BIONTECH

Project Lightspeed

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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

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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

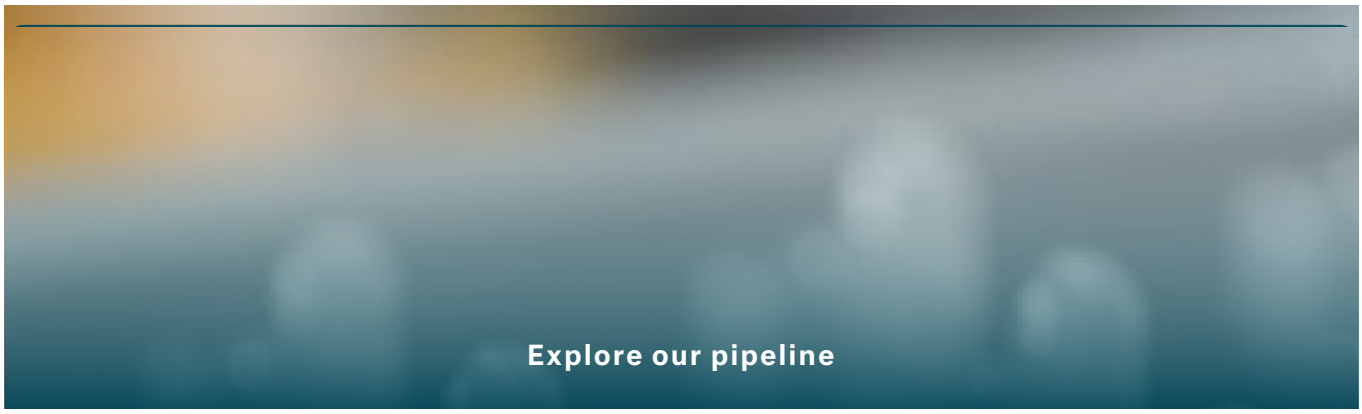
For more information about our manufacturing capabilities please visit:

- 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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We look forward to connecting with you

SEND US A MESSAGE

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For any other questions, please use our contact form at **connect.biontech.de**

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

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