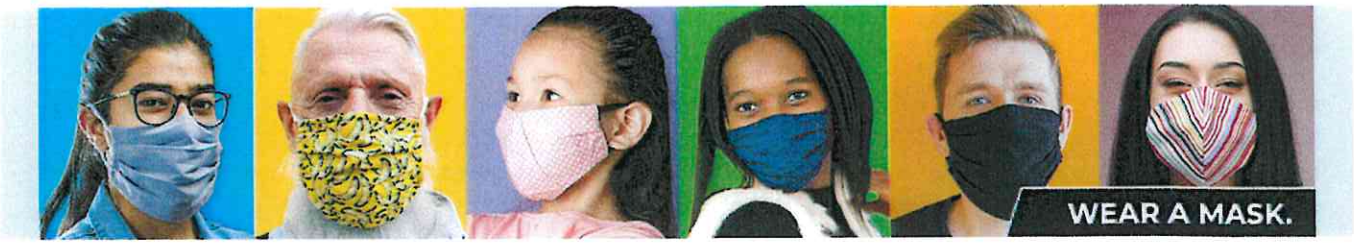

Facts about COVID-19 Vaccines

Updated Nov. 23, 2020 Print

In the United States, there is not yet an authorized or approved vaccine to prevent coronavirus disease 2019 (COVID-19). With the possibility of a limited supply of one or more COVID-19 vaccines becoming available before the end of 2020, accurate vaccine information is critical.

FACT: COVID-19 vaccines will not give you COVID-19

None of the COVID-19 vaccines currently in development in the United States use the live virus that causes COVID-19. There are several different types of vaccines in development. However, the goal for each of them is to teach our immune systems how to recognize and fight the virus that causes COVID-19. Sometimes this process can cause symptoms, such as fever. These symptoms are normal and are a sign that the body is building immunity. Learn more about how COVID-19 vaccines work.

It typically takes a few weeks for the body to build immunity after vaccination. That means it's possible a person could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick. This is because the vaccine has not had enough time to provide protection.

FACT: COVID-19 vaccines will not cause you to test positive on COVID-19 viral tests

Vaccines currently in clinical trials in the United States won't cause you to test positive on viral tests, which are used to see if you have a **current infection**.

If your body develops an immune response, which is the goal of vaccination, there is a possibility you may test positive on some antibody tests. Antibody tests indicate you had a **previous infection** and that you may have some level of protection against the virus. Experts are currently looking at how COVID-19 vaccination may affect antibody testing results.

FACT: People who have gotten sick with COVID-19 may still benefit from getting vaccinated

Due to the severe health risks associated with COVID-19 and the fact that re-infection with COVID-19 is possible, people may be advised to get a COVID-19 vaccine even if they have been sick with COVID-19 before.

At this time, experts do not know how long someone is protected from getting sick again after recovering from COVID-19. The immunity someone gains from having an infection, called natural immunity, varies from person to person. Some early evidence suggests natural immunity may not last very long.

We won't know how long immunity produced by vaccination lasts until we have a vaccine and more data on how well it works.

Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are trying to learn more about, and CDC will keep the public informed as new evidence becomes available.

FACT: Getting vaccinated can help prevent getting sick with COVID-19

While many people with COVID-19 have only a mild illness, others may get a severe illness or they may even die. There is no way to know how COVID-19 will affect you, even if you are not at increased risk of severe complications. If you get sick, you also may spread the disease to friends, family, and others around you while you are sick. COVID-19 vaccination helps protect you by creating an antibody response without having to experience sickness. Learn more about how COVID-19 vaccines work.

FACT: Receiving an mRNA vaccine will not alter your DNA

mRNA stands for messenger ribonucleic acid and can most easily be described as instructions for how to make a protein or even just a piece of a protein. mRNA is not able to alter or modify a person's genetic makeup (DNA). The mRNA from a COVID-19 vaccine never enter the nucleus of the cell, which is where our DNA are kept. This means the mRNA does not affect or interact with our DNA in any way. Instead, COVID-19 vaccines that use mRNA work with the body's natural defenses to safely develop protection (immunity) to disease. Learn more about how COVID-19 mRNA vaccines work.

How do I know which sources of COVID-19 vaccine information are accurate?

It can be difficult to know which sources of information you can trust. Learn more about finding credible vaccine information.

Last Updated Nov. 23, 2020

Frequently Asked Questions about COVID-19 Vaccination

Updated Dec. 3, 2020 Print

In the United States, there is not yet an authorized or approved vaccine to prevent coronavirus disease 2019 (COVID-19). The federal government, through Operation Warp Speed, has been working since the pandemic started to make one or more COVID-19 vaccines available as soon as possible. Although CDC does not have a role in developing COVID-19 vaccines, CDC has been working closely with health departments and partners to develop vaccination plans for when a vaccine is available. CDC is working with partners at all levels, including healthcare associations, on flexible COVID-19 vaccination programs that can accommodate different vaccines and scenarios.

Below are answers to commonly asked questions. Regular updates will be made as needed.

Planning for a Vaccine

What is Operation Warp Speed's role with COVID-19 vaccines?

Operation Warp Speed is a partnership among components of the Department of Health and Human Services (HHS) and the Department of Defense to help develop, make, and distribute millions of vaccine doses for COVID-19 as quickly as possible while ensuring that the vaccines are safe and that they work. Learn more about Operation Warp Speed:

- HHS Fact Sheet: Explaining Operation Warp Speed
- New England Journal of Medicine article: Developing Safe and Effective COVID Vaccines — Operation Warp Speed's Strategy and Approach

When will a COVID-19 vaccine be available in the United States?

The goal for Operation Warp Speed is to deliver safe vaccines that work, with the first supply becoming available before the end of 2020. When a vaccine is authorized or approved in the United States, there may not be enough doses available for all adults. Supplies will increase over time, and all adults should be able to get vaccinated later in 2021. However, a COVID-19 vaccine may not be available for young children until more studies are completed.

What has been done to plan for the distribution of COVID-19 vaccines?

The federal government will oversee a centralized system to order, distribute, and track COVID-19 vaccines. All vaccines will be ordered through CDC. Vaccine providers will receive vaccines from CDC's centralized distributor or directly from a vaccine manufacturer

a vaccine manufacturer.

Many COVID-19 vaccine candidates are in development, and clinical trials are being conducted at the same time with large-scale manufacturing. With first doses expected before the end of 2020, planning and preparing for a COVID-19 vaccination program is very important.

Planning efforts have focused on every step and detail of the process, including:

- Establishing and testing logistics plans with manufacturers and commercial partners that are part of CDC's centralized COVID-19 vaccine delivery system
- Coordinating the first distribution of vaccines and needed supplies from centralized locations
- Ordering processes for additional doses of the vaccine after the first supply has been shipped
- Receiving, storing, and handling vaccines properly at very specific temperatures
- Deciding who should receive a vaccine first, based on national recommendations, if there are not enough doses of the vaccine for everyone
- Giving the vaccines in a safe way during an ongoing pandemic
- Reporting on vaccine inventory, administration, and safety using a variety of new and enhanced data systems
- Expanding safety surveillance through new systems and additional information sources, as well as scaling up existing safety monitoring systems
- Developing plans to assess vaccine effectiveness, which means how well the vaccines protect against COVID-19 under real-life conditions
- Making sure timely, credible, and clear communication is provided to the public and stakeholders around all aspects of the vaccination program

This situation continues to change, and planning will progress as more information about any authorized or approved vaccines becomes available. A safe and effective COVID-19 vaccine is a critical component of the U.S. strategy to reduce COVID-19-related illnesses, hospitalizations, and deaths and to help society function as it did before COVID-19. The goal of the U.S. government is to have enough COVID-19 vaccine doses for all people in the United States who choose to be vaccinated.

Who has CDC worked with to plan for the distribution of COVID-19 vaccines?

State, tribal, territorial, and local jurisdictions: CDC is working with state, tribal, territorial, and local jurisdictions on the development of COVID-19 vaccination plans for their respective areas. CDC released a playbook on September 16, 2020, to provide specific information to consider during vaccination plan development. The playbook was updated on October 30, 2020.

Private partners and federal agencies: CDC has also worked with private partners, such as chain and networks of independent pharmacies, and other federal agencies (e.g., the Indian Health Service) on plans to more widely distribute COVID-19 vaccines. For example, CDC is working with pharmacies to offer on-site COVID-19 vaccination services for residents in long-term care settings, including skilled nursing facilities, nursing homes, and assisted living facilities where most individuals are over 65 years of age.

Does CDC have a national campaign to address any concerns people may have about getting a COVID-19 vaccine?

No, CDC is not leading a national campaign on COVID-19 vaccination. CDC's vaccination activities fit within and are guided by a *Vaccinate with Confidence* strategic framework. This strategic framework focuses on strengthening vaccine confidence and preventing outbreaks of vaccine-preventable diseases in the United States. It builds on longstanding practices that CDC and partners have used to talk with the public and healthcare providers about the life-saving protection of vaccines.

The *Vaccinate with Confidence* strategic framework is being customized to address the unique information and health equity needs created by the COVID-19 pandemic. The new *Vaccinate with Confidence for COVID-19* strategic framework will strive to support public and healthcare personnel acceptance of future COVID-19 vaccines. CDC will provide updates once the new strategic framework is completed.

How is CDC working to make sure people want to and can get vaccinated once a COVID-19 vaccine is available?

CDC is working with partners across the country to make sure people have the information they need to be confident in deciding to get vaccinated. Key priorities for CDC are:

- **Regularly sharing clear and accurate information** with people to make sure they understand the risks and benefits of getting vaccinated and can make informed decisions.
- **Helping healthcare personnel feel confident** in their decision to get a COVID-19 vaccine and **helping healthcare providers** answer their patients' questions about the vaccine.
- **Engaging communities and individuals in an equitable and inclusive way** to ensure that people have opportunities to ask questions and get clear, accurate information about the COVID-19 vaccine.

Easy access to COVID-19 vaccines is equally critical. CDC is working with public health, healthcare providers, and other partners to make sure people can easily get a COVID-19 vaccine and that cost is not a barrier.

Will there be enough vaccine for everyone?

When FDA first authorizes or approves the use of one or more COVID-19 vaccines in the United States, there may be a limited supply. This would mean that not everyone will be able to be vaccinated right away. It is understandable how concerning this would be for people, especially for those who are at increased risk for serious illness from this virus and for their loved ones.

That is why, early in the response, the federal government began investing in select vaccine manufacturers to help them increase their ability to quickly make and distribute a large amount of COVID-19 vaccine. This will allow the United States to start with as much vaccine as possible and continually increase the supply in the weeks and months to follow. The goal is for everyone to be able to easily get a COVID-19 vaccine as soon as large quantities are available. Several thousand vaccination providers will be available, including doctors' offices, retail pharmacies, hospitals, and federally qualified health centers.

What can I do now to help protect myself from getting COVID-19 since a vaccine is not yet available?

You should cover your mouth and nose with a mask when around others, avoid close contact with people who are sick, stay 6 feet away from others, avoid crowds, and wash your hands often. Get more information about these and other steps you can take to protect yourself and others from COVID-19.

Vaccine Development

How many COVID-19 vaccines are under development?

Multiple COVID-19 vaccines are under development. As of November 24, 2020, large-scale (Phase 3) clinical trials are in progress or being planned for five COVID-19 vaccines in the United States.

Has there been a coronavirus vaccine developed before? What's known about it, and can it be helpful today in working toward a COVID-19 vaccine?

Severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) are two diseases caused by coronaviruses that are closely related to the virus that causes COVID-19. Researchers began working on developing vaccines for these diseases after they were discovered in 2003 and 2012, respectively. None of the SARS vaccines ever made it past the first stages of development and testing, in large part due to lack of interest because the virus disappeared. One MERS vaccine (MVA-MERS-S) successfully completed a phase 1 clinical trial in 2019. Lessons learned from this earlier vaccine research have been used to inform strategies for developing a COVID-19 vaccine.

Why is it taking so long to develop a COVID-19 vaccine? It only took a few months for the H1N1 influenza (flu) vaccine to be developed.

When a new flu strain is identified, like H1N1 in 2009, vaccine manufacturers can use the same processes that are used to make the annual seasonal flu vaccine, saving valuable time. Unlike flu, coronaviruses do not yet have licensed vaccines or processes to build on. In addition, the coronavirus that causes COVID-19 is a new virus, so entirely new vaccines must be developed and tested to ensure they work and are safe. There are many steps in the vaccine testing and approval process. Multiple agencies and groups in the United States are working together to make sure that a safe and effective COVID-19 vaccine is available as quickly as possible.

Getting Vaccinated

How many shots of COVID-19 vaccine will be needed?

All but one of the COVID-19 vaccines currently in Phase 3 clinical trials in the United States need two shots to be effective. The other COVID-19 vaccine uses one shot.

Do I need to wear a mask when I receive a COVID-19 vaccine?

Yes. CDC recommends that during the pandemic people wear a mask that covers their nose and mouth when in contact with others outside your household, when in healthcare facilities, and when receiving any vaccine, including a COVID-19 vaccine. Anyone who has trouble breathing or is unable to remove a mask without assistance should not wear a mask. For more information, visit considerations for wearing masks.

Who is paying for COVID-19 vaccine?

Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. However, vaccination providers will be able to charge an administration fee for giving the shot to someone. Vaccine providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund.

Are there special considerations on who should get the COVID-19 vaccine first?

At first, there will be a limited supply of COVID-19 vaccine. Operation Warp Speed is working to get those first vaccine doses out once a vaccine is authorized or approved and recommended, rather than waiting until there is enough

vaccine for everyone. However, it is important that the initial supplies of vaccine are given to people in a fair, ethical, and transparent way. Learn how CDC is making COVID-19 vaccine recommendations, including recommendations if there is a limited supply, based on input from the Advisory Committee on Immunization Practices (ACIP).

If I have already had COVID-19 and recovered, do I still need to get vaccinated with a COVID-19 vaccine when it's available?

There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again; this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this. Until we have a vaccine available and the Advisory Committee on Immunization Practices makes recommendations to CDC on how to best use COVID-19 vaccines, CDC cannot comment on whether people who had COVID-19 should get a COVID-19 vaccine.

Why would a vaccine be needed if we can do other things, like social distancing and wearing masks, to prevent the virus that causes COVID-19 from spreading?

Stopping a pandemic requires using all the tools available. Vaccines work with your immune system so your body will be ready to fight the virus if you are exposed. Other steps, like covering your mouth and nose with a mask and staying at least 6 feet away from others, help reduce your chance of being exposed to the virus or spreading it to others. Together, COVID-19 vaccination and following CDC's recommendations to protect yourself and others will offer the best protection from COVID-19.

Do I need to wear a mask and avoid close contact with others if I have received 2 doses of the vaccine?

Yes. While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using **all the tools** available to us to help stop this pandemic, like covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others. Together, COVID-19 vaccination and following CDC's recommendations for how to protect yourself and others will offer the best protection from getting and spreading COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before deciding to change recommendations on steps everyone should take to slow the spread of the virus that causes COVID-19. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

When can I stop wearing a mask and avoiding close contact with others after I have been vaccinated?

There is not enough information currently available to say if or when CDC will stop recommending that people wear masks and avoid close contact with others to help prevent the spread of the virus that causes COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before making that decision. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

Are there other vaccines that can help prevent me from getting COVID-19?

There are currently no available vaccines that will prevent COVID-19. However, multiple agencies and groups in the United States are working together to make sure that a safe and effective COVID-19 vaccine is available as quickly as possible.

A flu vaccine will not protect you from getting COVID-19, but it can prevent you from getting influenza (flu) at the same time as COVID-19. This can keep you from having a more severe illness. While it's not possible to say with certainty what will happen in the winter, CDC believes it's likely that flu viruses and the virus that causes COVID-19 will both be

Does immunity after getting COVID-19 last longer than protection from COVID-19 vaccines?

The protection someone gains from having an infection (called natural immunity) varies depending on the disease, and it varies from person to person. Since this virus is new, we don't know how long natural immunity might last. Some early evidence—based on some people— seems to suggest that natural immunity may not last very long.

Regarding vaccination, we won't know how long immunity lasts until we have a vaccine and more data on how well it works.

Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are trying to learn more about, and CDC will keep the public informed as new evidence becomes available.

What percentage of the population needs to get vaccinated to have herd immunity to COVID-19?

Experts do not know what percentage of people would need to get vaccinated to achieve herd immunity to COVID-19. Herd immunity is a term used to describe when enough people have protection—either from previous infection or vaccination—that it is unlikely a virus or bacteria can spread and cause disease. As a result, everyone within the community is protected even if some people don't have any protection themselves. The percentage of people who need to have protection in order to achieve herd immunity varies by disease.

Safety

How do I report it if I have a problem or bad reaction after getting a COVID-19 vaccine?

CDC and FDA encourage the public to report possible side effects (called adverse events) to the Vaccine Adverse Event Reporting System (VAERS) . This national system collects these data to look for adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns of occurrence. Learn about the difference between a vaccine side effect and an adverse event. Reports to VAERS help CDC monitor the safety of vaccines. Safety is a top priority.

Healthcare providers will be required to report certain adverse events following vaccination to VAERS. Healthcare providers also have to adhere to any revised safety reporting requirements according to FDA's conditions of authorized use throughout the duration of any Emergency Use Authorization; these requirements would be posted on FDA's website .

CDC is also implementing a new smartphone-based tool called **v-safe** to check-in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a **v-safe** information sheet telling you how to enroll in **v-safe**. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

What does it mean if a clinical trial is temporarily paused?

Safety is a top priority during the vaccine approval process. It is not unusual for a clinical trial to be temporarily paused when a possible side effect (called an adverse event) is detected. Clinical trials are designed to pause when an unexpected health event (called a safety signal) is detected so scientists and physicians can investigate potential safety concerns. The approval process for COVID-19 vaccines is no different — safety is always the focus.

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Pfizer and BioNTech Conclude Phase 3 Study of COVID-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints

- *Primary efficacy analysis demonstrates BNT162b2 to be 95% effective against COVID-19 beginning 28 days after the first dose; 170 confirmed cases of COVID-19 were evaluated, with 162 observed in the placebo group versus 8 in the vaccine group*
- *Efficacy was consistent across age, gender, race and ethnicity demographics; observed efficacy in adults over 65 years of age was over 94%*
- *Safety data milestone required by U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) has been achieved*
- *Data demonstrate vaccine was well tolerated across all populations with over 43,000 participants enrolled; no serious safety concerns observed; the only Grade 3 adverse event greater than 2% in frequency was fatigue at 3.8% and headache at 2.0%*
- *Companies plan to submit within days to the FDA for EUA and share data with other regulatory agencies around the globe*
- *The companies expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses by the end of 2021*
- *Pfizer is confident in its vast experience, expertise and existing cold-chain infrastructure to distribute the vaccine around the world*

November 18, 2020 06:59 AM Eastern Standard Time

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced that, after conducting the final efficacy analysis in their ongoing Phase 3 study, their mRNA-based COVID-19 vaccine candidate, BNT162b2, met all of the study's primary efficacy endpoints. Analysis of the data indicates a vaccine efficacy rate of 95% ($p<0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose. The first primary objective analysis is based on 170 cases of COVID-19, as specified in the study protocol, of which 162 cases of COVID-19 were observed in the placebo group versus 8 cases in the BNT162b2 group. Efficacy was consistent across age, gender, race and ethnicity demographics. The observed efficacy in adults over 65 years of age was over 94%.

There were 10 severe cases of COVID-19 observed in the trial, with nine of the cases occurring in the placebo group and one in the BNT162b2 vaccinated group.

To date, the Data Monitoring Committee for the study has not reported any serious safety concerns related to the vaccine. A review of unblinded reactogenicity data from the final analysis which consisted of a randomized subset of at least 8,000 participants 18 years and older in the phase 2/3 study demonstrates that the vaccine was well tolerated, with most solicited adverse events resolving shortly after vaccination. The only Grade 3 (severe) solicited adverse events greater than or equal to 2% in frequency after the first or second dose was fatigue at 3.8% and headache at 2.0% following dose 2. Consistent with earlier shared results, older adults tended to report fewer and milder solicited adverse events following vaccination.

for Emergency Use Authorization (EUA) has been achieved. Pfizer and BioNTech plan to submit a request within days to the FDA for an EUA based on the totality of safety and efficacy data collected to date, as well as manufacturing data relating to the quality and consistency of the vaccine. These data also will be submitted to other regulatory agencies around the world.

"The study results mark an important step in this historic eight-month journey to bring forward a vaccine capable of helping to end this devastating pandemic. We continue to move at the speed of science to compile all the data collected thus far and share with regulators around the world," said Dr. Albert Bourla, Pfizer Chairman and CEO. "With hundreds of thousands of people around the globe infected every day, we urgently need to get a safe and effective vaccine to the world."

"We are grateful that the first global trial to reach the final efficacy analysis mark indicates that a high rate of protection against COVID-19 can be achieved very fast after the first 30 µg dose, underscoring the power of BNT162 in providing early protection," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "These achievements highlight the potential of mRNA as a new drug class. Our objective from the very beginning was to design and develop a vaccine that would generate rapid and potent protection against COVID-19 with a benign tolerability profile across all ages. We believe we have achieved this with our vaccine candidate BNT162b2 in all age groups studied so far and look forward to sharing further details with the regulatory authorities. I want to thank all the devoted women and men who contributed to this historically unprecedented achievement. We will continue to work with our partners and governments around the world to prepare for global distribution in 2020 and beyond."

The Phase 3 clinical trial of BNT162b2 began on July 27 and has enrolled 43,661 participants to date, 41,135 of whom have received a second dose of the vaccine candidate as of November 13, 2020. Approximately 42% of global participants and 30% of U.S. participants have racially and ethnically diverse backgrounds, and 41% of global and 45% of U.S. participants are 56-85 years of age. A breakdown of the diversity of clinical trial participants can be found here from approximately 150 clinical trials sites in United States, Germany, Turkey, South Africa, Brazil and Argentina. The trial will continue to collect efficacy and safety data in participants for an additional two years.

Based on current projections, the companies expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses by the end of 2021. Four of Pfizer's facilities are part of the manufacturing and supply chain; St. Louis, MO; Andover, MA; and Kalamazoo, MI in the U.S.; and Puurs in Belgium. BioNTech's German sites will also be leveraged for global supply.

Pfizer is confident in its vast experience, expertise and existing cold-chain infrastructure to distribute the vaccine around the world. The companies have developed specially designed, temperature-controlled thermal shippers utilizing dry ice to maintain temperature conditions of -70°C±10°C. They can be used be as temporary storage units for 15 days by refilling with dry ice. Each shipper contains a GPS-enabled thermal sensor to track the location and temperature of each vaccine shipment across their pre-set routes leveraging Pfizer's broad distribution network.

Pfizer and BioNTech plan to submit the efficacy and safety data from the study for peer-review in a scientific journal once analysis of the data is completed.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

The information contained in this release is as of November 18, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine, the BNT162 mRNA vaccine program, and modRNA candidate BNT162b2 (including qualitative assessments of available data, potential benefits, expectations for clinical trials, anticipated timing of regulatory submissions and anticipated manufacturing, distribution and supply), that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with clinical data (including the Phase 3 data that is the subject of this release), including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial or in larger, more diverse populations upon commercialization; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when any biologics license and/or emergency use authorization applications may be filed in any jurisdictions for BNT162b2 or any other potential vaccine candidates; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners or third-party suppliers; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine candidate's ultra-low temperature formulation and attendant storage, distribution and administration requirements, including risks related to handling after delivery by Pfizer; the risk that we may not be able to successfully develop non-frozen formulations; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or have access to logistics or supply channels commensurate with global demand for any potential approved vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine candidate within the projected time periods indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

About BioNTech

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a

Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.de.

BioNTech Forward-looking statements

This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine; our expectations regarding the potential characteristics of BNT162b2 in our Phase 2/3 trial and/or in commercial use based on data observations to date; the expected timepoint for additional readouts on efficacy data of BNT162b2 in our Phase 2/3 trial; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any potential Emergency Use Authorization; the timing for submission of manufacturing data to the FDA; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 2021. Any forward-looking statements in this press release are based on BioNTech current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our productions capabilities; and other potential difficulties. For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F filed with the SEC on March 31, 2020, which is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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