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Arcturus Therapeutics

Global Late-Stage Clinical mRNA Medicines Company

Nasdaq: ARCT

Headquarters: San Diego, CA

Employees: 200

Founded: 2013

mRNA Medicine Candidates

LUNAR-OTC Ornithine Transcarbamylase Deficiency

LUNAR-CF Cystic Fibrosis

Additional Earlier Stage Programs

Multiple Strategic Partners

CSL

ultragenyx

Cystic Fibrosis Foundation

BARD
Proprietary mRNA Technologies Driving Therapeutic Programs

Broad Intellectual Property Portfolio

**mRNA Technology**
- mRNA for protein replacement
- Self-amplifying mRNA (STARR™)
- low-dose vaccine technology

**LUNAR® Delivery**
- Hepatocytes – *intravenous*
- Myocytes – *intramuscular*
- Bronchial Cells – *inhaled*

**Manufacturing Know-How**
- mRNA Drug Substance Production
- mRNA Purification
- LNP Drug Product Production
- Fill Finish / Lyophilization

280+ Patents & Patent Applications
### Pipeline of Arcturus-Owned mRNA Therapeutic Candidates

<table>
<thead>
<tr>
<th>Franchise</th>
<th>Candidate</th>
<th>Funded By</th>
<th>Indication</th>
<th>Global Prevalence</th>
<th>Upcoming Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatic</td>
<td>LUNAR-OTC (ARCT-810)</td>
<td>Arcturus Therapeutics</td>
<td>Ornithine Transcarbamylase Deficiency</td>
<td>&gt; 10,000</td>
<td>Phase 2 Interim Data 2023</td>
</tr>
<tr>
<td>Respiratory</td>
<td>LUNAR-CF (ARCT-032)</td>
<td>Cystic Fibrosis Foundation</td>
<td>Cystic Fibrosis</td>
<td>85,000-100,000</td>
<td>Phase 1 Data 2023</td>
</tr>
</tbody>
</table>
## Pipeline of Partnered mRNA Therapeutics and Vaccines

<table>
<thead>
<tr>
<th>Franchise</th>
<th>Candidate</th>
<th>Partner</th>
<th>Indication</th>
<th>Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine</td>
<td>LUNAR-COV19 (ARCT-154)</td>
<td>CSL™</td>
<td>COVID-19</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Vaccine</td>
<td>LUNAR-FLU (Seasonal)</td>
<td>CSL™</td>
<td>Seasonal Influenza</td>
<td>Pre-clinical</td>
</tr>
<tr>
<td>Vaccine</td>
<td>LUNAR-FLU (Pandemic)</td>
<td>BARDA™</td>
<td>Pandemic Influenza</td>
<td>Pre-clinical</td>
</tr>
</tbody>
</table>
CSL Vaccine Partnership

Deal Value: Up to $4.5 billion

• Collaboration combines CSL’s global vaccine commercial and manufacturing infrastructure with Arcturus’ expertise in mRNA design and modification, LUNAR® lipid nanoparticle (LNP) technology and manufacturing know-how.

• Deal terms encompass the development, manufacture, and commercialization of mRNA-based vaccines targeting COVID-19, Influenza, and three other respiratory infectious disease vaccines.

Terms of the Partnership

<table>
<thead>
<tr>
<th>CSL™</th>
<th>ARCTURUS® therapeutics</th>
</tr>
</thead>
<tbody>
<tr>
<td>$200 million</td>
<td>Upfront Payment</td>
</tr>
<tr>
<td>$1.3 billion</td>
<td>Development Milestones</td>
</tr>
<tr>
<td>$3.0 billion</td>
<td>Commercial Milestones</td>
</tr>
</tbody>
</table>

40% profit sharing for COVID-19 vaccines

Up to double digit royalties for influenza and three additional respiratory infectious disease vaccines
Meiji Seika Pharma Japan Phase 3 Trial of ARCT-154

Trial to test self-amplifying mRNA vaccine ARCT-154 as a booster compared to Comirnaty®

Background
- Japan has high rate of covid vaccinations and boosters: > 2.9 doses / person (source: NY Times Jan 2023)
- Meiji Seika Pharma received rights to conduct ARCT-154 clinical study in Japan
- Meiji Seika Pharma received significant subsidy from Japanese government in Q4 2022
- Meiji Seika Pharma entered into agreement with CSL Seqirus; responsible for distribution and sales of ARCT-154 in Japan

Study Design Summary
- Phase 3 Non-inferiority safety and immunogenicity trial
- Conducted in Japan, fully funded by Meiji Seika Pharma
- Test ARCT-154 as a booster compared to Comirnaty®
- The ARCT-154 Phase 3 study being conducted by Meiji Seiki Pharma has completed enrollment (N=828)
  - 50% of participants received ARCT-154 (5 mcg); 50% of participants received Comirnaty® (30 mcg)

Study Update
- Study initiated Dec 2022; enrollment completed Feb 2023
- NDA submitted Apr 2023 to Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) for primary immunization
- Interim Phase 3 booster trial results submitted to the PMDA Q2 2023
- NDA submitted Jun 2023 to PMDA for booster use

Manufacturing Update
- $23.6 Million advanced for the manufacturing and supply of ARCT-154

ARCT-154 has opportunity for PMDA approval in 2023
ARCT-810

Systemically Delivered mRNA for Ornithine Transcarbamylase (OTC) Deficiency
LUNAR® - Lipid Nanoparticle (LNP) Delivery Technology
Proprietary, Biodegradable, Optimized for Each Cell Type

1. LUNAR® interacts with cell membrane
2. LUNAR® internalized inside endosome
3. mRNA release
4. mRNA translated into protein of interest
The most common urea cycle disorder
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.
10,000 worldwide prevalence.

Unmet Medical Need
Present standard of care involves a strict diet (low protein, high fluid intake) plus ammonia scavengers (e.g. glycerol phenylbutyrate).
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.
LUNAR-OTC
Exceeds Target of 5% Enzyme Replacement in OTC-Deficient Mouse Model

• OTC deficiency impacts ureagenesis (ammonia detoxification)

• The main site of ureagenesis is the periportal region of the liver*

• The critical threshold of 5% residual enzymatic OTC activity helps avoid severe manifestations of the disease (neonatal coma, mortality)*

LUNAR-OTC treatment increases OTC expression in mouse periportal hepatocytes (main site of ureagenesis)

*Liu, L. et al. PGC-1α Promotes Ureagenesis in Mouse Periportal Hepatocytes through SIRT3 and SIRT5 in Response to Glucagon. Scientific Reports. 6:24156 | DOI: 10.1038/srep24156, April 2016


ARCT-810 Clinical Update

Phase 1 (NZ) Study in Healthy Volunteers
• Completed dosing up to 0.4 mg/kg, total number of subjects N = 24, generally safe and well tolerated

Phase 1b (U.S.) Single Ascending Dose (SAD) Study in OTCD Adults
• Completed enrollment of three cohorts (0.2, 0.3, and 0.4 mg/kg) in Nov 2022
• No serious or severe adverse events
• Initiated screening of fourth cohort (0.5 mg/kg, N = 4)
• Total number of subjects to be expanded to N = 16

Phase 2 (UK and EU) Single and Multiple Ascending Dose, Placebo-controlled Study in OTCD Adolescents & Adults
• Enrolling up to 24 subjects across two dose cohorts
• Interim data this year (2023)
  • Primary Endpoints: Safety and tolerability
  • Secondary Endpoints: PK and PD measures (ureagenesis assay, 24-hr ammonia profile)
  • Exploratory Endpoints: Plasma amino acids and OTC enzyme activity; urine orotic acid

Interim Phase 2 data expected in 2023 in conjunction with the announcement of additional liver therapeutic programs
ARCT-032

Inhaled mRNA Therapeutic Candidate for Cystic Fibrosis
Cystic Fibrosis
ARCT-032 Market Opportunity

Cystic Fibrosis
85,000-100,000 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
Highly effective CFTR modulators are not approved for treatment of all people with CF and may not be tolerated in others.
Standard of care therapies do not prevent the chronic, progressive loss of lung function that ultimately requires lung transplantation or leads to early death

LUNAR-CF Aims to Restore CFTR Function
An mRNA replacement therapy has the potential to produce wild-type CFTR into 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
LUNAR®-mRNA in Healthy Animals (four different species)
Successful delivery to airway epithelium; transduction demonstrated by Brown and Green staining

LUNAR® delivery to airway epithelium is demonstrated in rodent and non-rodent species
LUNAR®-mRNA in Cystic Fibrosis Ferret Model
Successfully Transduces Epithelium in the Presence of CF Mucus

LUNAR® effectively delivers mRNA expressing Cre in a Ferret CF Model (G551D)

Green denotes functional expression of protein (Cre)

In collaboration with Univ. of Iowa John Engelhardt and Xioming Liu
High Expression Levels of CFTR protein

Restored chloride activity (chloride gradient)

**P<0.01; Data from two F508del donors; Using chamber studies performed with chloride secretory gradient

Restoration of CFTR expression and function in CF human bronchial epithelial cells
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