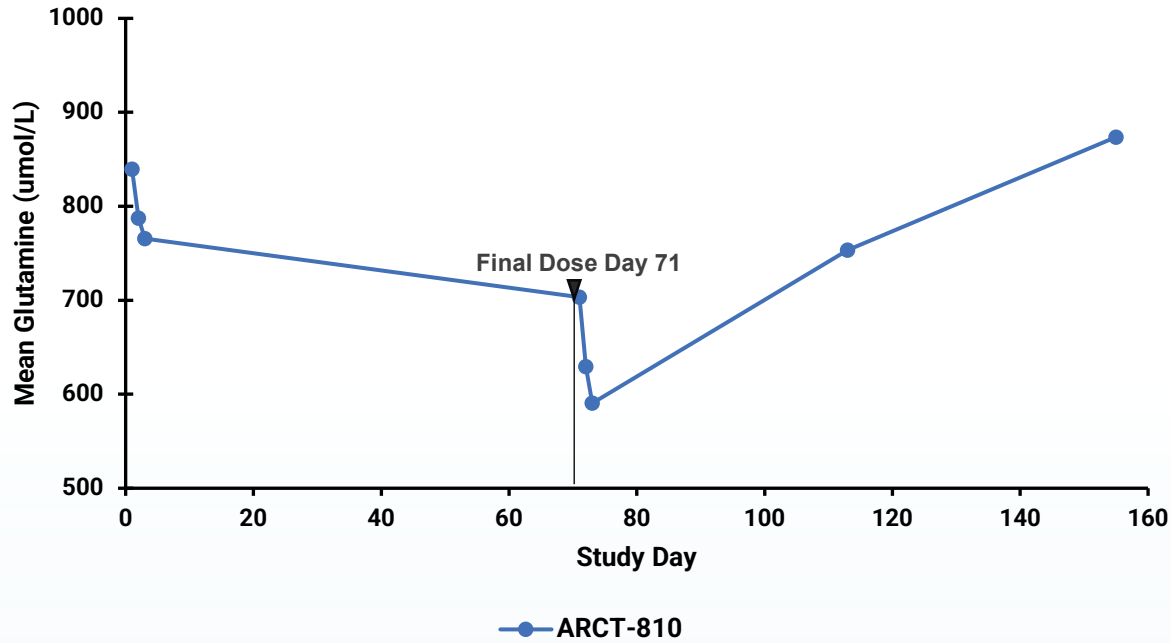


# ARCT-810 Phase 2 Interim Data

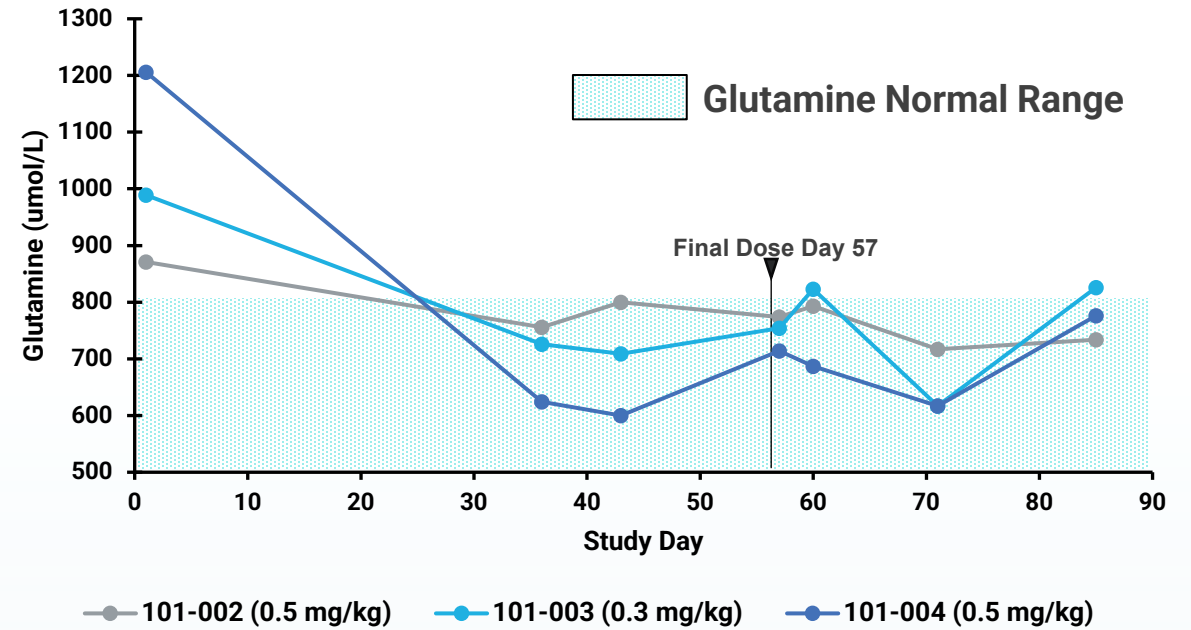
# Glutamine Normalization Following ARCT-810 Administration

Glutamine normal values range from ~400 to 800  $\mu\text{mol/L}$

Phase 2 (EU - 6 dose)



Phase 2 (US - 5 dose) (Interim)



**Interim data show significant reduction in glutamine levels following ARCT-810 administration**  
**High glutamine levels are normalized during treatment course**  
**Approximately one month after the final dose, glutamine levels elevate above normal**

# ARCT-810 Significantly Increases <sup>15</sup>N-Ureagenesis

## Interim Phase 2 Data U.S. Open Label Study (N = 3):

**Mean Relative Ureagenesis Function (RUF) increased +14.7% from baseline to 28 days post-fifth dose-- from 29.0% (SD 9.1%) to 43.7% (SD 21.7%)**

**Mean RUF increase is statistically significant**

-- p-value = 0.026, LMM analysis

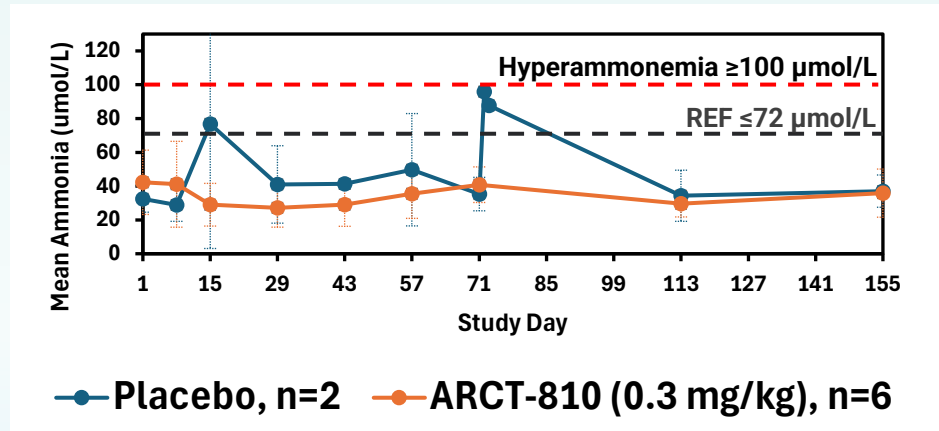
**Two of three participants achieved > 50% RUF**

**Data suggest ARCT-810 progressively increases functional OTC enzyme in the liver resulting in improved urea cycle function**

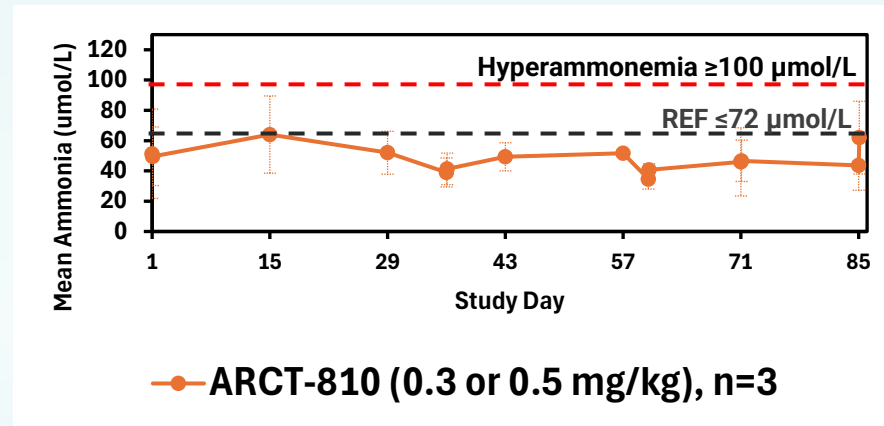
**Encouraging <sup>15</sup>N-Ureagenesis data provide additional support and confidence in the favorable glutamine results**

# ARCT-810: Ammonia Stable and Within Normal Range

## Phase 2 (Europe)



## Interim Phase 2 (U.S.)



Ammonia levels stabilized within normal range following two administrations of ARCT-810 and remained stable for approximately 28 days after completion of dosing

**Ammonia level stabilization adds robustness to the favorable glutamine and ureagenesis data**

# ARCT-810: Summary of Phase 2 Interim Data<sup>1</sup>

- **Significant and consistent reduction in glutamine levels in both Phase 2 studies** – from abnormal to normal levels
- **Significant increase in <sup>15</sup>N-ureagenesis in the U.S. Phase 2 study** – additional evidence of urea cycle improvement
- **Ammonia – stable and within normal range**
- **ARCT-810 continues to be safe and well tolerated at all tested dose levels**

**End of Phase 2 (EOP2) Meeting H2 2026**

<sup>1</sup>Reference <https://ir.arcturusrx.com/static-files/f01ce22c-25cd-4886-850d-18e8db4484b8> for full Phase 2 interim data presentation

# VACCINES

# STARR<sup>®</sup> Self-amplifying mRNA Vaccine

STARR<sup>®</sup> self-replicating RNA-based prophylactic vaccine triggers rapid and prolonged antigen expression within host cells resulting in protective immunity against infectious pathogens



## Potential advantages over conventional mRNA Vaccine

**Superior immune response:** Induces higher neutralizing antibody response and increased immunogenicity

**Durable immune response:** Requires less frequent boosters due to longer and more durable immune response

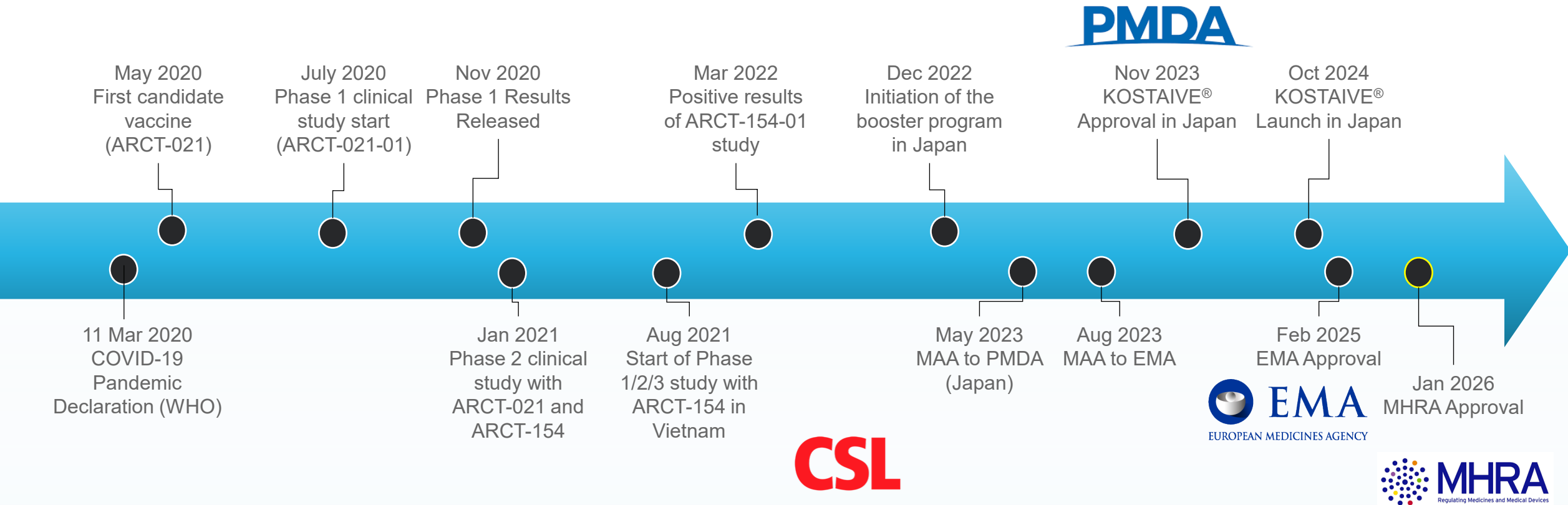
**Broad immune response:** Demonstrated higher immune response to evolving variants of COVID-19

**Lower dose level:** Increase the potential for combined vaccines

**Manufacturing speed:** Lower dose levels enabling vaccines do be produced more quickly and simply

# KOSTAIVE® (sa-mRNA COVID-19 Vaccine)

## Key Development Milestones



# KOSTAIVE® Phase 3 Clinical Studies

## Enduring vaccine with strong clinical data

Arcturus recently published a comprehensive analysis of safety data for KOSTAIVE, with a 12-month follow-up from the pivotal clinical study in Vietnam (NCT05012943), which had 17,582 participants who received at least one dose of the study vaccine.<sup>1</sup>

### Phase 3 Non-inferiority safety and immunogenicity trial

- KOSTAIVE® administered at an 83.3% lower dose than Comirnaty®
- Adults ≥18 years who previously received 3 doses of mRNA vaccines (≥3 mo before enrollment)
- Conducted in Japan
- **Achieved Primary Endpoint** of non-inferiority of neutralizing antibody response against SARS-CoV-2 Ancestral strain compared to Comirnaty®
- **Achieved Secondary Endpoint** of non-inferiority/superiority of KOSTAIVE® in neutralizing antibody response against SARS-CoV-2 Omicron BA.4/5 variant; longer-lasting immune response with KOSTAIVE® versus Comirnaty® at 12 months post booster
- **Phase 3 Study published** in *The Lancet Infectious Diseases*<sup>2</sup>
- **Generally safe and well tolerated**

THE LANCET  
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### KOSTAIVE® (Bivalent, ARCT-2301)

**Bivalent KOSTAIVE®**  
(ARCT-2301: ancestral D614G and Omicron BA.4-5)

- Results consistent with monovalent KOSTAIVE®
- Phase 3 clinical booster vaccination study was also conducted in Japan

**Bivalent KOSTAIVE®** was assessed in comparison with bivalent conventional mRNA vaccine (Comirnaty®):

- Superiority of neutralizing antibody response against SARS-CoV-2 Ancestral strain was established at 6 months post booster
- Superiority of neutralizing antibody response against SARS-CoV-2 Omicron BA.4/5 subvariant was established at 6 months post booster
- Neutralizing immune response against SARS-CoV-2 Omicron XBB.1.5 subvariant was higher compared to Comirnaty at 6 months post booster

### KOSTAIVE® (ARCT-2303)

**ARCT-2303: with or without co-administration of seasonal inactivated influenza vaccine in adults**  
(ARCT-2303: Omicron XBB.1.5.6)

- **ARCT-2303** induces a robust immune response against the vaccine variant of SARS-CoV-2 and can be co-administered with licensed influenza vaccines in adults with no impact on the safety or immunogenicity of either vaccine
- Day 29 superiority of neutralizing antibodies against Omicron XBB.1.5.6 was established for the geometric mean ratio ( ARCT-2303/ARCT-154)
- Non-inferiority of the immune response against Omicron XBB.1.5.6 was also demonstrated when ARCT-2303 was co-administered or administered separately.
- The result was published in *eClinicalMedicine*<sup>3</sup>

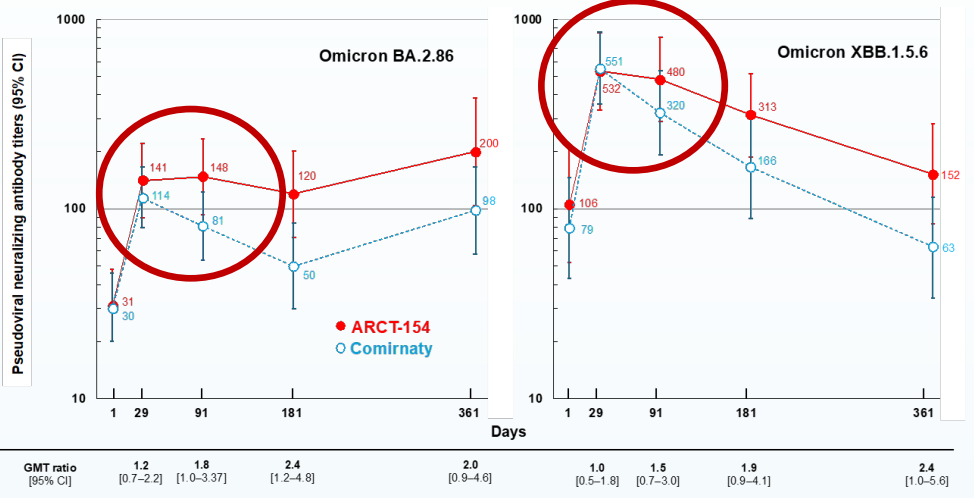
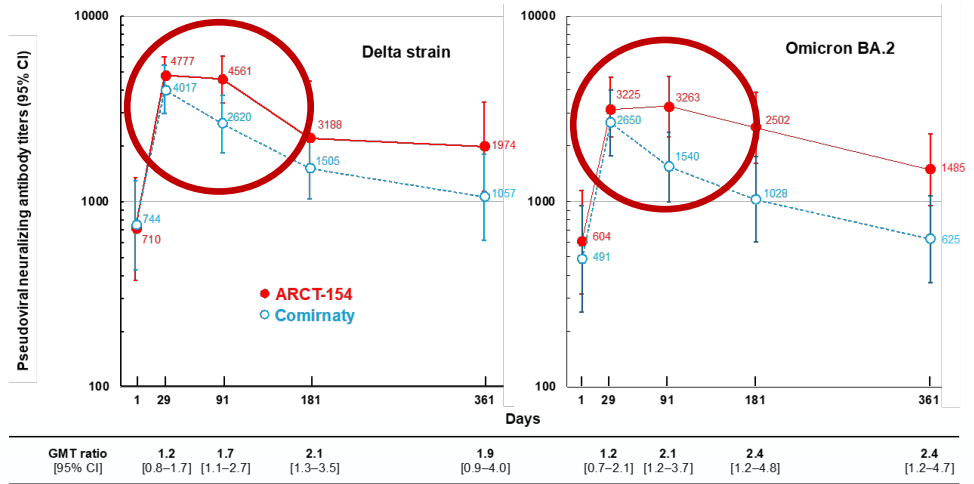
<sup>1</sup> Ho, N. T., Smolenov, I., Thi Le Tran, L., et al. (2025). Safety profile of self-amplifying mRNA SARS-CoV-2 vaccine ARCT-154 in adults: a pooled phase 1/2/3 randomized clinical study. *Expert Review of Vaccines*, 24(1), 299–312. <https://doi.org/10.1080/14760584.2025.2487542>

<sup>2</sup> Yoshiaki Oda · Yuji Kumagaib · Manabu Kanaia · Yasuhiro Iwamaa · Iori Okuraa · Takeshi Minamidaa · Yukihiko Yaglia · Toru Kurosawaa · Pad Chivukula · Ye Zhang · Judd L Watson. 12-month persistence of immune responses to self-amplifying mRNA COVID-19 vaccines: ARCT-154 versus BNT162b2 vaccine, *The Lancet Infectious Diseases*, 2024, [https://doi.org/10.1016/S1473-3099\(24\)00615-7](https://doi.org/10.1016/S1473-3099(24)00615-7)

<sup>3</sup> Michelle L. Gilesa. Carole Verhoeven · Igor Smolenov. Immunogenicity and safety of self-amplifying mRNA COVID-19 vaccine (ARCT-2303), with or without co-administration of seasonal inactivated influenza vaccine in adults: a phase 3, randomised, controlled, observer-blind, multicentre study, *eClinicalMedicine*, 2025, DOI: [10.1016/j.eclinm.2025.103428](https://doi.org/10.1016/j.eclinm.2025.103428)

# KOSTAIVE®: More Durable Immune Response

Phase 3 Persistence Data Comparing KOSTAIVE® (5 mcg) to Comirnaty® (30 mcg)



- ✓ A booster dose of ARCT-154 induced a similar or higher immune response against 4 epidemiologically relevant SARS-CoV-2 variants – Delta, Omicron BA.2, Omicron XBB.1.5.6 and Omicron BA.2.85, compared to Comirnaty
- ✓ The kinetic of antibody waning for all 4 tested variants was similar to those for Wuhan-Hu1 strain, indicating a higher durability and breadth of neutralizing immune response

ARCT-154: Comirnaty GMT ratio (95% CI)

SARS-CoV-2 variant	Day 1	Day 29	Day 91	Day 181	Day 361
Delta	0.95 (0.42, 2.18)	1.19 (0.82, 1.72)	1.74 (1.11, 2.73)	2.12 (1.29, 3.48)	1.87 (0.87, 3.99)
Omicron BA.2	1.23 (0.50, 3.04)	1.22 (0.71, 2.09)	2.12 (1.21, 3.72)	2.43 (1.24, 4.77)	2.38 (1.19, 4.73)
Omicron XBB 1.5.6	1.33 (0.53, 3.35)	0.97 (0.52, 1.81)	1.50 (0.74, 3.03)	1.89 (0.87, 4.13)	2.42 (1.05, 5.59)
Omicron BA.2.86	1.02 (0.56, 1.86)	1.23 (0.70, 2.18)	1.82 (1.00, 3.33)	2.38 (1.17, 4.84)	2.04 (0.90, 4.62)

COMIRNATY® is the brand name of BNT162b2



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THE LANCET  
Infectious Diseases

Oda et al. Lancet Infect Dis. 2024 Dec;24(12): e729-e731.  
doi: 10.1016/S1473-3099(24)00615-7

# LUNAR-H5N1 (ARCT-2304)

Avian Influenza Program  
U.S. Pandemic Preparedness Initiative

# LUNAR-H5N1 (ARCT-2304)



BARDA funded the development program from the preclinical stage through Phase 1

Received clearance from the FDA in Nov 2024

Conducted in the US (Dec 2024 – Dec 2025)

Third STARR® mRNA vaccine candidate to enter clinical development

Arcturus Therapeutics received U.S. FDA Fast Track Designation for the STARR® mRNA vaccine candidate ARCT-2304 for Pandemic Influenza A Virus H5N1

The Company presented Phase 1 results from ARCT-2304, a sa-mRNA vaccine candidate for Pandemic Influenza A/H5N1 virus

## LUNAR-H5N1

### ▶ ARCT-2304

Utilizes clinically validated LUNAR® delivery and STARR® mRNA platform technologies. STARR mRNA has demonstrated in multiple clinical trials its ability to elicit a robust immune response at very low dose levels, with extended persistence of neutralizing antibodies compared to approved conventional mRNA vaccines

Fast Track Designation from the FDA is granted to vaccines intended to prevent serious conditions caused by infectious diseases. The designation is designed to expedite the development and review process, providing several benefits, including enhanced communication with the FDA and eligibility for priority review, and the possibility of a rolling review

### Phase 1 Randomized placebo-controlled trial (NCT06602531)

#### ▶ Achieved study objectives and potential for differentiation

- ARCT-2304 induced a humoral immune response after a single dose (as measured by the HA microneutralization and ELLA anti-neuraminidase assays) in all tested dose levels (N=212). The administration of a second dose of ARCT-2304 further increases anti-HA immune response, which is maintained for at least 7 months post-vaccination
- The magnitude of anti-HA response was higher after an 8-week interval compared to a 4-week interval.
- Regardless of the serological assay, ARCT-2304 in dose levels 5 and 12 µg (both vaccination schedules) and 1.5 µg (8-week interval) induces an HA-specific immune response that is similar to or higher than that after the MF59-adjuvanted pandemic vaccine
- ARCT-2304 increases the frequency of IFN-γ-secreting T-cells and IL-2-secreting T-cells after a single dose administration in a dose-dependent manner, indicating Th1 type of immune polarization
- No safety or tolerability concerns were raised from available data

## H5N1 Influenza

H5N1 influenza is a significant concern in animal health. To date, H5N1 flu has affected over 10,000 wild birds, nearly a thousand dairy cows, and over 130 million poultry. Elevated H5N1 infections in animals have led to increasing numbers of human infections including two confirmed severe cases in the United States and one death. Most of the confirmed 67 human infections were due to exposure of U.S. dairy and poultry workers to infected dairy cows and poultry

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