Twist Bioscience Announces Positive Preclinical Data for SARS-CoV-2 Antibodies

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 23, 2020-- Twist Bioscience Corporation (Nasdaq: TWST) today announced preclinical data for three of its proprietary antibodies against the S1 protein in SARS-CoV-2, the virus that causes COVID-19. The data show that TB202-3 and TB202-63, both single domain VHH “nanobodies,” protect against weight loss, a key indicator of disease severity, at the lowest dose of 1 mg/kg in a preclinical hamster challenge model. In addition, TB181-36, an IgG antibody discovered through Twist’s collaboration with Vanderbilt University Medical Center (VUMC), was found to protect against weight loss at 5 mg/kg and 10 mg/kg.

“We are highly encouraged that the antibodies we discovered using our proprietary platform demonstrated equivalent protection against weight loss when compared to convalescent plasma in preclinical studies,” said Emily M. Leproust, Ph.D., CEO and co-founder of Twist Bioscience. “In addition to applicability in traditional development pathways for therapeutics and diagnostics, the small size, selectivity and active neutralization of our single domain VHH antibodies could potentially enable new approaches to treatment, prevention and diagnosis of COVID-19. We believe one such opportunity would be a preventive daily nasal spray that would block aerosolized particles of the SARS-CoV-2 virus from entering the nasal passage and therefore the body.”

Preclinical studies of TB202-63, TB202-3 and TB181-36 were conducted at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). Immunosuppressed animals were given 1, 5 or 10 mg/kg of each of the Twist antibodies, and were assessed for weight loss. Animals treated with all doses of TB202-63 and TB202-3 were protected against weight loss, whereas control animals lost a mean of 11.7% of their body weight. Animals treated with the higher two doses of TB181-36 were protected against weight loss.

“With cases rising globally and a need for effective SARS-CoV-2 treatments, nanobodies, with their very small size, may offer an advantage over traditional antibodies. For example, they could be delivered intranasally to prevent infection or reduce transmission; or they could be part of a more conventional therapeutic treatment regimen,” commented Jay Hooper, Ph.D., chief of the molecular virology branch at USAMRIID. “The preclinical data are supported by live-virus neutralization testing we conducted, and we look forward to working with Twist on next steps.”

TB202-63 and TB202-3 are single domain VHH “nanobody” candidates identified by Twist Biopharma, a division of Twist Bioscience, by screening its proprietary synthetic antibody discovery libraries each containing more than 10 billion single domain antibody sequences. These antibodies potently neutralize SARS-CoV-2 live virus *in vitro* by binding the S1 receptor binding domain and directly blocking its binding to ACE2 receptors found in humans and other susceptible animals such as mink and cats.

TB181-36 is an IgG antibody based upon antibodies identified in individuals who recovered from COVID-19 in a collaborative research project with Vanderbilt University Medical Center researchers James E. Crowe, Jr and Robert Carnahan in the Vanderbilt Vaccine Center. The intellectual property covering such antibodies was later licensed by Vanderbilt University to Twist Biopharma for use in product development. Because the human immune system naturally generates a variety of antibodies against specific foreign invaders, including SARS-CoV-2, the virus that causes COVID-19, antibodies from recovered individuals have the potential to treat other people infected with the virus. Twist Biopharma built a proprietary synthetic antibody discovery library based on these sequences to identify the antibodies, one of which is TB181-36, which also neutralizes live SARS-CoV-2 virus *in vitro.* Unlike our single domain leads that directly block ACE2 binding, this antibody binds a unique epitope on the N terminal domain of S1 and neutralizes the virus through an alternate mechanism.

Twist intends to explore opportunities for further development of all three antibodies both internally and potentially with partners.

About Twist Biopharma Antibodies

About 75 percent of the antibodies in the blood are IgGs. IgGs are made up of two heavy protein chains and two light protein chains that must pair together and cooperate to specifically recognize a target, in this case the Spike Protein on SARS-CoV-2. This specific targeting affords our immune systems “memory,” allowing it to selectively and precisely eliminate pathogenic threats.

Target recognition by VHH single domains, on the other hand, requires just a single domain found on heavy chain only antibody. With VHH-based antibodies able to exhibit pharmaceutically relevant properties comparable to IgGs, they are a promising therapeutic with several advantages over their bulkier, more complex counterparts. The small size of VHH antibodies means they can squeeze into spaces and bind or block to parts of molecules that would otherwise be inaccessible to human IgG antibodies. They are also more thermally and chemically stable, making VHH-based therapeutics good candidates to address respiratory infections, administered by inhaler directly to the respiratory tract where the infection is concentrated. In addition, the small size simplifies manufacturing of VHH antibodies.

In addition to SARS-CoV-2, Twist Biopharma discovers and develops IgG and VHH antibodies to numerous different targets for partners and internal development.

About the U.S. Army Medical Research Institute of Infectious Diseases

For over 50 years, USAMRIID has provided leading edge medical capabilities to deter and defend against current and emerging biological threat agents. The Institute is the only laboratory in the Department of Defense equipped to safely study highly hazardous viruses requiring maximum containment at Biosafety Level 4. Research conducted at USAMRIID leads to medical solutions – vaccines, drugs, diagnostics, information, and

training programs – that benefit both military personnel and civilians. Established in 1969, the Institute plays a key role as the lead military medical research laboratory for the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Development Command. For more information, visit www.usamriid.army.mil.

The information contained in this press release does not necessarily reflect the position or the policy of the Government and no official endorsement should be inferred.

About Twist Bioscience Corporation

Twist Bioscience is a leading and rapidly growing synthetic biology and genomics company that has developed a disruptive DNA synthesis platform to industrialize the engineering of biology. The core of the platform is a proprietary technology that pioneers a new method of manufacturing synthetic DNA by "writing" DNA on a silicon chip. Twist is leveraging its unique technology to manufacture a broad range of synthetic DNA-based products, including synthetic genes, tools for next-generation sequencing (NGS) preparation, and antibody libraries for drug discovery and development. Twist is also pursuing longer-term opportunities in digital data storage in DNA and biologics drug discovery. Twist makes products for use across many industries including healthcare, industrial chemicals, agriculture and academic research.

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This press release contains forward-looking statements. All statements other than statements of historical facts contained herein, including but not limited to the effectiveness of the monoclonal antibody and VHH nanobody candidates identified by Twist Biopharma as therapeutics for COVID-19, are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause Twist's actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties of the duration, extent and impact of the COVID-19 pandemic, including any reductions in demand for our products (or deferred or canceled orders) globally or in certain regions; the ability to attract new customers and retain and grow sales from existing customers; risks and uncertainties of rapidly changing technologies and extensive competition in synthetic biology could make the products Twist is developing obsolete or non-competitive; uncertainties of the retention of a significant customer; supply chain and other disruptions caused by the COVID-19 pandemic or otherwise; risks of third party claims alleging infringement of patents and proprietary rights or seeking to invalidate Twist's patents or proprietary rights; and the risk that Twist's proprietary rights may be insufficient to protect its technologies. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Twist's business in general, see Twist's risk factors set forth in Twist's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 12, 2020 and subsequent filings with the SEC. In addition, many of the foregoing risks and uncertainties are, and could be, exacerbated by the COVID-19 pandemic and any worsening of global or regional business and economic environment as a result. We cannot at this time predict the extent of the impact of the COVID-19 pandemic and any resulting business or economic impact, but it could have a material adverse effect on our business, financial condition, results of operations and cash flows. Any forward-looking statements contained in this press release speak only as of the date hereof, and Twist Bioscience specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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