# Arcturus Therapeutics Updates Data from ARCT-154 and ARCT-165 Booster Clinical Trial Demonstrating Robust Neutralizing Antibody Responses to SARS-CoV-2 and Several Variants

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*Full cohort data from the ARCT-154 (5 mcg) arm of the ongoing Phase 1/2 booster study shows 30-fold increase in neutralizing antibody geometric mean concentrations against SARS-CoV-2 at Day 15 post-boost, maintained at 28-fold increase at Day 29, using a validated pseudovirus microneutralization (MNT) assay*

*Robust neutralizing antibody responses observed post-boost for both ARCT-154 (5 mcg) and ARCT-165 (5 mcg) against several variants of concern and variants of interest in a surrogate virus neutralization (sVNT) assay*

SAN DIEGO--(BUSINESS WIRE)--Jan. 24, 2022-- Arcturus Therapeutics Holdings Inc. (the “Company”, “Arcturus”, Nasdaq: ARCT), a leading clinical-stage messenger RNA medicines company focused on the development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases, today announced updated data from clinical development programs for ARCT-154 and ARCT-165, its investigational, next-generation, self-amplifying mRNA vaccine candidates targeting the variants of concern.

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Figure 1: Pseudovirus (D614G variant) microneutralization (MNT) assay results. Virus neutralization concentrations (arbitrary units per milliliter, AU/mL) for participants at Day 1 (prior to boosting), and Days 15 and 29 after boosting with ARCT-154 (left; n = 12/12 for Days 1 and 29, 11/12 for Day 15) and ARCT-165 (right; n = 12/12 all time points). Within each panel, the left graphic shows values from individuals, and the right graphic shows the geometric mean neutralization concentrations, with 95% confidence intervals. The multiples are fold rises of neutralization concentrations on Day 15 and Day 29, respectively, over Day 1 values. (Graphic: Business Wire)

Figure 2: Surrogate virus neutralization (sVNT) assay results for SARS-CoV-2 variants. Top panels show geometric mean concentrations and 95% confidence intervals on Day 1 (prior to boosting), and Days 15 and Day 29 post-boost administration with ARCT-154 (left; n = 12/12 for Days 1 and 29, 11/12 for Day 15) and ARCT-165 (right; n = 12/12 all time points). The bottom panels show the results for individual participants for the Beta and Delta variants on Day 1 (prior to boosting), and Days 15 and 29 post-boost. VOC: variant of concern; VOI: variant of interest; ULOQ: upper limit of quantification; LLOQ: lower limit of quantification (Graphic: Business Wire)

Data from the Phase 1/2 booster trial, sponsored by Arcturus and currently ongoing in U.S. and Singapore, show that both ARCT-154 and ARCT-165, when administered as low-dose (5 mcg) boosters at least five months following initial vaccination with Comirnaty®, demonstrated robust geometric mean antibody responses against SARS-CoV-2 as measured in a validated pseudovirus microneutralization (MNT, D614G) assay and neutralizing antibody concentrations were maintained between 15 and 29 days post-administration. These results, along with the robust levels of neutralizing antibodies recorded against several variants of concern (including Alpha, Beta, Gamma, and Delta) in this study, as measured by a surrogate virus neutralization (sVNT) assay are expected to support further clinical development of these candidates as booster vaccines.

“We continue to gather highly encouraging data from our next-generation, self-amplifying mRNA vaccine candidates ARCT-154 and ARCT-165 that have now both demonstrated encouraging neutralizing antibody concentrations against a broad range of variants upon boosting,” said Joseph Payne, President and CEO of Arcturus Therapeutics. “We believe the STARR™ self-amplifying mRNA technology is an ideal platform that could address the ongoing need for updated booster vaccines at substantially lower dose levels, not just for COVID-19, but also for other infectious diseases.”

In the ARCT-154 and ARCT-165 arms of the booster cohort of the ongoing Phase 1/2 study being conducted in the U.S. and Singapore, 24 participants divided into two equal groups of 12 received 5 micrograms of ARCT-154 or ARCT-165 following primary vaccination with Comirnaty® at least 5 months earlier. All participants were below 65 years of age at the time of receiving the booster dose. Figures 1 and 2 show the Day 15 and Day 29 post-boost results from validated pseudovirus microneutralization (MNT) and exploratory surrogate virus neutralization (sVNT) assays, respectively, performed with sera from the participants in the ARCT-154 and ARCT-165 groups.

**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 likelihood of success (including safety and efficacy) of the Company's platform or pipeline (including ARCT-154 and ARCT-165), the Company's efforts to develop a vaccine against COVID-19 and therapeutic potential thereof based on the Company's mRNA therapeutics, the planned initiation, design or completion of clinical trials, the likelihood that the Company will obtain clearance from regulatory authorities to proceed with future planned clinical trials, the likelihood that preclinical or clinical data will be predictive of future clinical results (including with respect to safety, immunogenicity and efficacy), the likelihood that a preliminary, interim or partial data set will be representative of a complete or larger data set, the likelihood that clinical data will be sufficient to support further clinical development, for regulatory approval or will be completed in time to submit an application for regulatory approval within a particular timeframe, 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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