

## Lilly Announces Start of a Phase 1 Study for its Second Potential COVID-19 Antibody Treatment

June 8, 2020

- The first healthy volunteer has been dosed in a Phase 1 study of JS016, the lead antibody from Lilly's collaboration with Junshi Biosciences
- Junshi Biosciences is conducting its Phase 1 study in China with Lilly to imminently begin its Phase 1 study in the United States
  - Lilly will evaluate efficacy of JS016 as both a single agent and a combination with other antibody treatments in COVID-19 patients
- Should Phase 1 results show the antibody can be safely administered, the companies will initiate Phase 2 studies to assess efficacy

INDIANAPOLIS, June 8, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today its partner Junshi Biosciences (HKEX: 1877) has dosed the first healthy volunteer in a study of a potential neutralizing antibody treatment designed to fight COVID-19.

The investigational medicine, referred to as JS016, is being co-developed by Junshi Biosciences and Lilly, with Junshi Biosciences leading development in Greater China. Lilly has exclusive rights in the rest of the world and will begin dosing patients in a complementary Phase 1 study in the United States in the coming days. Both Phase 1 studies aim to evaluate the safety, tolerability, pharmacokinetics and immunogenicity of JS016 in healthy participants who have not been diagnosed with COVID-19. This is Lilly's second neutralizing antibody to start clinical trials, following LY-CoV555 that recently entered Phase 1 and is currently being tested in hospitalized COVID-19 patients.

Lilly is planning a clinical development program which includes a portfolio of monotherapy and combination antibody regimens (the latter often referred to as antibody "cocktails") in order to understand which provide the best efficacy and tolerability in patients. These cocktails will include JS016, LY-CoV555, as well as additional antibodies currently in preclinical development. JS016 and LY-CoV555 bind different epitopes on the spike protein and thus expand the diversity of options for achieving efficacy and avoiding resistance.

"There is much we still don't know about COVID-19," said Daniel Skovronsky, M.D., Ph.D., Lilly's chief scientific officer and president of Lilly Research Laboratories. "The best path to learn more about the potential for neutralizing antibodies, either as monotherapy or in combination, is through carefully controlled randomized trials. We look forward to the results of such trials in the coming months."

# About JS016

JS016 is a recombinant fully human monoclonal neutralizing antibody, which has been modified to diminish effector function. JS016 specifically binds to the SARS-CoV-2 surface spike protein receptor binding domain and can effectively block the binding of viruses to the ACE2 host cell surface receptor. The project is jointly developed by Junshi Biosciences and Institute of Microbiology, Chinese Academy of Science, with Junshi Biosciences leading development in Greater China and Lilly leading development in the rest of the world.

#### **About Lilly's COVID-19 Efforts**

Lilly is bringing the full force of its scientific and medical expertise to attack COVID-19 around the world. We're fighting the pandemic with everything we can: discovering potential medicines to treat and prevent COVID-19, maintaining a reliable supply of our medicines, and supporting patients and communities in times of need. Lilly is studying multiple approaches to treat COVID-19, including potential antibodies designed specifically to attack the virus and existing Lilly medicines to understand their potential in treating complications of COVID-19.

### **About Eli Lilly and Company**

Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at <a href="https://www.lilly.com">www.lilly.com</a> and <a href="https://www.lilly.com">newsroom.lilly.com</a>/social-channels.

## Lilly Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about JS016 and LY-CoV555 as potential treatments for patients with COVID-19 and reflects Lilly's current beliefs. However, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. Among other things, there can be no guarantee that JS016 and/or LY-CoV555 will prove to be effective in treating or preventing COVID-19. For a further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, please see Lilly's most recent Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements. P-LLY

Refer to: Nicole Hebert; Nicole Hebert@lilly.com; +1-317-701-9984 (media) Kevin Hern; Hern Kevin r@lilly.com; +1-317-277-1838 (investors)



C View original content to download multimedia: <a href="http://www.prnewswire.com/news-releases/lilly-announces-start-of-a-phase-1-study-for-its-second-potential-covid-19-antibody-treatment-301071911.html">http://www.prnewswire.com/news-releases/lilly-announces-start-of-a-phase-1-study-for-its-second-potential-covid-19-antibody-treatment-301071911.html</a>

SOURCE Eli Lilly and Company