

CORONASYS INNOVATION SHEET 17

BNT162B2- VACCINE

Background

Since the start of the pandemic, researchers have been working hard to develop a vaccine against SARS-CoV-2. Worldwide more than 160 potential vaccines are being tested as of now¹. One of the promising candidates is the BNT162b2- vaccine developed by BioNTech² in cooperation with Pfizer³.

Features

The European Medical Association EMA just started the rolling review process for the potential vaccine⁴. The Rolling Review process is a regulatory tool that the EMA can use to assess a promising drug during a public health emergency, such as the current pandemic⁵.

The potential vaccine belongs to the group of gene-based vaccines – it is a mRNA vaccine. It contains genetic information of the pathogen in order to produce the surface protein (spike protein), with which the virus penetrates cells. The aim of the vaccination is then to encourage the body to form antibodies and T-cells against this protein⁶. In addition, the active substance is supposed to activate other immune system defense mechanisms⁷.

Potentials

BioNTech is, after AstraZeneca, the second company to be in the EMA rolling review process⁸. The vaccine is currently being tested in a phase II/III clinical trial⁹. In this phase, the efficacy is further tested, and the appropriate dosage is determined¹⁰. If successful, the vaccine could help to end the pandemic. One advantage of mRNA vaccines is that they can be produced more rapidly and cheaper than traditional vaccines¹¹.

Points to consider

If the rolling review process is completed successfully, the company still has to go through a formal application process for marketing authorization¹². As of now, it is not clear how many doses of the vaccine are needed to induce a sufficient immune response, but experts estimate that it will take as long as summer 2021 to produce the necessary amounts of vaccine to immunize the population^{13,14}.

Conclusion

The agent might be one of the vaccines against Covid-19 if the trial is completed successfully.

State of information: 10/11/2020

Public announcement: October 2020

Country: Germany, USA

Focus area: Vaccination

Developers: BioNTech (Germany) in Cooperation with Pfizer (USA, Germany)

Beneficiaries: General public

-
- ¹ WHO.int. "Draft Landscape of COVID-19 Candidate Vaccines," October 2, 2020. <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>.
- ² BioNTech. "BioNTech: We Aspire to Individualize Cancer Medicine." BioNTech. Accessed October 12, 2020. <https://www.biontech.de>.
- ³ Pfizer. "Pfizer Deutschland: COVID-19-Spezial." Accessed October 12, 2020. <https://www.pfizer.de/covid-19-spezial>.
- ⁴ Dimitrova, Elena Kostadinova. "EMA Starts Second Rolling Review of a COVID-19 Vaccine." Text. European Medicines Agency, October 5, 2020. <https://www.ema.europa.eu/en/news/ema-starts-second-rolling-review-covid-19-vaccine>.
- ⁵ Müller, Celine. "EMA Prüft Zweiten Corona-Impfstoff." DAZ.online, October 7, 2020. <https://www.deutsche-apotheker-zeitung.de/news/artikel/2020/10/07/ema-prueft-zweiten-corona-impfstoff>.
- ⁶ Dimitrova, Elena Kostadinova. "EMA Starts Second Rolling Review of a COVID-19 Vaccine." Text. European Medicines Agency, October 5, 2020. <https://www.ema.europa.eu/en/news/ema-starts-second-rolling-review-covid-19-vaccine>.
- ⁷ Stern.de. "Impfstoff-Zulassungsprozess von Mainzer Unternehmen startet." stern.de. Accessed October 12, 2020. <https://www.stern.de/panorama/medizin/ema-impfstoff-zulassungsprozess-von-mainzer-unternehmen-startet-9441630.html>.
- ⁸ CNBC. "EU Launches a Rolling Review of the Pfizer-BioNTech Coronavirus Vaccine," October 6, 2020. <https://www.cnbc.com/2020/10/06/eu-launches-rolling-review-of-pfizer-biontech-coronavirus-vaccine.html>.
- ⁹ Clinical Trials Register. "2020-001038-36." clinicaltrialsregister.eu. Accessed October 12, 2020. <https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-001038-36/DE>.
- ¹⁰ Stern.de. "Impfstoff-Zulassungsprozess von Mainzer Unternehmen startet." stern.de. Accessed October 12, 2020. <https://www.stern.de/panorama/medizin/ema-impfstoff-zulassungsprozess-von-mainzer-unternehmen-startet-9441630.html>.
- ¹¹ University of Cambridge. "RNA Vaccines: An Introduction." PHG Foundation. Accessed October 12, 2020. <https://www.phgfoundation.org/briefing/rna-vaccines>.
- ¹² Dimitrova, Elena Kostadinova. "EMA Starts Second Rolling Review of a COVID-19 Vaccine." Text. European Medicines Agency, October 5, 2020. <https://www.ema.europa.eu/en/news/ema-starts-second-rolling-review-covid-19-vaccine>.
- ¹³ Klapsa, Kaja. "Corona: Impfstoff Für „weite Teile Der Bevölkerung“ Kommt Bis Mitte 2021 - WELT." WELT.de, September 15, 2020. <https://www.welt.de/politik/deutschland/article215812388/Corona-Impfstoff-fuer-weite-Teile-der-Bevoelkerung-kommt-bis-Mitte-2021.html>.
- ¹⁴ Deutschlandfunk. "Covid-19 - So weit ist die Impfstoffforschung gegen das Coronavirus." Deutschlandfunk. Accessed October 12, 2020. https://www.deutschlandfunk.de/covid-19-so-weit-ist-die-impfstoffforschung-gegen-das.1939.de.html?drn:news_id=1182116.

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

All previous CoronaSys Innovation Sheets are available online:

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

Project lead:

Prof. Dr. Martin Voss

Email: voss@a-kfs.de

Phone: +49 30 838 72613

Website: <http://coronasys.a-kfs.de>



SPONSORED BY THE



Federal Ministry
of Education
and Research

© 2020 ADRU - All rights reserved

The authors are solely responsible for the content of the document. Any commercial use of the documents, including parts and excerpts, is expressly prohibited without prior consultation and permission by the authors.

Citation: Academy of the Disaster Research Unit (2020): BNT162b2-vaccine. CoronaSys Innovation Sheet 17. Berlin: ADRU.

Akademie der Katastrophenforschungsstelle (AKFS) gGmbH
c/o Katastrophenforschungsstelle
Carl-Heinrich-Becker-Weg 6-10
12165 Berlin