



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

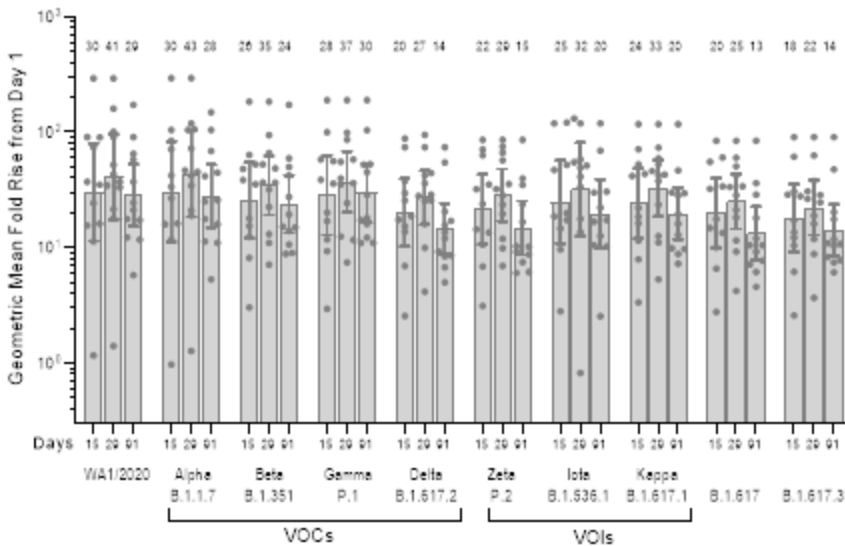
International pivotal Phase 3 booster trial preparations initiated with global CRO

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.

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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. Three 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.

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

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 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](#).

Forward Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact included in this press release, are forward-looking statements, including those regarding strategy, future operations, the expectations for or likelihood of success of any collaborations, the promise of the company's platform technologies for multiple types of nucleic acid medicines, the likelihood that ARCT-154 will be advanced or receive any regulatory approval, the likelihood that the ARCT-154 data from the booster study, or any other non-clinical or clinical data, will be predictive of future clinical results, efficacy, durability for longer periods of time or results against COVID variants, the likelihood that ARCT-154 data will be sufficient for any regulatory approval, the timing, design (including number of participants), initiation, conduct or completion of a pivotal booster study of ARCT-154 or any other clinical trial, the Company's expectation of sharing further analysis from evaluation of sera samples, the likelihood that a patent will issue from any patent application, and the impact of general business and economic conditions. Arcturus may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in any forward-looking statements such as the foregoing and you should not place undue reliance on such forward-looking statements. These statements are only current predictions or expectations, and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements, including those discussed under the heading "Risk Factors" in Arcturus' most recent Annual Report on Form 10-K, and in subsequent filings with, or submissions to, the SEC, which are available on the SEC's website at www.sec.gov. Except as otherwise required by law, Arcturus disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

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Source: Arcturus Therapeutics Holdings Inc.