

CORONASYS INNOVATION SHEET 27

FOLLOW-UP ON BNT162B2-VACCINE

Background

This innovation sheet is a follow-up on Innovation sheet No. 17 of this series from October 11th, 2020¹. 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 developed, 10 of them are in the phase 3 trial stage². One of the promising candidates is the BNT162b2-vaccine developed by BioNTech³ in cooperation with Pfizer⁴. This week the developers announced that an interim analysis showed very promising results⁵.

Features

The BioNTech-vaccine is a mRNA-vaccine and belongs to a new group of gene-based vaccines. It stimulates the body to produce antibodies and T-cells by inserting an m-RNA-part responsible for producing the virus' spike protein⁶. The vaccine is likely to activate other immune system defense mechanisms as well⁷. According to the manufacturer, serious side effects have not yet been registered and vaccination protection is achieved one week after the second vaccination dose and 28 days after the first injection⁸.

Potentials

The vaccine is currently being tested in a multicentered phase II/III clinical trial^{9,10} with more than 44.000 patients where efficacy is further tested and the appropriate dosage is determined¹¹. BioNTech and Pfizer reported an efficacy of 90% for their vaccine. This would suggest a high protective effect, similar to vaccines for measles or rubella¹². One advantage of mRNA vaccines is that they can be produced more rapidly and cheaper than traditional vaccines¹³. In terms of tolerability, a positive factor could be that BNT162b2 works without an adjuvant¹⁴.

Points to consider

As of now, the data are not published yet and a comprehensive subgroup-analysis needs to determine whether the vaccine is effective in different subsets of the population (e.g. the elderly and high-risk groups) as well¹⁵. One major problem regarding vaccine distribution is that the BNT162b2- vaccine needs to be stored at minus 70 degrees so that areas without proper cooling facilities are not eligible for distribution which could be a major disadvantage for poorer countries¹⁶. (Some of the other potential vaccines, however, can be cooled by a regular fridge and do not need such low temperatures). Furthermore, some companies have already contracted with large and rich states, so that it might be increasingly difficult for Low- and Middle-Income Countries (LMIC) to access the vaccine timely¹⁷.

State of information:

- 10/11/2020
- Updated 11/13/2020

Public announcement: November 2020

Country: Germany, USA

Focus area: Vaccination

Developers:

- BioNTech (Germany) in Cooperation with
- Pfizer (USA, Germany)

Beneficiaries: General public

Conclusion

The vaccine surely raised hope for a nearing end to the pandemic and is a positive sign for the development of other potential vaccines as well. Still, the trial has to be completed, formal approval has to be granted by the various authorities and the vaccine has to be distributed and administered. This process will take well into the next year and it remains to be seen if the COVAX initiative¹⁸ can ensure fair and transparent availability and accessibility to the vaccine for all people in need.

¹ Academy of the Disaster Research Unit (2020): BNT162b2-vaccine. CoronaSys Innovation Sheet 17. Berlin: ADRU. <http://coronasys.a-kfs.de/category/innovation-stream/>

² WHO. "Draft Landscape of COVID-19 Candidate Vaccines," November 13, 2020. <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>.

³ BioNTech. "BioNTech: We Aspire to Individualize Cancer Medicine." BioNTech. Accessed October 12, 2020. <https://www.biontech.de>.

⁴ Pfizer. "Pfizer Deutschland: COVID-19-Spezial." Accessed October 12, 2020. <https://www.pfizer.de/covid-19-spezial>.

⁵ BioNTech. "Pfizer and BioNTech Announce Vaccine Candidate Against COVID-19 Achieved Success in First Interim Analysis from Phase 3 Study. Press Release." investors.biontech.de, November 9, 2020. <https://investors.biontech.de/news-releases/news-release-details/pfizer-and-biontech-announce-vaccine-candidate-against-covid-19/>.

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/arzneimittelbehoerde-ema-impfstoff-zulassungsprozess-von-mainzer-unternehmen-startet-9441630.html>.

⁸ Deutsches Ärzteblatt. "SARS-CoV-2: Impfstoff von Biontech/Pfizer verhindert in Phase-3-Studie..." Deutsches Ärzteblatt, November 9, 2020. <https://www.aerzteblatt.de/nachrichten/118189/SARS-CoV-2-Impfstoff-von-Biontech-Pfizer-verhindert-in-Phase-3-Studie-mehr-als-90-der-bestaetigten-Infektionen>.

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 US National Library of Clinical Medicine. "Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals - Full Text View - ClinicalTrials.Gov." Accessed November 13, 2020. <https://clinicaltrials.gov/ct2/show/NCT04368728>.

¹¹ Stern.de. "Impfstoff-Zulassungsprozess von Mainzer Unternehmen startet." stern.de. Accessed October 12, 2020. <https://www.stern.de/panorama/arzneimittelbehoerde-ema-impfstoff-zulassungsprozess-von-mainzer-unternehmen-startet-9441630.html>.

¹² Deutsches Ärzteblatt. "SARS-CoV-2: Impfstoff von Biontech/Pfizer verhindert in Phase-3-Studie..." Deutsches Ärzteblatt, November 9, 2020. <https://www.aerzteblatt.de/nachrichten/118189/SARS-CoV-2-Impfstoff-von-Biontech-Pfizer-verhindert-in-Phase-3-Studie-mehr-als-90-der-bestaetigten-Infektionen>.

¹³ University of Cambridge. "RNA Vaccines: An Introduction." PHG Foundation. Accessed October 12, 2020. <https://www.phgfoundation.org/briefing/rna-vaccines>.

¹⁴ Deutsches Ärzteblatt. "SARS-CoV-2: Impfstoff von Biontech/Pfizer verhindert in Phase-3-Studie..." Deutsches Ärzteblatt, November 9, 2020. <https://www.aerzteblatt.de/nachrichten/118189/SARS-CoV-2-Impfstoff-von-Biontech-Pfizer-verhindert-in-Phase-3-Studie-mehr-als-90-der-bestaetigten-Infektionen>.

¹⁵ Deutschlandfunk. "Corona-Impfstoff von Biontech/Pfizer - Noch viele offene Fragen." Deutschlandfunk, November 10, 2020. https://www.deutschlandfunk.de/corona-impfstoff-von-biontech-pfizer-noch-viele-offene.2897.de.html?dram:article_id=487291.

¹⁶ Deutsches Ärzteblatt. "Bei Minus 70 Grad Um Die Welt." Ärzteblatt.de, November 12, 2020. <https://www.aerzteblatt.de/nachrichten/118314/Bei-minus-70-Grad-um-die-Welt>.

¹⁷ Dohmen, Caspar. "Gesundheit und Gewinne - Das Rennen um den Corona-Impfstoff." Deutschlandfunk, October 28, 2020. https://www.deutschlandfunk.de/gesundheits-und-gewinne-das-rennen-um-den-corona-impfstoff.724.de.html?dram:article_id=486560.

¹⁸ who.int. "COVAX: Working for Global Equitable Access to COVID-19 Vaccines," 2020. <https://www.who.int/initiatives/act-accelerator/covax>.

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.

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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).

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- 1 "New" Antiviral Face Masks
- 2 "Dyphox" Surface Coating
- 3 MOVES SLC Portable ICU
- 4 Portable TRI- KLEEN 500UV
- 5 Convalescent Plasma Therapy
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- 7 BinaxNOW Antigen Test
- 8 Corona Traffic Light
- 9 Aproof at Home Antibody Test
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- 25 Cough-Analyzing App
- 26 Follow Up on LY-CoV555 Antibody Treatment

All previous CoronaSys Innovation Sheets are available online:

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

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