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**

- Ugur Sahin read a publication in the Lancet about a new virus that emerged in the Chinese province of Wuhan.
- Immediately, Ugur realized that this virus had the potential to spread beyond Chinese borders. Not only was the virus novel and highly infectious, but treatments were also unavailable and several infected individuals did not show any symptoms. In addition, Wuhan is a heavily populated city with over one million inhabitants that is highly connected to the rest of the world.
- He discussed this with Özlem Türeci and the management team and, a few days later, BioNTech initiated "Project Lightspeed" in order to develop a potential vaccine against COVID-19.

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

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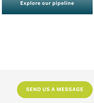

Explore our pipeline

We look forward to connecting with you

SEND US A MESSAGE

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For questions on logistics, handling or other issues: **service@biontech.de**

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