Arcturus Reports Durability Data Against Omicron Variants, Including BA.5, at Six-Month Timepoint Following Booster with ARCT-154 COVID-19 Vaccine

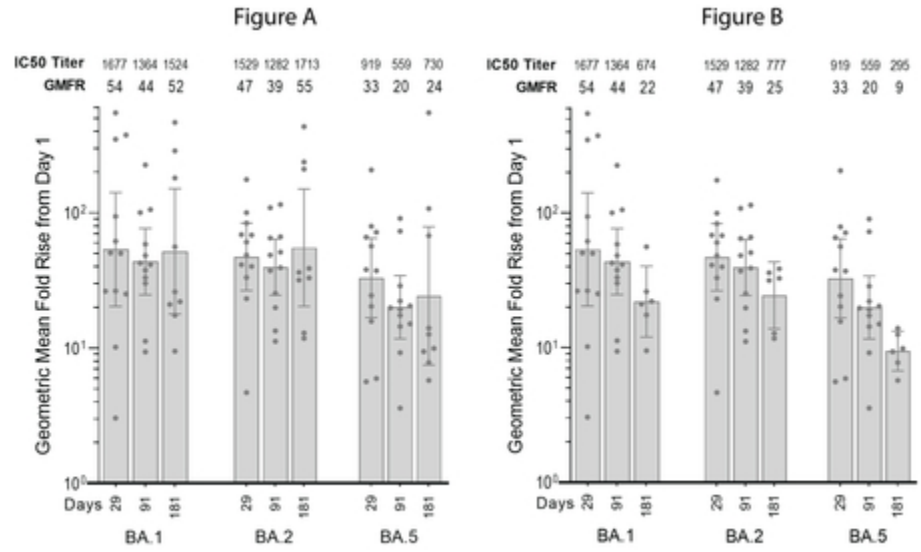
August 18, 2022

New clinical data demonstrate high and sustained geometric mean fold rises (GMFR) in neutralizing antibodies against all evaluated Omicron variants

Six months after booster dose of ARCT-154:
BA.1: GMFR = 22 to 52; Titer = 674 to 1524
BA.2: GMFR = 25 to 55; Titer = 777 to 1713
BA.5: GMFR = 9 to 24; Titer = 295 to 730

SAN DIEGO--(BUSINESS WIRE)--Aug. 18, 2022-- Arcturus Therapeutics Holdings Inc. (the “Company”, “Arcturus”, “Arcturus Therapeutics”, 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 announced updated data from its ongoing ARCT-154 booster clinical trial. The new results demonstrate broad neutralizing antibody response against Omicron variants of concern, including BA.5, lasting for up to at least six months after administration of low-dose (5 mcg) ARCT-154 booster.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20220818005266/en/



Exploratory pseudovirus microneutralization (MNT) assay results (left: BA.1, middle: BA.2, right: BA.5), showing geometric mean fold rise (GMFR) levels of neutralizing antibody responses over Day 1 (baseline levels prior to boosting with 5 mcg ARCT-154) calculated with virus neutralization concentrations (with 95% C.I.) obtained for n=12 participants at days 29 and 91. In Figure A, three participants were removed from the day 181 analysis (n=9, day 181): two participants received off-study vaccines during the period between day 91 and day 181, and one participant has a confirmed COVID-19 diagnosis with mild symptoms during this same period. In Figure B, three additional participants with suspected asymptomatic seroconversion were removed from the day 181 analysis (n=6, day 181). Neutralizing antibody responses against Omicron variants BA.1, BA.2, and BA.5 were measured at the Moore Lab in South Africa. (Graphic: Business Wire)

“Our next generation low-dose self-amplifying (STARR™) mRNA technology continues to differentiate itself from conventional mRNA vaccine technology as a highly and broadly immunogenic endemic vaccine platform with durable responses against the most challenging variants including Omicron BA.5 for at least 6 months,” said Joseph Payne, President and CEO of Arcturus Therapeutics. “Further validation of the breadth and duration for the immune responses to ARCT-154 are planned in upcoming pivotal clinical trial activities.”

Data shown above illustrate the ongoing antibody responses to single, low (5 microgram) booster doses of ARCT-154 in healthy adults (n=12) previously vaccinated with Comirnaty®. Samples taken at one, three, and six months after vaccination are shown.

After one month (day 29) and three months (day 91), neutralizing antibody responses to Omicron BA.5 were 33- and 20-fold elevated over pre-boost responses, respectively. After six months (day 181), neutralizing antibody responses to Omicron BA.1, BA.2, BA.5 ranged from 22- to 52-fold, 25- to 55-fold, and 9 to 24-fold elevated over pre-boost responses, respectively.

These data show sustained neutralizing responses to antigenically distinct variants of concern, including Omicron BA.5, for at least six months after vaccination.

About Arcturus Therapeutics

Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a global late-stage clinical mRNA medicines and vaccines company with enabling technologies: (i) LUNAR® lipid-mediated delivery, (ii) STARR™ mRNA Technology (samRNA) 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, and hepatitis B virus. 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 protected by 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 including, amongst others, Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, Ultragenyx Pharmaceutical, Inc., and the Cystic Fibrosis Foundation. Please connect with us on Twitter and LinkedIn. For more information visit www.ArcturusRx.com.

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 pipeline (including ARCT-154), the likelihood that the updated data from the ongoing ARCT-154 booster trial will be predictive of future clinical results (including with respect to safety, immunogenicity and efficacy), the planned initiation, design or completion of a pivotal booster trial, 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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