

CORONASYS INNOVATION SHEET 26

FOLLOW-UP ON LY-CoV555 ANTIBODY TREATMENT

Background

This innovation sheet is a follow up on Innovationsheet No. 11 of this series from September 18th, 2020. Neutralizing antibodies are still one of the research foci in the search for a possible treatment for COVID-19¹. Several companies are researching different approaches to antibody treatment for the disease². Eli Lilly and Company published data from an interim analysis of the BLAZE-1 clinical trial³ on September 16. The data showed reduced hospitalization rates for patients treated with LY-CoV555, a SARS-CoV-2 neutralizing antibody. After further randomized- controlled trials the Federal Drug Administration (FDA) granted an Emergency Authorization for the antibody treatment now named Bamlanivimab on November 9th, 2020⁴.

Features

The antibody LY-CoV555 is one of about 500 antibodies that the immune system of one of Americas first Covid- patients had formed against SARS-CoV-2 after infection. The researchers were able to detect the B cells that produce the antibody, isolate the gene, and produce them in larger quantities using recombinant cells. The treatment consists of a single intravenous infusion of the antibodies⁵. The research was continued in the BLAZE- 1⁶ and BLAZE- 2⁷ trial as well as the ACTIV- 2⁸ and ACTIV- 3⁹ trials over the last months.

Potentials

The initial trials showed significant advantage over placebo in reducing viral load after 11 days after the mean dose of 2,800 mg. Patients with mild to moderate Covid-19 had to be hospitalized or treated by a physician at significantly lower rates than patients in the placebo group. This corresponded to an absolute risk reduction of 4.3 % and a relative risk reduction of 72%. Deaths, need for mechanical ventilation or serious side effects were not reported in the initial studies¹⁰¹¹. In the ACTIV- trials the efficacy was tested in different subsets of patients and larger cohorts. With the FDA's decision Bamlanivimab is now "authorized for the treatment of mild to moderate COVID-19 in adults and paediatric patients 12 years and older with a positive COVID-19 test, who are at high risk for progressing to severe COVID-19 and/or hospitalization"¹².

State of information:

- 18/09/2020
- Updated 11/13/2020

Launch: September 2020

Country: USA, Canada

Focus area: Treatment

Developers:

- Eli Lilly and Company in collaboration with
- AbCellera Biologics Inc.
- Shanghai Junshi Bioscience Co., Ltd.

Beneficiaries: patients with mild to moderate symptoms

Points to consider

The drug's efficacy in serious cases could not be proven which is why the company first paused¹³ and then terminated the ACTIV-3 trial with critically ill Covid-patients in October^{14,15}. It showed that the antibodies no longer have any significant effect once the disease is advanced and characterized by an excessive immune response. This is why the drug is not authorized for patients hospitalized with Covid or requiring oxygen therapy¹⁶. In order to be as effective as possible the drug should be administered as early as possible after the diagnosis. Right now, the drug is in short supply so that questions have been raised, as to who should be treated with the first doses available¹⁷. Antibodies are usually high-priced drugs¹⁸. The U.S. government has already purchased 300.000 doses for about 375. Mio US Dollars¹⁹.

Conclusion

For individual patients treated with Bamlanivimab, the drug could be a factor to save their lives and/ or regain their health. But although the drug proved to be effective in mild to moderate Covid-cases in an outpatient setting, it is in far too short supply to actually curb the virus even if the company can scale up its production and distribution capacities as planned.

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- ¹ Zhou, Guangyu, and Qi Zhao. "Perspectives on Therapeutic Neutralizing Antibodies against the Novel Coronavirus SARS-CoV-2." *International Journal of Biological Sciences* 16, no. 10 (March 15, 2020): 1718–23. <https://doi.org/10.7150/ijbs.45123>.
- ² Meredith, Sam. "Eli Lilly Reports a Reduced Rate of Hospitalization for Coronavirus Patients Using Its Antibody Treatment." *CNBC*, September 16, 2020. <https://www.cnbc.com/2020/09/16/coronavirus-eli-lilly-reports-a-reduced-rate-of-hospitalization-for-patients-using-its-antibody-treatment.html>.
- ³ U.S. National library of medicine. "A Study of LY3819253 (LY-CoV555) and LY3832479 (LY-CoV016) in Participants With Mild to Moderate COVID-19 Illness - Full Text View - ClinicalTrials.Gov." *ClinicalTrials.gov*. Accessed September 19, 2020. <https://clinicaltrials.gov/ct2/show/NCT04427501>.
- ⁴ Thomas, Katie, and Noah Weiland. "Eli Lilly's Antibody Treatment Gets Emergency F.D.A. Approval." *The New York Times*, November 10, 2020, sec. Health. <https://www.nytimes.com/2020/11/09/health/covid-antibody-treatment-eli-lilly.html>.
- ⁵ Deutsches Ärzteblatt. "COVID-19: Erstes Antikörperpräparat erzielt Schutzwirkung bei..." *Deutsches Ärzteblatt*, September 17, 2020. <https://www.aerzteblatt.de/nachrichten/116592/COVID-19-Erstes-Antikoerperpraeparat-erzielt-Schutzwirkung-bei-leichtereren-Erkrankungen>.
- ⁶ US National Library of Clinical Medicine. "A Study of LY3819253 (LY-CoV555) and LY3832479 (LY-CoV016) in Participants With Mild to Moderate COVID-19 Illness - Full Text View - ClinicalTrials.Gov." Accessed November 13, 2020. <https://clinicaltrials.gov/ct2/show/NCT04427501>.
- ⁷ US National Library of Clinical Medicine. "A Study of LY3819253 (LY-CoV555) in Preventing SARS-CoV-2 Infection and COVID-19 in Nursing Home Residents and Staff - Full Text View - ClinicalTrials.Gov," November 10, 2020. <https://clinicaltrials.gov/ct2/show/NCT04497987>.
- ⁸ "ACTIV-2: A Study for Outpatients With COVID-19 - Full Text View - ClinicalTrials.Gov," November 12, 2020. <https://clinicaltrials.gov/ct2/show/NCT04518410>.
- ⁹ US National Library of Clinical Medicine. "ACTIV-3: Therapeutics for Inpatients With COVID-19 - Full Text View - ClinicalTrials.Gov." *ClinicalTrials.gov*, November 9, 2020. <https://clinicaltrials.gov/ct2/show/NCT04501978>.
- ¹⁰ Eli Lilly and Company. "Lilly Announces Proof of Concept Data for Neutralizing Antibody LY-CoV555 in the COVID-19 Outpatient Setting | Eli Lilly and Company." *investor.lilly.com*, September 16, 2020. <https://investor.lilly.com/news-releases/news-release-details/lilly-announces-proof-concept-data-neutralizing-antibody-ly>.
- ¹¹ Deutsches Ärzteblatt. "COVID-19: Erstes Antikörperpräparat erzielt Schutzwirkung bei..." *Deutsches Ärzteblatt*, September 17, 2020. <https://www.aerzteblatt.de/nachrichten/116592/COVID-19-Erstes-Antikoerperpraeparat-erzielt-Schutzwirkung-bei-leichtereren-Erkrankungen>.

¹² Eli Lilly and Company. “Lilly’s Neutralizing Antibody Bamlanivimab (LY-CoV555) Receives FDA Emergency Use Authorization for the Treatment of Recently Diagnosed COVID-19 | Eli Lilly and Company,” November 9, 2020. <https://investor.lilly.com/news-releases/news-release-details/lillys-neutralizing-antibody-bamlanivimab-ly-cov555-receives-fda>.

¹³ Deutsche Apotheker- Zeitung. “Eli Lilly Unterbricht Erprobung von Corona-Antikörpertherapie.” DAZ.online, October 14, 2020. <https://www.deutsche-apotheker-zeitung.de/news/artikel/2020/10/14/eli-lilly-unterbricht-erprobung-von-antikoerpertherapie>.

¹⁴ Haseltine, William A. “Eli Lilly Stops Antibody Trial In Hospitalized Covid-19 Patients.” Forbes, October 28, 2020. <https://www.forbes.com/sites/williamhaseltine/2020/10/28/eli-lilly-stops-antibody-trial-in-hospitalized-covid-19-patients/>.

¹⁵ US National Library of Clinical Medicine. “ACTIV-3: Therapeutics for Inpatients With COVID-19 - Full Text View - ClinicalTrials.Gov.” ClinicalTrials.gov, November 9, 2020. <https://clinicaltrials.gov/ct2/show/NCT04501978>.

¹⁶ Eli Lilly and Company. “Lilly’s Neutralizing Antibody Bamlanivimab (LY-CoV555) Receives FDA Emergency Use Author-ization for the Treatment of Recently Diagnosed COVID-19 | Eli Lilly and Company,” November 9, 2020. <https://investor.lilly.com/news-releases/news-release-details/lillys-neutralizing-antibody-bamlanivimab-ly-cov555-receives-fda>.

¹⁷ Thomas, Katie, and Noah Weiland. “Eli Lilly’s Antibody Treatment Gets Emergency F.D.A. Approval.” The New York Times, November 10, 2020, sec. Health. <https://www.ny-times.com/2020/11/09/health/covid-antibody-treatment-eli-lilly.html>.

¹⁸ Deutsches Ärzteblatt. “COVID-19: Erstes Antikörperpräparat erzielt Schutzwirkung bei...” Deutsches Ärzteblatt, Sep-tember 17, 2020. <https://www.aerzteblatt.de/nachrichten/116592/COVID-19-Erstes-Antikoerperpraeparat-erzielt-Schutzwirkung-bei-leichtereren-Erkrankungen>.

¹⁹ Thomas, Katie, and Noah Weiland. “Eli Lilly’s Antibody Treatment Gets Emergency F.D.A. Approval.” The New York Times, November 10, 2020, sec. Health. <https://www.ny-times.com/2020/11/09/health/covid-antibody-treatment-eli-lilly.html>.

Background on Innovation Sheet Series

As part of a real-time evaluation of the SARS CoV 2 pandemic (with focus on epidemiological, medical, economical, societal, technical, and cultural developments in Germany and Armenia) the CoronaSys research team, under the leadership of Prof. Dr. Martin Voss, is conducting a continuous monitoring of developments and medical, technical, and social innovations concerning Covid-19.

Multiple national and international media outlets, research platforms, and scientific and organizational guidelines, briefs, and updates are screened to feed into this outlet. The rationale behind this is to support the projects' network partners in Armenia and Germany with short summaries of key developments and promising innovations that are shaping the global, German, and Armenian outbreak response and recovery.

The aim of these short briefs is to give condensed and structured information on selected innovations emerging out of the conducted horizon scanning. This could be mainstream big-ticket items or fringe subjects that are easily overlooked in the global flood of information. Some innovations will be followed through their evolution in time while others may only appear once. While subjectively selected, the briefs are descriptive in nature and leave analysis and critical interpretation to the reader. Network partners in both countries are invited to provide feedback on their interest areas and suggest particularly relevant topics for the CoronaSys Workshop series.

The CoronaSys Innovation Sheet Series is published by the [Academy of the Disaster Research Unit](#), which is, as a non-profit limited liability company, a spin-off of the [Disaster Research Unit](#) at the Free University of Berlin. The series is part of the research project "[CoronaSys](#): Addressing the corona pandemic in Armenia through systemic risk management", sponsored by the German Federal Ministry of Education and Research.

If you have any questions, suggestions, or if you wish to be taken on (or off) the project mailing list for CoronaSys updates, innovation sheets, and workshop invitations, please send a message to Janina Schäfer (schaefer@a-kfs.de). For general project inquiries, you may contact the team lead Sara Merkes (merkes@a-kfs.de) or the project lead Martin Voss (voss@a-kfs.de).

Previous CoronaSys Innovation Sheets

- 1 “New” Antiviral Face Masks
- 2 ”Dyphox” Surface Coating
- 3 MOVES SLC Portable ICU
- 4 Portable TRI- KLEEN 500UV
- 5 Convalescent Plasma Therapy
- 6 ASIC-App
- 7 BinaxNOW Antigen Test
- 8 Corona Traffic Light
- 9 Aproof at Home Antibody Test
- 10 IVAT Hygiene Tower
- 11 LY-CoV555 Antibody Treatment
- 12 4C Mortality Score
- 13 Regional Corona Prediction Model
- 14 Computer-designed Mini- Proteins
- 15 Covid-19 Simulator
- 16 Trimodulin
- 17 BNT162b2-Vaccine
- 18 SARS-COV-2 Rapidplex
- 19 European Corona- Map
- 20 FELUDA Paper Strip Test
- 21 Humanitarian Action Mapping Tool
- 22 IKKA Score
- 23 WHO Digital Implementation Investment Guide
- 24 RCCE Toolkit
- 25 Cough-Analyzing App

All previous CoronaSys Innovation Sheets are available online:

<http://coronasys.a-kfs.de/category/innovation-stream/>

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Citation: Academy of the Disaster Research Unit (2020): Follow- up on LY-CoV555 Antibody Treatment. CoronaSys Innovation Sheet 26. Berlin: ADRU.

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