Arcturus Reports Strong Three-Month Durability Results from ARCT-154 Booster Trial

May 5, 2022

Three-month data from ARCT-154 booster trial show persistent neutralizing antibody activity against multiple variants of SARS-CoV-2

International pivotal Phase 3 booster trial preparations initiated with global CRO

SAN DIEGO--(BUSINESS WIRE)--May 5, 2022-- Arcturus Therapeutics Holdings Inc. (the “Company”, “Arcturus”, Nasdaq: ARCT), a global late-stage clinical messenger RNA medicines company focused on the development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases, today provided updated data from its Phase 1/2 booster clinical trial showing durability of antibody response with ARCT-154 for at least three months after low-dose (5 mcg) booster.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20220505005501/en/

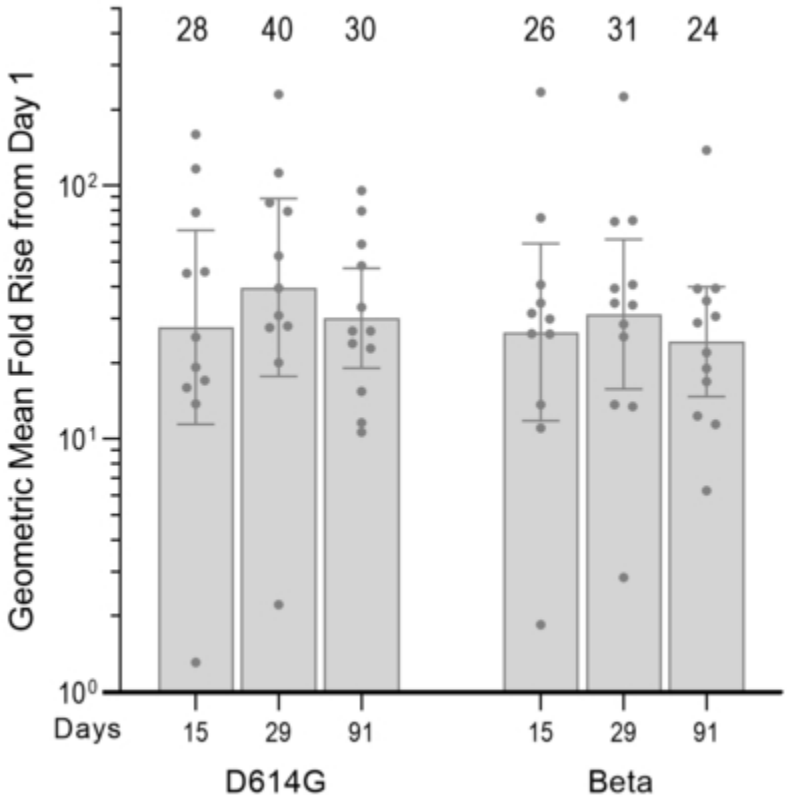

Figure 1: Validated pseudovirus microneutralization (MNT) assay results (left: D614G; right: Beta), showing GMFR levels of neutralizing antibody responses over Day 1 (baseline levels prior to boosting with ARCT-154) calculated with virus neutralization concentrations (with 95% confidence intervals) obtained for participants (for D614G: n = 12/12 for Days 1, 91 and 11/12 for Days 15 29; For Beta: n = 12/12 for Days 1, 29, 91 and 11/12 for Day 15). (Graphic: Business Wire)

“We are very pleased to see our self-amplifying mRNA vaccine ARCT-154 demonstrate meaningful and durable increases of neutralizing antibodies against SARS-CoV-2 and variants of concern – for at least three months,” said Joseph Payne, President and CEO of Arcturus Therapeutics. “These results provide additional validation of Arcturus’ next generation STARR™ mRNA technology for vaccines.”

In the ARCT-154 arm of the ongoing Phase 1/2 booster study in the U.S. and Singapore, data from neutralizing antibody assays demonstrate that booster vaccination generated strong immune responses, both with respect to the magnitude of response and duration of response for at least three months post-boost. Twelve participants in this arm received 5 mcg of ARCT-154 at least five months after receiving two primary doses of Comirnaty®. Results from validated pseudovirus microneutralization assay (MNT) to detect responses against the D614G SARS-CoV-2 strain (Figure 1, left) show a single 5 mcg dose of ARCT-154 led to neutralizing antibody responses that remained 30-fold ($p = 0.007$) elevated for geometric mean fold rise (GMFR) over baseline (pre-boost) levels at three months after vaccination. 28-fold and 40-fold increases in neutralizing antibody responses from baseline levels were seen on Day 15 and Day 29, respectively. Validated pseudovirus MNT assay for the Beta strain also demonstrated notable durability of neutralizing antibody response with 24-fold ($p = 0.017$) GMFR at three months after booster vaccination, compared to 26-fold and 31-fold over baseline on Day 15 and Day 29, respectively (Figure 1, right).

Similar to the microneutralization responses, surrogate virus neutralization (sVNT) assay results evaluating a panel of SARS-CoV-2 strains (Figure 2) also illustrated persistent and broad neutralizing antibody responses. Three months following booster dose administration of ARCT-154, antibody responses remained 13 to 30-fold elevated over Day 1 (pre-boost) baseline for all SARS-CoV-2 strains tested. Samples from the trial will be further

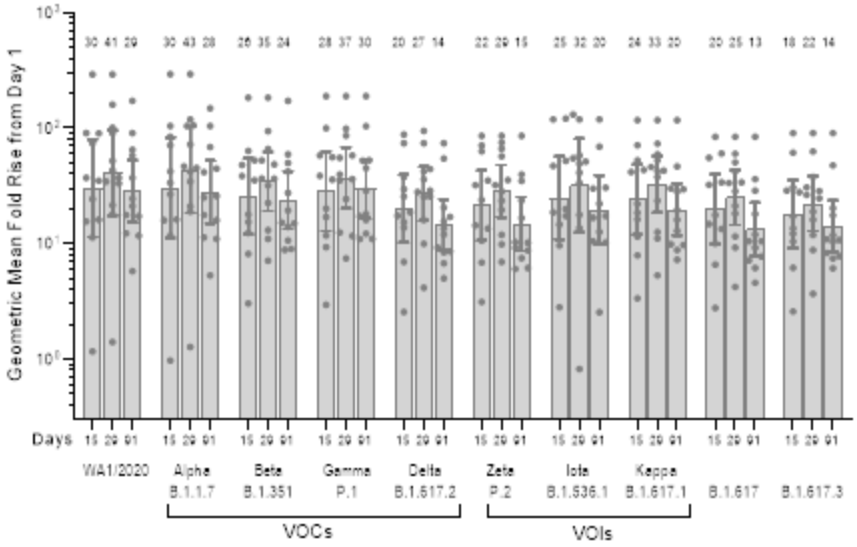

Figure 2: Surrogate virus neutralization (sVNT) assay results for SARS-CoV-2 variants. The panel shows GMFR on Days 15, 29, and 91 over Day 1 (pre-boost baseline levels; n = 12/12 for Days 1, 29, 91; n = 11/12 for Day 15). VOCs = Variants of Concern; VOIs = Variants of Interest

analyzed for neutralizing antibody activity against different strains of SARS-CoV-2, including the Omicron lineage.

The Company has initiated start-up activities with an international CRO toward a pivotal Phase 3 booster trial intended to support global registration.

About Arcturus Therapeutics

Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a clinical-stage mRNA medicines and vaccines company with enabling technologies: (i) LUNAR® lipid-mediated delivery, (ii) STARR™ mRNA Technology and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus' diverse pipeline of RNA therapeutic and vaccine candidates includes mRNA vaccine programs for SARS-CoV-2 (COVID-19) and influenza, and other programs to potentially treat ornithine transcarbamylase (OTC) deficiency, and cystic fibrosis along with partnered programs including glycogen storage disease type III (GSD III), hepatitis B virus (HBV), and non-alcoholic steatohepatitis (NASH). Arcturus' versatile RNA therapeutics platforms can be applied toward multiple types of nucleic acid medicines including messenger RNA, small interfering RNA, replicon RNA, antisense RNA, microRNA, DNA, and gene editing therapeutics. Arcturus' technologies are covered by its extensive patent portfolio (with patents and patent applications issued in the U.S., Europe, Japan, China and other countries). Arcturus' commitment to the development of novel RNA therapeutics has led to collaborations with Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, Ultragenyx Pharmaceutical, Inc., Takeda Pharmaceutical Company Limited, CureVac AG, Duke-NUS Medical School, and the Cystic Fibrosis Foundation. For more information visit www.ArcturusRx.com. In addition, please connect with us on Twitter and LinkedIn.

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