Project Lightspeed

This website is intended for a global audience.

Aiming to address the global coronavirus pandemic: Project Lightspeed

Together with all companies, research institutes and governments currently working on the development of a vaccine against COVID-19, we, at BioNTech, are also working around the clock to develop a COVID-19 vaccine to contribute to global efforts to combat the global COVID-19 pandemic and protect against COVID-19.

Our effort to accelerate the rapid development of a vaccine to fight COVID-19 has been named „Project Lightspeed." The project leverages BioNTech's proprietary mRNA-based technology, with which we have more than 20 years of experience, and is also supported by Pfizer's global vaccine development capabilities.

Like any other pharmaceutical product, a potential vaccine has to go through stringent clinical testing and must be manufactured to high standards (termed "GMP" or good manufacturing practice) consistently and reliably. BioNTech received German regulatory authority approval in 2011 to manufacture mRNA under GMP, and has been producing mRNA for clinical testing since then, including the entire clinical supply for our COVID-19 mRNA vaccine.

"We feel a duty to exploit our full technology and immunotherapy expertise to help address the COVID-19 pandemic emergency. Our aim is clear: Making a potential vaccine available to the public as quickly as possible – worldwide."

Prof. Ugur Sahin, M.D., Chief Executive Officer

Where are we with Project Lightspeed, our COVID-19 vaccine development program? These are the milestones at a glance:

1. **January 12, 2020:** SARS-CoV-2 genetic sequence
2. **Mid-January, 2020:** Start of global development program
3. **March 16/17, 2020:** Collaborations
4. **April 22, 2020:** Phase 1/2 Study in Germany
5. **April 23, May 4, 2020** Start of two Phase 1/2 trials in Germany and the U.S.
6. **July 1, 2020:** First results from U.S. Phase 1/2 study
7. **July 13, 2020:** U.S. FDA Fast Track Designation
8. **July 20, 2020:** First data from German Phase 1/2-study
9. **July 20, 22, and 31, 2020:** First supply agreements
10. **July 27, 2020:** Global Phase 2/3 efficacy study in the U.S. started
11. **August 5, 2020:** Start of the clinical study in China and supply agreement with Canada
12. **August 20, 2020:** Preliminary data from ongoing Phase 1/2 study of lead COVID-19 mRNA vaccine candidate
13. **September 7, 2020:** Start of Phase 2/3 study in Germany
14. **September 17, 2020:** Acquisition of GMP manufacturing site
15. **October 6–9, 2020:** Rolling submissions initiated
16. **November 9, 2020:** Preliminary data: first positive interim analysis from global phase 3 study
17. **November 11, 2020:** Vaccine Supply Agreement with the EU
18. **November 16, 2020:** Approval of Phase 2 study in China
19. **November 18, 2020:** Conclusion of global Phase 3 study
20. **November 20, 2020:** Emergency Use Authorization Request submitted to U.S. FDA
21. **November 25, 2020:** Start of clinical Phase 2 study in China
22. **November 30, 2020:** Conditional Marketing Authorization Submission to EMA
23. **December 2, 2020:** First approval of a temporary emergency supply in UK
24. **December 11, 2020:** U.S. FDA authorizes COVID-19 mRNA vaccine for emergency use
25. **December 21, 2020:** Conditional Marketing Authorization in the European Union for BioNTech's COVID-19 mRNA vaccine

For more information about our manufacturing capabilities please visit:

- https://biontech.de/how-we-translate/manufacturing

For more information on the current status of the vaccine program please follow:

- Press releases

Read also

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SEND US A MESSAGE

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We aspire to utilize the full potential of the immune system to fight cancer and infectious diseases

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