ARCTURUS® therapeutics

NEXT GENERATION RNA MEDICINES

November 2026

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Arcturus – mRNA Therapeutics Company

LUNAR-CF
mRNA for cystic fibrosis

LUNAR-OTC
mRNA for OTC deficiency

Based in San Diego



Partners

ThermoFisher SCIENTIFIC

CYSTIC FIBROSIS FOUNDATION®

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Pipeline of mRNA Therapeutic Candidates



Franchise	Candidate	Indication	Global Prevalence	Upcoming Data
Respiratory	LUNAR®-CF (ARCT-032)	Cystic Fibrosis	>100,000	Phase 2 12-Week Data **Q2 2027**
Hepatic	LUNAR®-OTC (ARCT-2601)	Ornithine Transcarbamylase (OTC) Deficiency	>10,000	Phase 2 Interim Data **H2 2027**

Each Program is First-in-Class and Represents a Significant Commercial Opportunity

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Proprietary mRNA Technologies Driving Therapeutic Programs

Broad Intellectual Property Portfolio

500+
Patents & Patent Applications



mRNA Technology



LUNAR 2.0™ Delivery



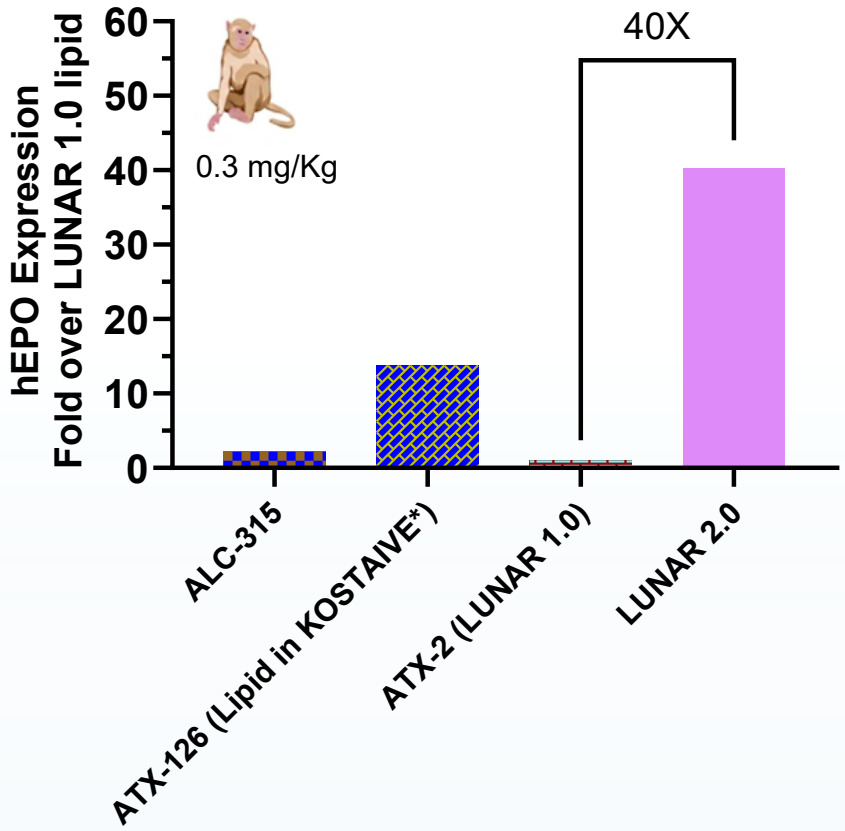
Manufacturing Know-How
Proven, Scalable, Proprietary, End-to-end

myNEO Therapeutics
A wholly owned subsidiary of
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AI mRNA Design Capability

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LUNAR 2.0™ Next Generation LNP: 40-Fold Higher Expression



Relative Fold Enhancement in Human EPO Protein Expression

Lipid	Fold Enhancement Over LUNAR 1.0
ALC-315	2.2
ATX-126 (Lipid in KOSTAIVE®)	14
ATX-2 (LUNAR 1.0)	1.0
LUNAR 2.0™	**40**

- NHPs (n=3) treated, IV 60-min infusion @ 0.3 mg/kg)
- Plasma concentration 48 hours post infusion
- Only the ionizable lipid differs between arms — same hEPO mRNA, same dose, same infusion

LUNAR 2.0™ produced 40-fold higher hEPO expression in NHPs compared to LUNAR 1.0

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LUNAR 2.0™ – Opens Door to Reduced Infusion Time

Better potency × higher concentration → reduces dose volume → minimizes chair time

The Challenge: mRNA-LNP therapeutics targeting the liver must be infused IV

CURRENT

3 Hours

infusion time





VOLUME
250 mL

DOSE
0.5 mg/kg

PROPOSED — NEAR TERM

1 Hour

infusion time





VOLUME
40 mL

DOSE
0.3 mg/kg

FUTURE — SYRINGE PUMP

< 5 Min

infusion time





VOLUME
5 mL

DOSE
0.15 mg/kg

36×	**shorter clinic time** *(3 hr → 5 min)*	**50×**	**lower infusion volume** *(250 mL → 5 mL)*	**7×**	**fewer drug product vials** *(7 vials → 1 vial)*	**RTU**	**ready-to-use** *(no dilution required)*

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LUNAR-CF (ARCT-032)

Inhaled mRNA Therapeutic Candidate for Cystic Fibrosis

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ARCT-032 Background

- An inhaled mRNA therapeutic that can produce new CFTR protein in the lung cells of individuals with CF is desired
- Generally safe and well tolerated in Phase 2 studies after 28 daily treatments (up to 15 mg)
- Arcturus initiated Phase 2 study in Q1 2026 enrolling up to ~20 people with CF (primarily Class I) over a period of 12 weeks
- The Cystic Fibrosis Foundation has committed ~$25 Million to ARCT-032
- 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)
- If Phase 2 results positive, Thermo Fisher contributes significant support

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Cystic Fibrosis

ARCT-032 Market Opportunity



Cystic Fibrosis

- **>100,000 worldwide prevalence**
- Caused by mutations in the CFTR gene, resulting in poor chloride transport and dehydrated, sticky mucus in the airways
- 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
- Standard of care therapies do not prevent chronic, progressive loss of lung function that ultimately requires lung transplantation or leads to early death

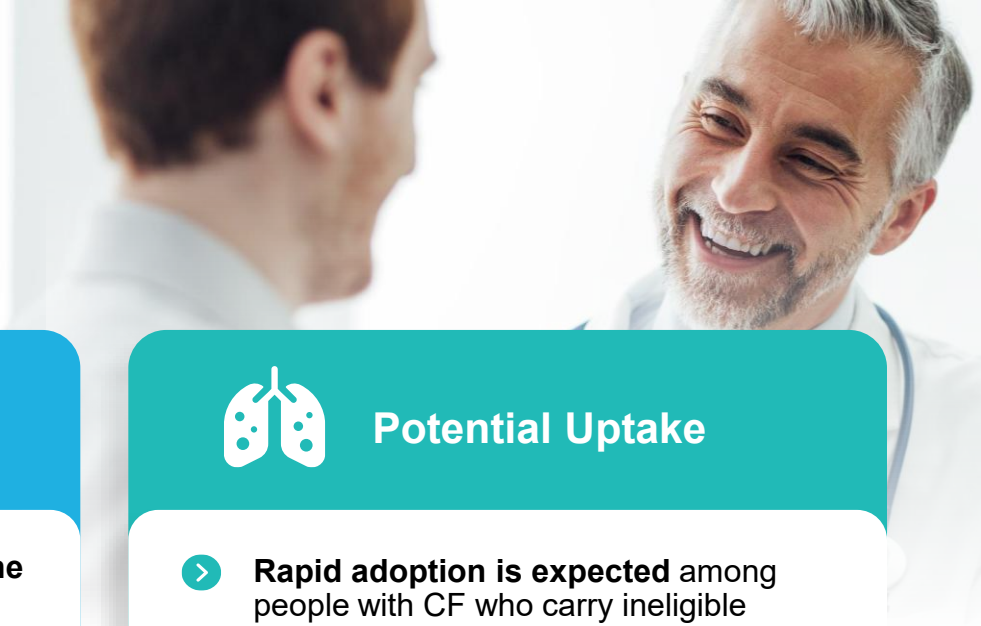
LUNAR-CF Aims to Restore CFTR Function

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

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Class I Cystic Fibrosis

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

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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 Class I CF (U.S., Israel, Turkey)

- Inhaled treatments of ARCT-032 over a period of 12 Weeks (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.
- Enrolling in US, Turkey, Israel

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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[1] 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

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[1.] Turkovic L, Caudri D, Rosenow T, et al. Structural determinants of long-term functional outcomes in young children with cystic fibrosis. Eur Respir J 2020; 55: 1900748 [https://doi.org/ 10.1183/13993003.00748-2019].

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

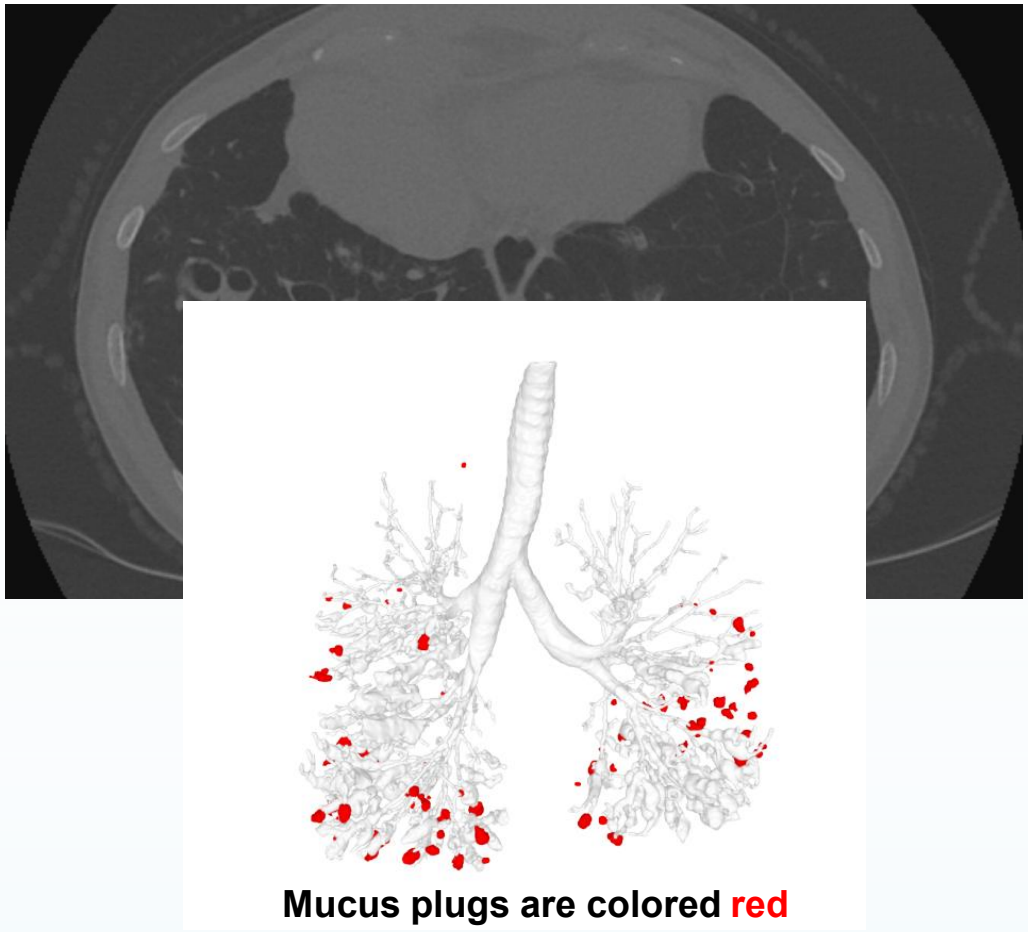
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HRCT Imaging Background

Example of Adult Healthy Lung



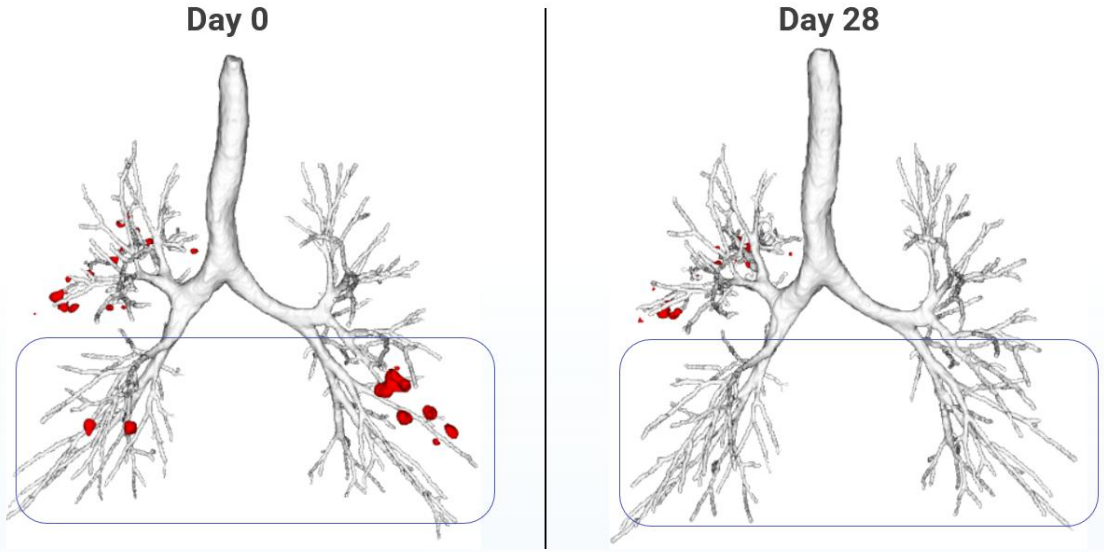
Example of Adult Class I CF Lung



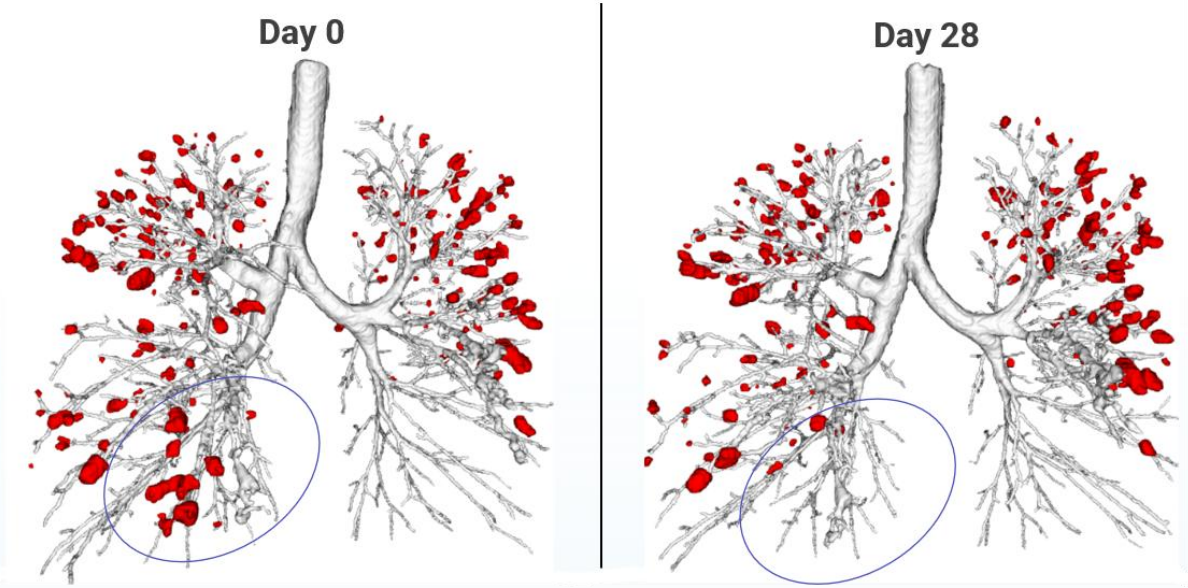
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HRCT Scans of Selected Class I CF Participants

Cohort 2: Patient 2



Cohort 2: Patient 5



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

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ARCT-032: Summary of Phase 2 Interim Data

- **ARCT-032 is 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, dose 10 mg); open label study with longer duration (12 wks)**

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

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LUNAR-OTC (ARCT-810)

mRNA Therapeutic Candidate
for Ornithine Transcarbamylase (OTC) Deficiency

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Ornithine Transcarbamylase (OTC) Deficiency

The most common urea cycle disorder

- 10,000 prevalence in U.S./Europe
- 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 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 liver has potential to restore urea cycle activity to detoxify ammonia, preventing neurological damage and potentially removing need for liver transplantation

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ARCT-810 Clinical Trials

Phase 1 – Healthy Volunteers

- Safe and generally well-tolerated in 24 adults

Phase 1b – Single, Ascending Dose Study in OTC Deficiency Adults

- 0.2 – 0.5 mg/kg in 16 adults
- Safe and generally well-tolerated

Phase 2 (UK, EU) – Single Dose, Multiple Administrations, Placebo-Controlled Study in OTC Deficiency Adolescents and Adults

- Enrollment of 6 subjects at the 0.3 mg/kg dose level (x6 IV infusions every 2 weeks) and 2 participants with placebo
- Safe and generally well-tolerated
- Limited glutamine measurements suggested reduction in glutamine compared to placebo

Phase 2 (U.S.) – Multiple Doses, Multiple Administrations, Open Label Study

- Examination of 0.3 mg/kg and 0.5 mg/kg doses (x5 IV infusions every 2 weeks)
- More frequent measurements of urea cycle biomarkers glutamine and Ammand function

ARCT-810 has been consistently safe and well-tolerated with data suggesting improved urea cycle function

U.S. Phase 2 Study Overview

- **Open-label, dose-ascending, multiple dose administration study**
  - 0.3 mg/kg and 0.5 mg/kg, 5 IV infusions every 2 weeks with 4-week follow-up
- **Enrolled adolescents and adults with confirmed OTC deficiency**
  - Participants directed to maintain baseline diet (e.g., protein intake) and medical management (e.g., ammonia scavenger medications)
- **8 participants were enrolled across both dosing cohorts (n=4 each)**

All dosing has been completed with preliminary findings presented here

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U.S. Phase 2 Summary of Safety and Tolerability

- **No serious adverse events**
- **Most treatment emergent adverse events (TEAEs) in both 0.3 mg/kg and 0.5 mg/kg dosing cohorts were mild to moderate in severity** – Most common TEAEs were headache (2/8), transaminitis (2/8), and IRRs (2/8)
  - Both Grade 3 non-serious asymptomatic transaminitis events resolved without additional intervention after stopping study drug

	0.3 mg/kg (N=4)	0.5 mg/kg (N=4)
Participants with TEAE, n	4	4
TEAE events, n	14	11
Participants with related TEAE, n	3	4
Related TEAE events, n	8	8
Grade 1	3	6
Grade 2	4[+]	1
Grade 3	1	1
Discontinued due to AE	1[+]	0
Serious AEs, n	0	0
AESIs (hyperammonemia)	0	0
Participants with IRR, n	1	1

ARCT-810 was generally safe and well-tolerated following multiple dose administrations

[+]One participant discontinued after a single dose of ARCT-810 due to a non-serious Grade 2 AE of IV infiltration with a subsequent Grade 2 site injection reaction.

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U.S. Phase 2 Efficacy Measures

- **Clinically-relevant biomarkers of urea cycle** – plasma ammonia and glutamine
- **OTC enzyme activity through urea cycle byproduct enrichment** – Relative urea function (RUF)
- **Dietary intake** – Focus on protein intake given its centrality to OTC deficiency clinical management

Participant Baseline Characteristics

	0.3 mg/kg (N=3[+])	0.5 mg/kg (N=4)
Sex n (%)	F 3 (100%)	F 4 (100%)
Race n (%)	White 3 (100%)	White 4 (100%)
Ethnicity (n,%)	Hispanic 1 (33%)	Hispanic 1 (25%)
Age (yrs) Median (Range)	46 (14 – 57)	32 (17 – 42)
BMI (kg/m^2) Median (Range)	24.1 (20.4 – 30.7)	23.5 (17.0 – 24.8)
Nitrogen Scavengers n (%)	2 (67%)	4 (100%)

Expansion of prior Phase 2 study measures to better understand ARCT-810's impact on urea cycle function

[+]One participant discontinued after a single dose of ARCT-810 due to a non-serious Grade 2 AE of IV infiltration with a subsequent Grade 2 site injection reaction.

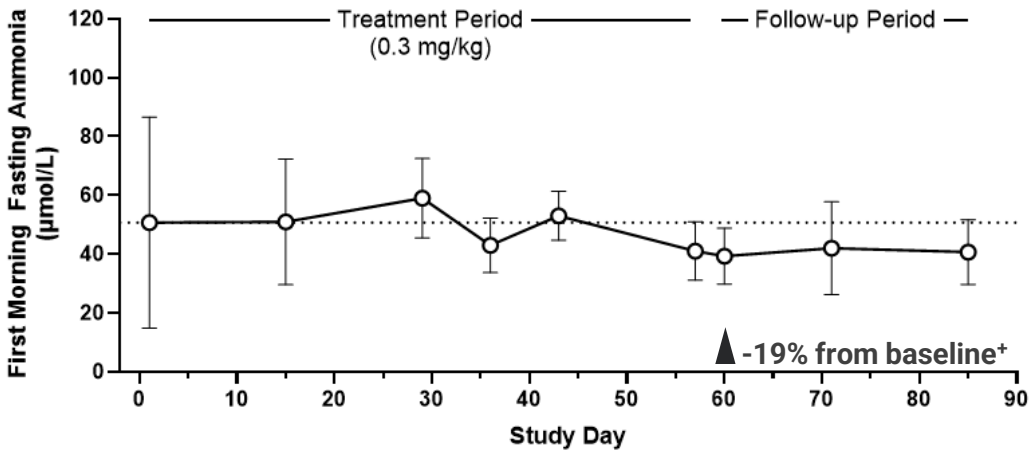
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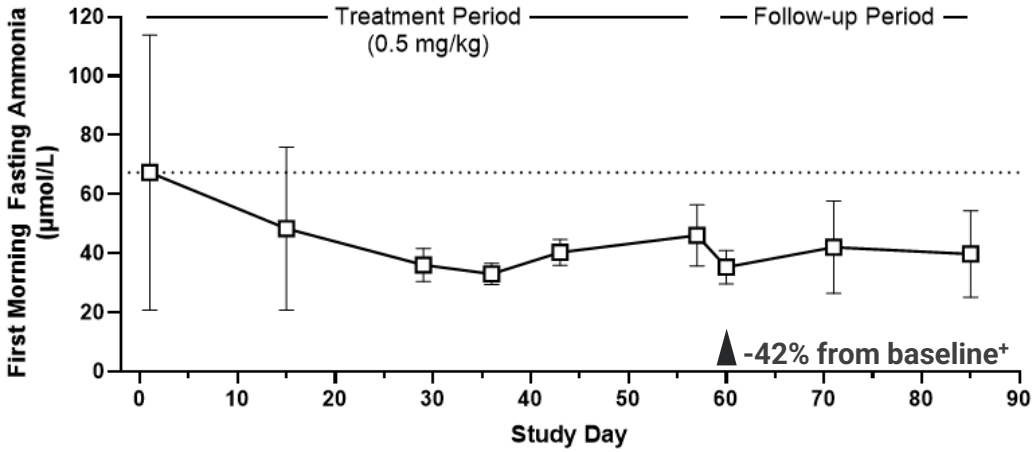
Changes in Clinically Relevant Biomarkers: Ammonia

Objective: Stable first morning fasting plasma ammonia levels with ARCT-810

Results

- 2/7 (29%) participants had elevated ammonia at baseline
- At 0.3 mg/kg and 0.5 mg/kg dose levels, mean ammonia levels were similar or lower than baseline





All participants achieved and maintained normal ammonia levels following ARCT-810

Points represent means ± SD of 3-4 participants. Dotted line indicates mean baseline value. +Mean difference between Day 60 (3 days after last dose) and baseline. Best available data as of 11Sep2026.

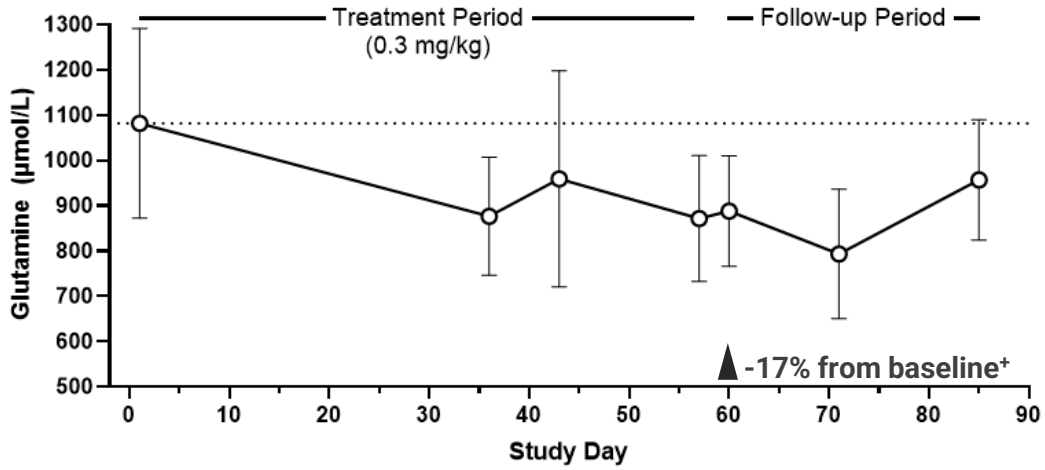
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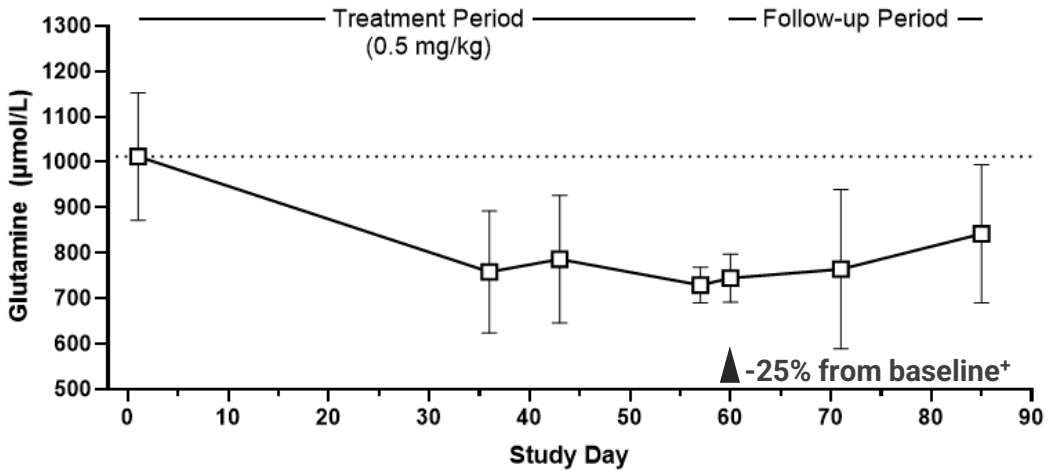
Changes in Clinically Relevant Biomarkers: Glutamine

Objective: Reduction in plasma glutamine levels following ARCT-810

Results

- 7/7 (100%) participants had elevated glutamine at baseline
- At 0.3 mg/kg and 0.5 mg/kg dose levels, mean glutamine levels were lower than baseline





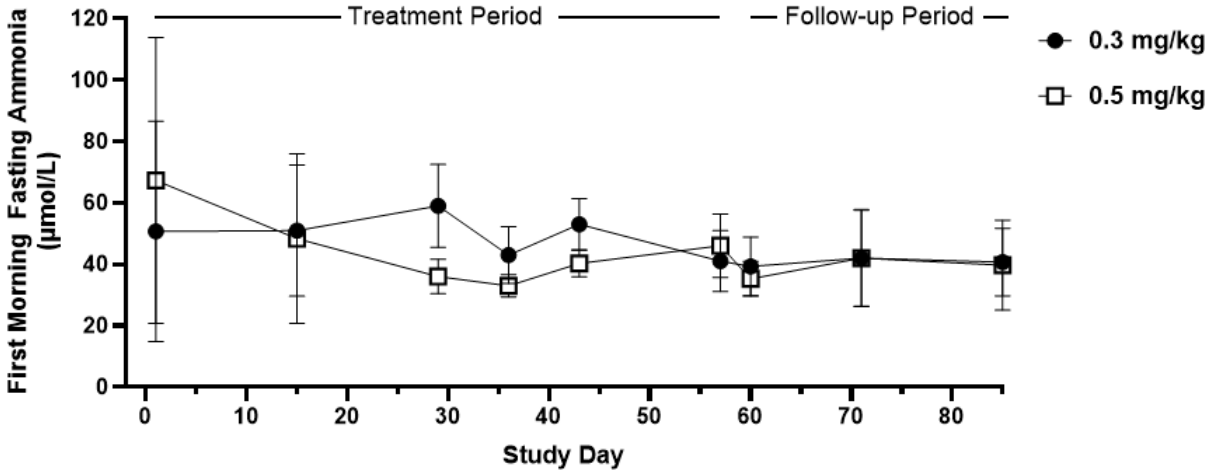
All participants exhibited reduction in glutamine levels following ARCT-810

Points represent means ± SD of 3-4 participants. Dotted line indicates mean baseline value. +Mean difference between Day 60 (3 days after last dose) and baseline. Best available data as of 11Sep2026.

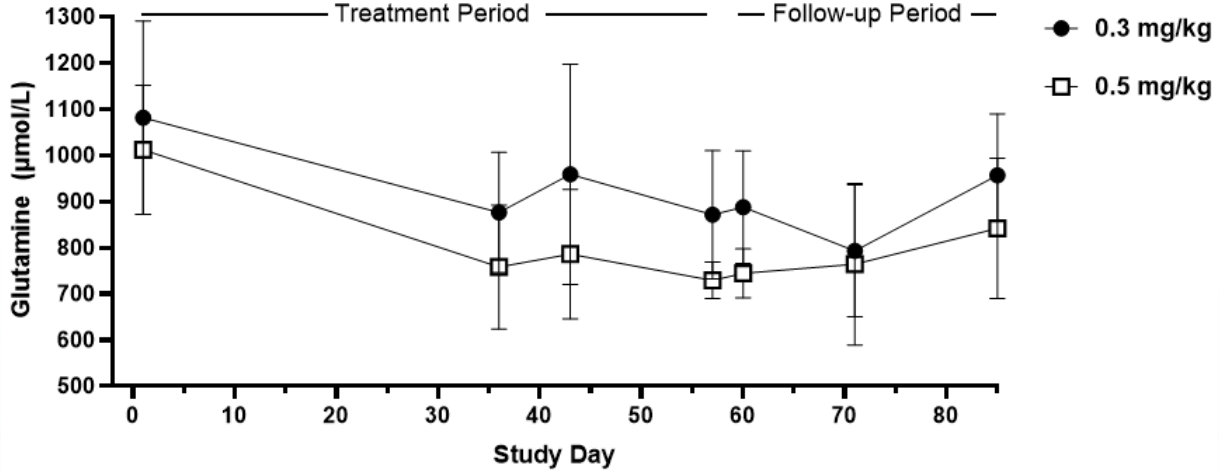
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Ammonia & Glutamine ARCT-810 Dose Comparison

Ammonia



Glutamine



Consistent reductions observed at both 0.3 & 0.5 mg/kg ARCT-810 doses studied

Points represent means ± SD of 3-4 participants. Best available data as of 11Sep2026.

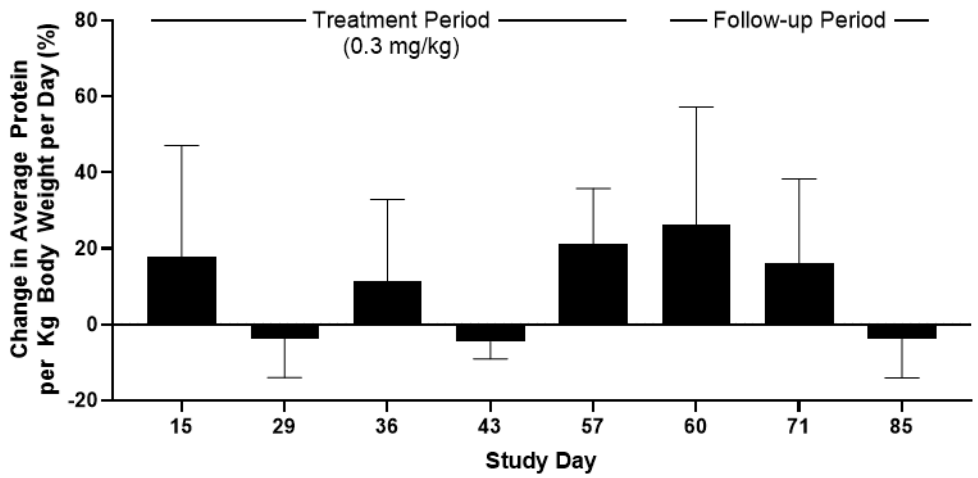
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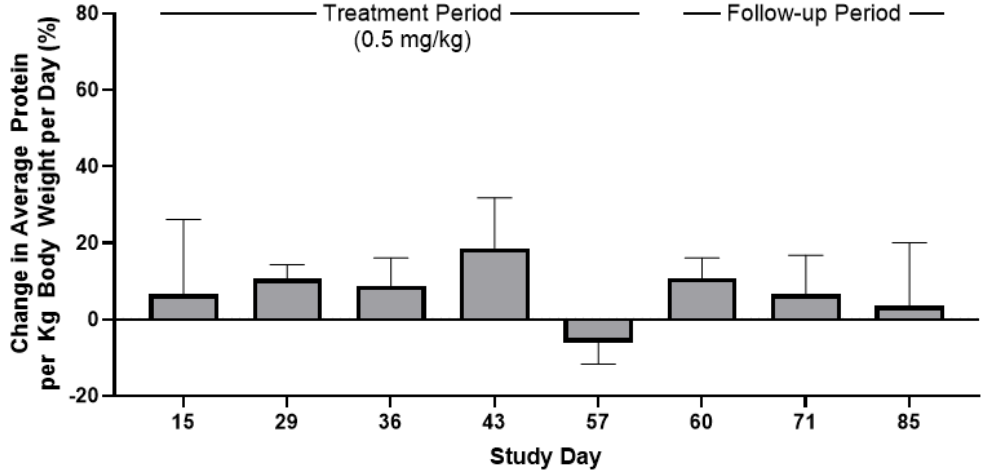
Biomarker Reductions Observed Despite Increased Protein Intake

Objective: Stable protein intake (within 25% of baseline)

Results

- At 0.3 mg/kg and 0.5 mg/kg dose levels, mean protein intake generally increased above baseline
- 5/7 (71%) participants had ≥1 timepoint that exceeded 25% baseline protein intake
  - All participants gained weight over course of study





Increased protein intake + reductions in ammonia & glutamine → suggests increased urea cycle activity

Columns represent means ± SD of 3-4 participants. Best available data as of 11Sep2026.

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U.S. Phase 2 Study Summary

- **Multiple doses of ARCT-810 at both dose levels was generally safe and well-tolerated** – Similar safety profiles between 0.3 mg/kg and 0.5 mg/kg
- **Evidence suggesting ARCT-810 increases urea cycle function –** As detected by clinically-relevant biomarkers of urea cycle activity (ammonia and glutamine)
- **Increases in protein intake suggests ARCT-810 may allow for better protein tolerance** – Important clinical outcome

ARCT-810 shows good safety profile and evidence of improvements in urea cycle function

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LUNAR-OTC (ARCT-2601)

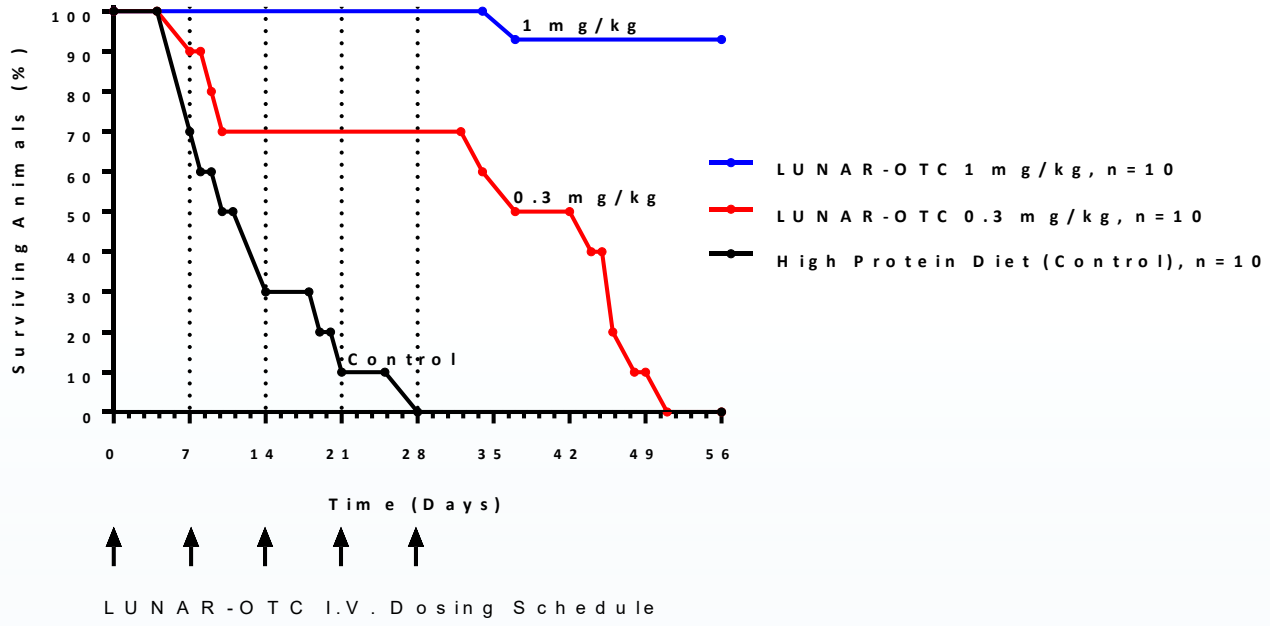
mRNA Therapeutic Candidate
for Ornithine Transcarbamylase (OTC) Deficiency

Formulated with Next Generation **LUNAR 2.0™** Technology

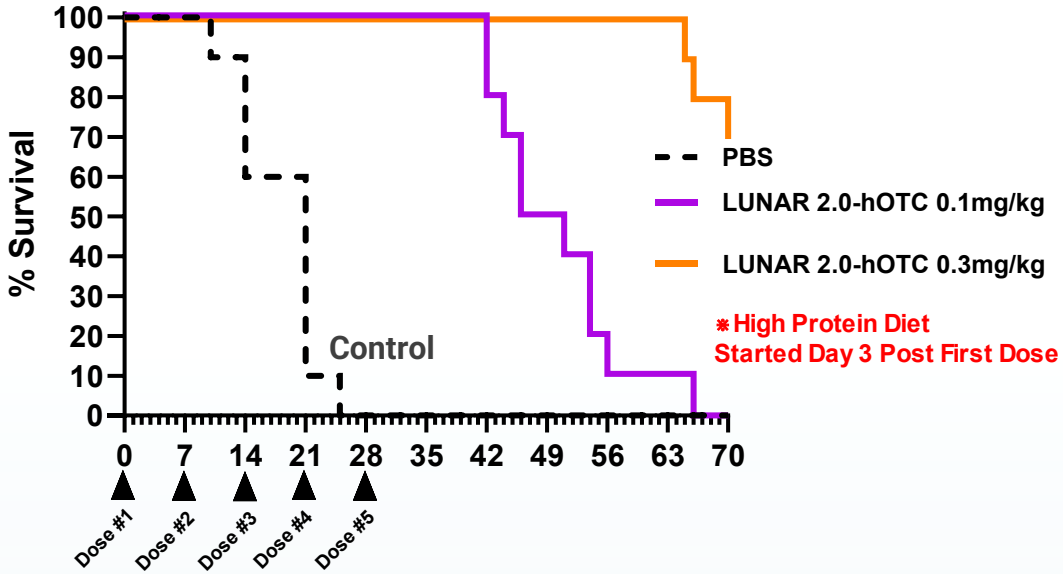
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LUNAR 2.0™ ARCT-2601 Highly Effective in OTC-Deficient Model

Survival in OTC-deficient mice on a high-protein diet



ARCT-810 utilizes ATX-95



ARCT-2601 utilizes LUNAR 2.0™

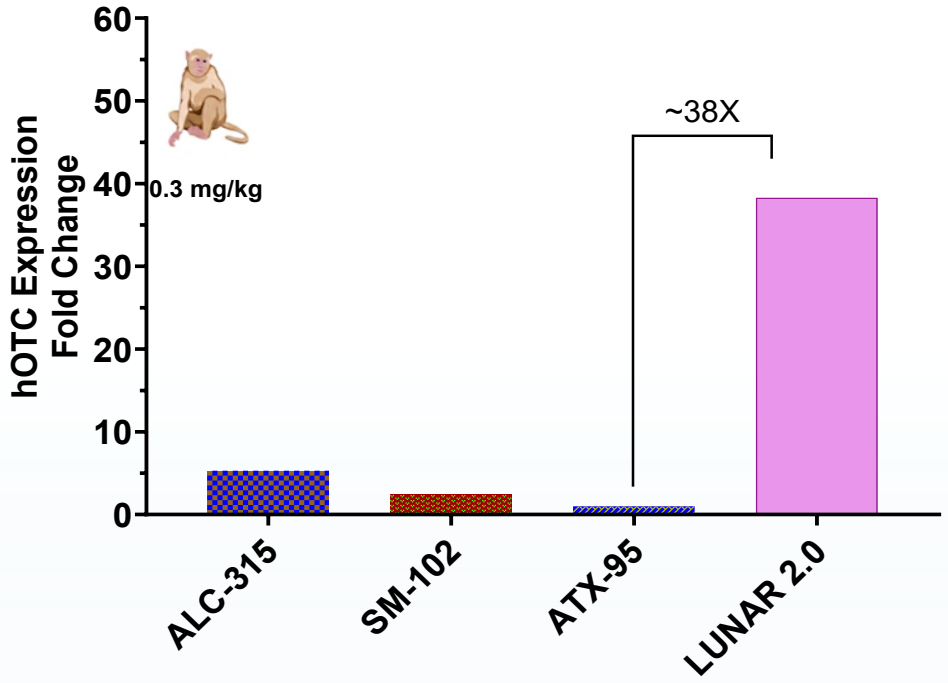
ARCT-2601 (LUNAR-OTC 2.0) treatment exhibits dose-dependent survival in lethal OTCD murine model

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LUNAR 2.0™

ARCT-2601: 38-Fold Higher hOTC Expression in NHP

compared to ATX-95 (Lipid in ARCT-810)



Relative Fold Enhancement in Human OTC Protein Expression

Lipid	Fold Enhancement Over ATX-95
ALC-315	5.3
SM-102	2.5
ATX-95 (used in ARCT-810)	1.0
LUNAR 2.0™ (used in ARCT-2601)	**38**

- NHPs (n=3) treated, and PBS control; IV 60-min infusion @ 0.3 mg/kg
- Liver biopsies 48h post-infusion analyzed for hOTC via mass spec

LUNAR 2.0™ exhibits 38-fold higher hOTC expression in NHPs compared to ATX-95 (Lipid in ARCT-810)

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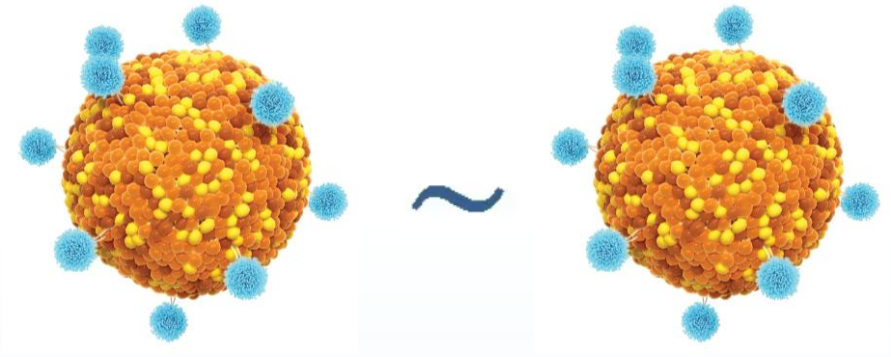
ARCT-2601 (LUNAR-OTC 2.0) Preliminary Safety Data

Three non-GLP preclinical studies, head-to-head against ARCT-810: no new findings

RODENT SAFETY STUDY · NON-GLP
No new findings versus ARCT-810

NHP TOLERABILITY STUDY · NON-GLP
No new findings versus ARCT-810

BIODISTRIBUTION
New LUNAR 2.0™ lipid clears faster



ARCT-2601
LUNAR-OTC 2.0

ARCT-810
LUNAR-OTC

No new safety signals vs. ARCT-810 — and the new LUNAR 2.0™ lipid clears faster

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ARCT-2601: FDA Feedback and Regulatory Plan

FDA Type C Meeting on ARCT-2601 Development: Conducted June 2026

- FDA agreed to leverage platform CMC, non-clinical and clinical data to accelerate the development
- FDA agreed to include ARCT-2601 as an arm in the current ongoing ARCT-810 Phase 2 study
- Evaluate preliminary safety, PK, and biomarker data for ARCT-2601 in a small number of patients
- Proceed to an adequate and well-controlled pivotal trial if the initial data are favorable

ARCT-2601 Regulatory / Clinical Plan

- IND Filing 4Q 2026: Evaluate ARCT-2601 in ongoing ARCT-810 Phase 2 study with 3–6 patients
  - Ages ≥12, with elevated baseline ammonia levels
- Advance to a Phase 2/3 pediatric study in H2 2027
  - Ages 0–12, neonatal-onset and severe late-onset patients with unmet medical needs

ARCT-2601 to be integrated into ongoing Phase 2 study as advised by the FDA

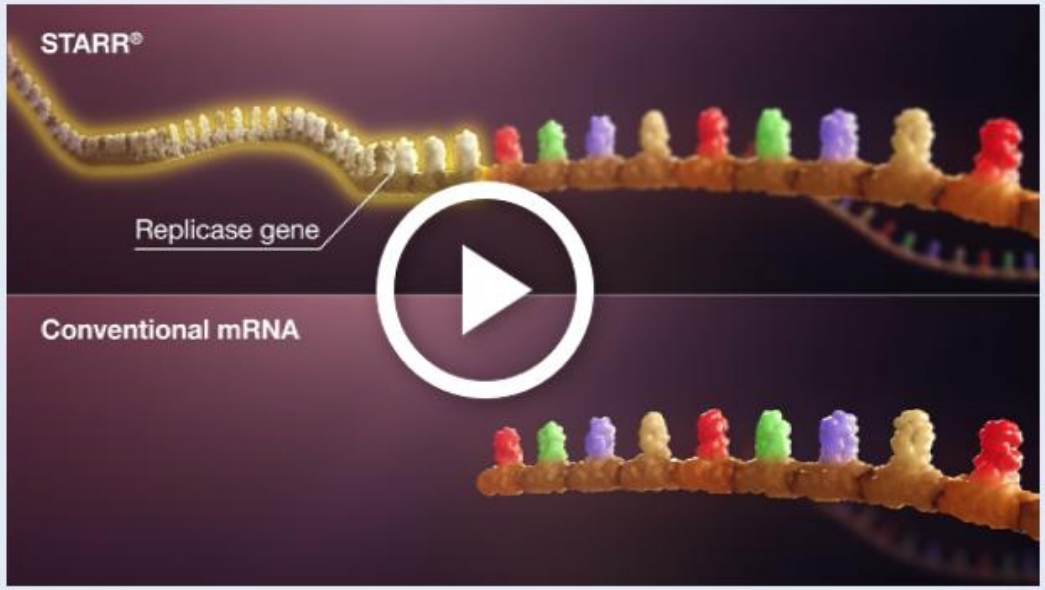
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VACCINES

ARCTURUS therapeutics

STARR® Self-amplifying mRNA Vaccine

STARR® 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

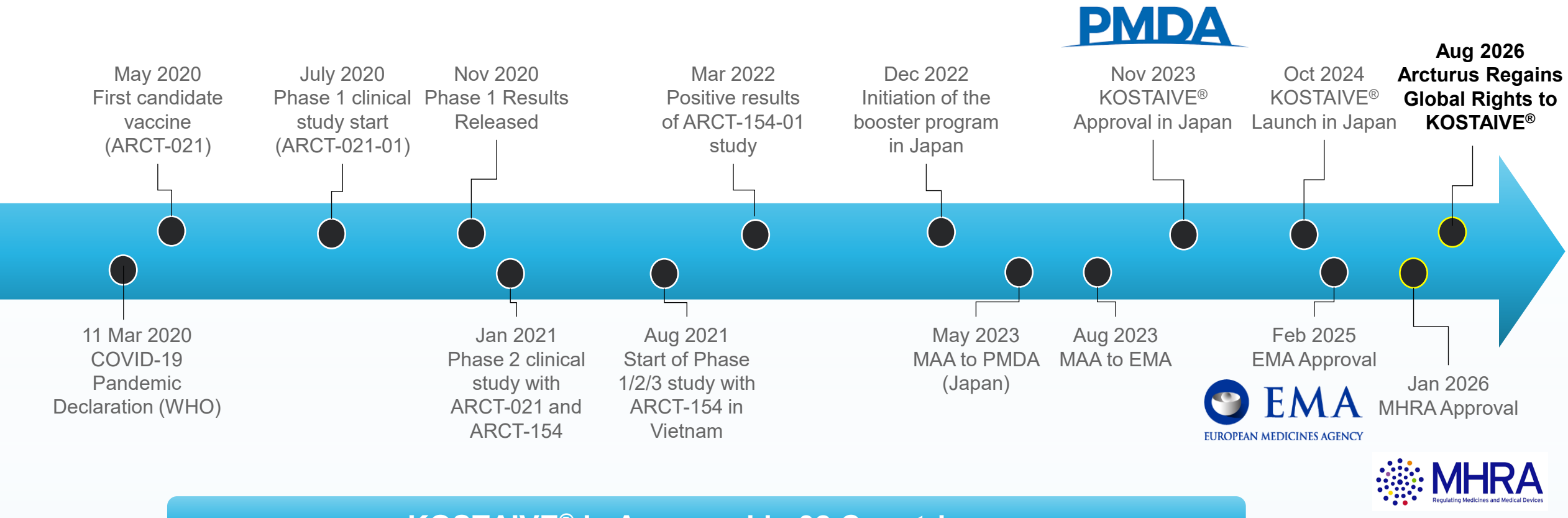
Lower dose level: Increase the potential for combined vaccines

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

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KOSTAIVE® (sa-mRNA COVID-19 Vaccine)

Key Development Milestones



KOSTAIVE® is Approved in 32 Countries

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KOSTAIVE® is Approved in 32 Countries

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.[1]

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®
- **Generally safe and well tolerated**
- **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*[2]

THE LANCET Infectious Diseases

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*[3]

1 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

[2] Yoshiaki Oda · Yuji Kumagaib · Manabu Kanaia · Yasuhiro Iwamaa · Iori Okuraa · Takeshi Minamidaa · Yukihiro Yagia · Toru Kurosawaa · Pad Chivukula · Ye Zhang · Judd L Walson. 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: 10.1016/S1473-3099(24)00615-7

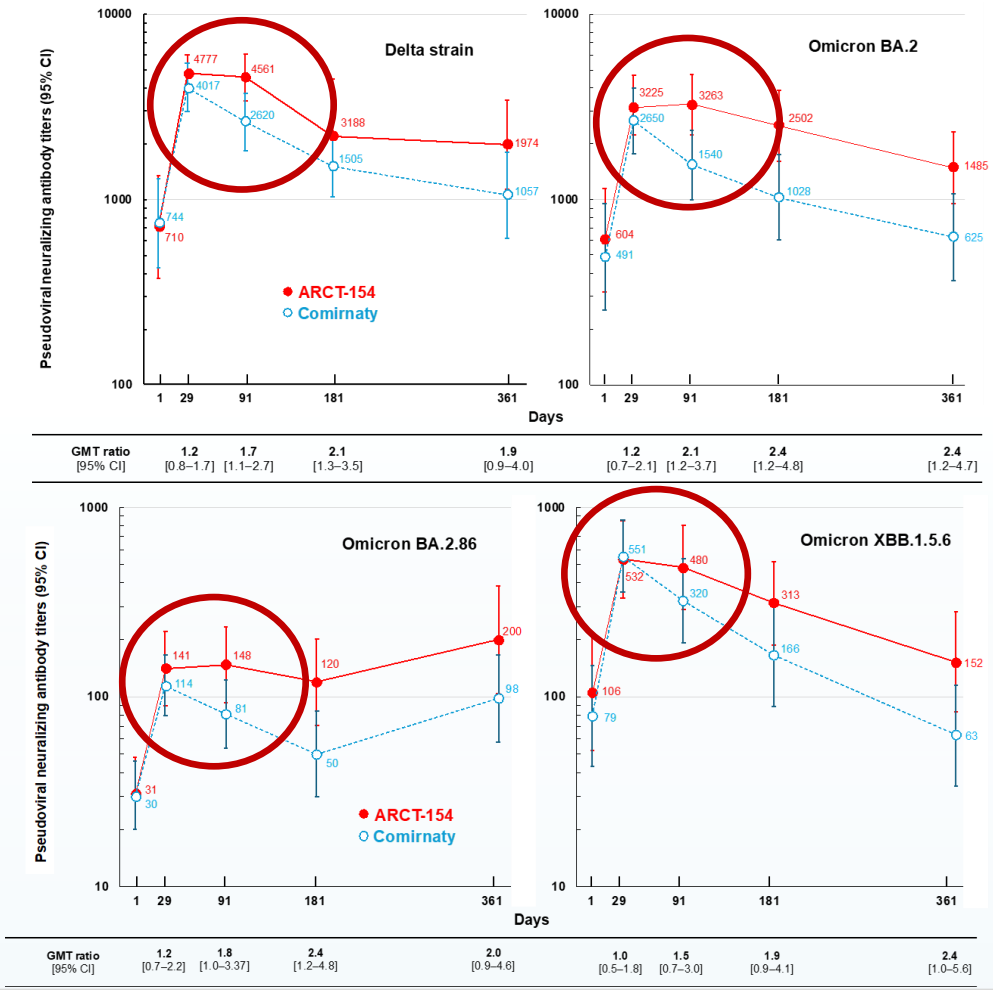
[3] Michelle L. Gilesa. Carole Verhoevenc · Igor Smolenov. Immunogenicity and safety of self-amplifying mRNA COVID-19 vaccine (ARCT-2303), with or without co-administration of seasonal inactivated influenza vaccine in adults: a phase 3, randomised, controlled, observer-blind, multicentre study, *eClinicalMedicine*,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

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KOSTAIVE® Represents a Significant Advancement in Vaccine Technology, Demonstrating Superior Immunogenicity and Antibody Persistence for up to 12 Months Post-Vaccination Compared to Conventional mRNA COVID-19 Vaccines in Clinical Trials

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

ARCTURUS therapeutics

LUNAR-H5N1 (ARCT-2304)

Arcturus published the results of the Phase 1 study of the sa-mRNA pandemic influenza vaccine in Nature Communications, indicating immunological benefits versus standard of care, a favorable safety profile, and the potential for a single-dose pandemic response[1]

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

The Immunogenicity, Reactogenicity, and Safety Data Support Further Development of ARCT-2304 candidate

[1] Pragalos, A.A., Pacciarini, F., Jin, H. *et al.* Extended dosing intervals enhance the durability of a self-amplifying mRNA vaccine against pandemic H5N1 influenza: a randomized, observer-blind, dose-finding Phase I study. *Nat Commun* **17**, 11091 (2026). https://doi.org/10.1038/s41467-026-78031-9

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