



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Basis for the EU approval of new vaccines

Presented by Harald Enzmann on behalf of EMA, as
Chair of Committee for Medicinal Products for Human Use (CHMP)

An agency of the European Union



Objective

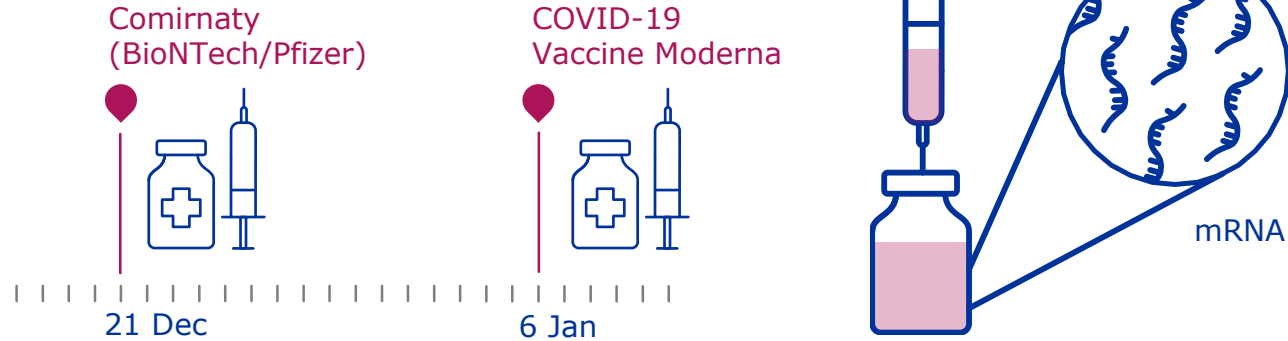
- This presentation has been prepared by EMA to inform the general public and non-technical audiences of the basis for **approval and use of COVID-19 mRNA vaccines in the EU**
- It uses public-friendly language and summarises the evaluation of COVID-19 vaccines
- The **full scientific details and product information** are available here:
 - [Comirnaty](#)
 - [COVID-19 Vaccine Moderna](#)



Outline

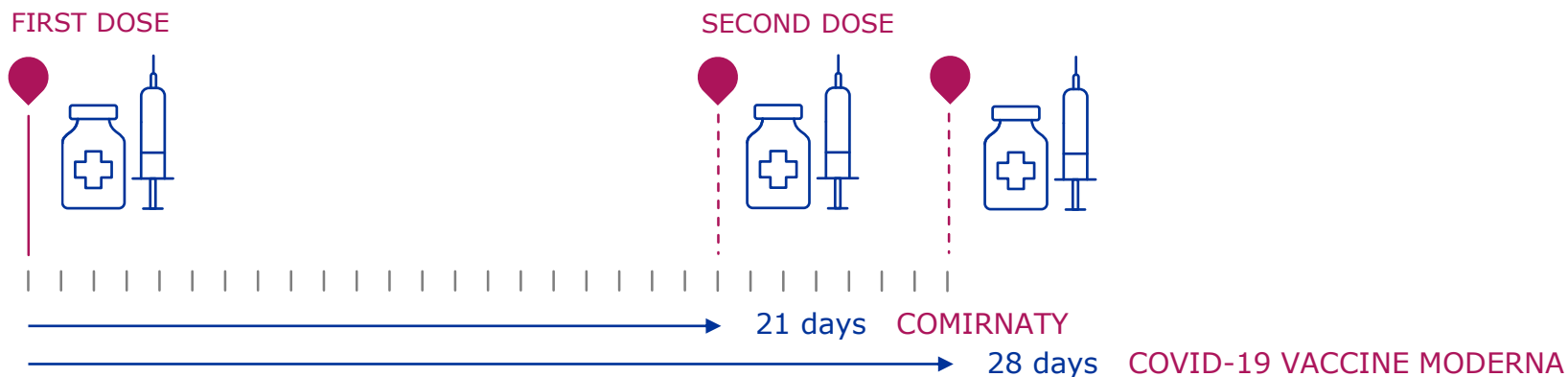
- 1 Which COVID-19 vaccines are authorised in the EU?
- 2 How are the mRNA COVID-19 vaccines used?
- 3 How do mRNA vaccines work?
- 4 How was efficacy of COVID-19 mRNA vaccines studied?
- 5 What benefits have been shown in studies?
- 6 Benefits and risks for Comirnaty and COVID-19 Vaccine Moderna
- 7 Can the vaccines reduce transmission of the virus from one person to another?
- 8 What about special populations?
- 9 Why are the vaccines approved in the EU?

Which COVID-19 vaccines are authorised in the EU?



- Currently 2 COVID-19 vaccines are **authorised in the EU**
- Both contain a molecule called **messenger RNA (mRNA)** with instructions for producing a protein from SARS-CoV-2, the virus that causes COVID-19
- The vaccines do not contain the virus itself and cannot cause COVID-19

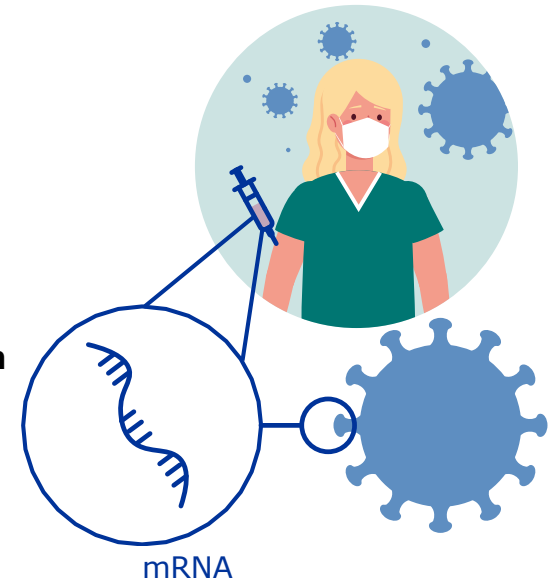
How are the mRNA COVID-19 vaccines used?



- Both vaccines are given as **two injections**, usually into the muscle of the upper arm
 - Comirnaty (BioNTech/Pfizer) is given **at least 21 days apart**
 - COVID-19 vaccine Moderna (Moderna Biotech Spain, S.L.) is given **28 days apart**
- You can check the specific conditions of use for Comirnaty or COVID-19 vaccine Moderna, **in the package leaflet or in the prescribing information**

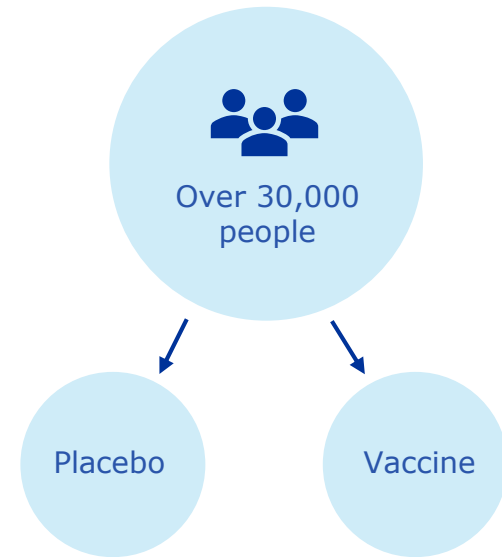
How do mRNA vaccines work?

- The vaccines **prepare the body to defend itself** against COVID-19
- The mRNA has **instructions for making the spike protein** – needed for SARS-CoV-2 virus to enter the body's cells
- When a person is given the vaccine, some of their cells 'read' the mRNA instructions and **temporarily** produce the spike protein
- The person's immune system recognise this protein as foreign and produce antibodies and white blood cells to attack it. If, later on, the person comes into contact with SARS-CoV-2 virus, their **immune system will recognise it and be ready to defend** the body against it
- The mRNA from the vaccine **does not stay in the body** but is broken down shortly after vaccination



How was efficacy of COVID-19 mRNA vaccines studied?

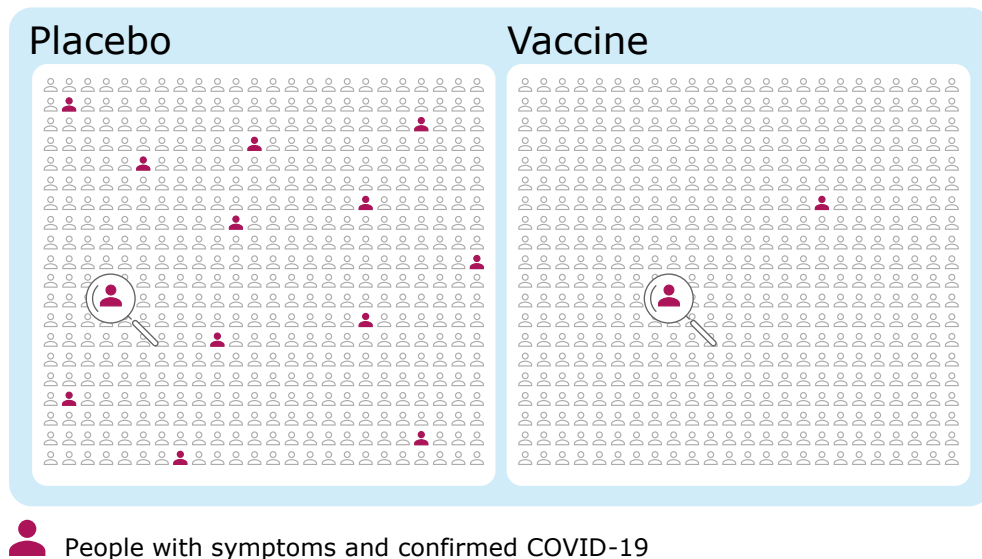
- **Very large trials** showed that the mRNA vaccines are effective at preventing COVID-19
- The main trials involved **very large numbers of people**:
 - around **44,000** for Comirnaty
 - around **30,000** for Moderna vaccine
- Half received the vaccine and half were given a placebo (dummy injection)
- People did not know whether they received the vaccine or the placebo



How was efficacy of COVID-19 mRNA vaccines studied?

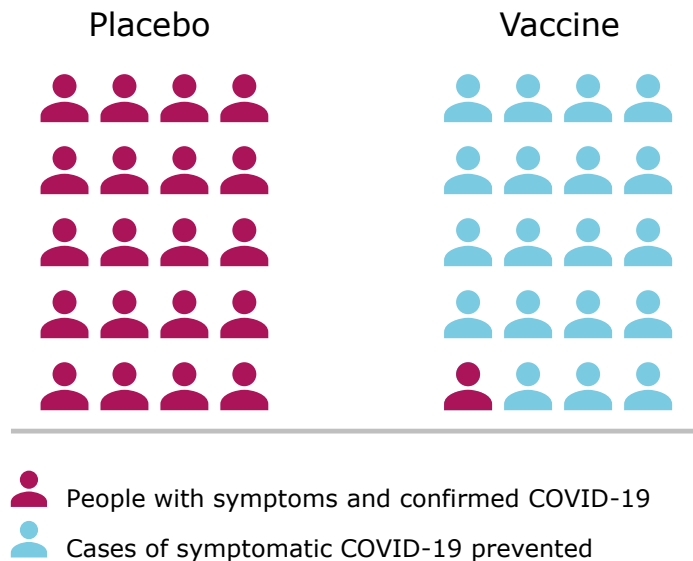
- Some people in each group developed COVID-19 with symptoms
- The study identified whether these people with COVID-19 symptoms had got the vaccine or placebo

More cases of COVID-19 disease with symptoms were found in the placebo group



What benefits have been shown in studies?

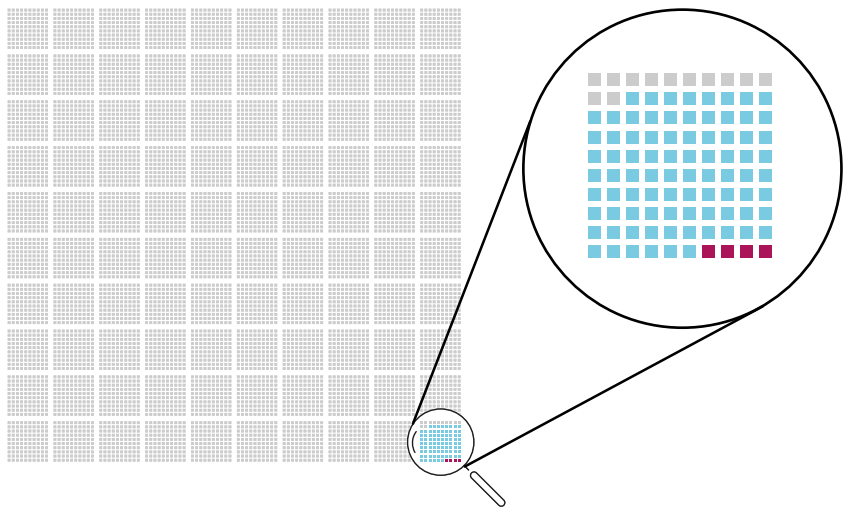
95% vaccine efficacy for every 20 people in the trial who developed symptomatic COVID-19



- **For each vaccine**, the main study showed **around 95% reduction** in the number of symptomatic COVID-19 cases in the people who received the vaccine compared with people who received placebo
- This means that the **mRNA vaccines demonstrated around 95% efficacy** in the respective trials

What benefits have been shown in studies?

For every 10,000 participants who received the vaccine, this is what happened compared to placebo

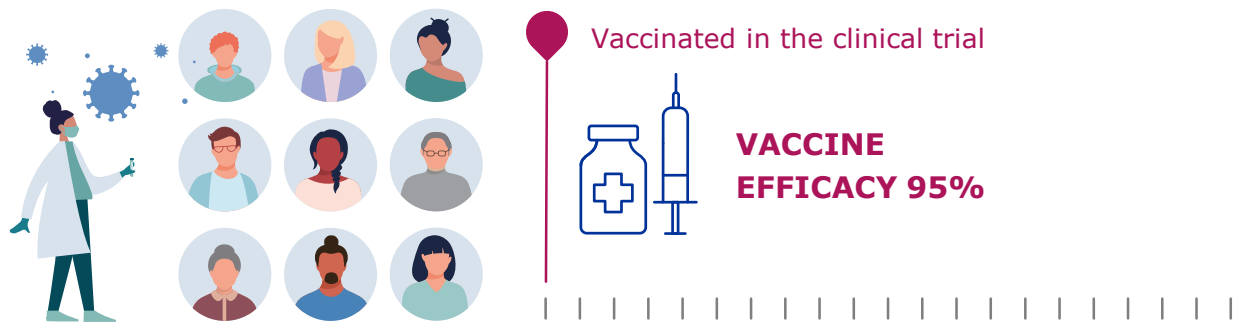


- 84 cases of symptomatic COVID-19 were **prevented by the vaccine (95% of all cases)**
- 4 cases of symptomatic COVID-19 occurred despite the vaccine (5% of all cases)
- 9,912 participants did not have COVID-19 symptoms

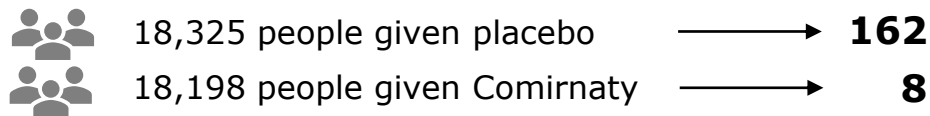
- **Snapshot of symptomatic COVID-19 cases** prevented at the time of analysis – around 1.5 months after 2nd dose
- **COVID-19 spreads quickly** and causes severe disease, death and large burden to healthcare systems
- Vaccines offer **individual benefit**
- Fewer people expected to go to hospital, **reducing the burden on healthcare** and freeing up resources to treat other illnesses

BENEFITS AND RISKS FOR COMIRNATY AND COVID-19 VACCINE MODERNA

Comirnaty – main benefit identified in study



How many people developed COVID-19 with symptoms?



Full information on the benefit-risk assessment for [Comirnaty](#)

Comirnaty – main side effects identified in main study

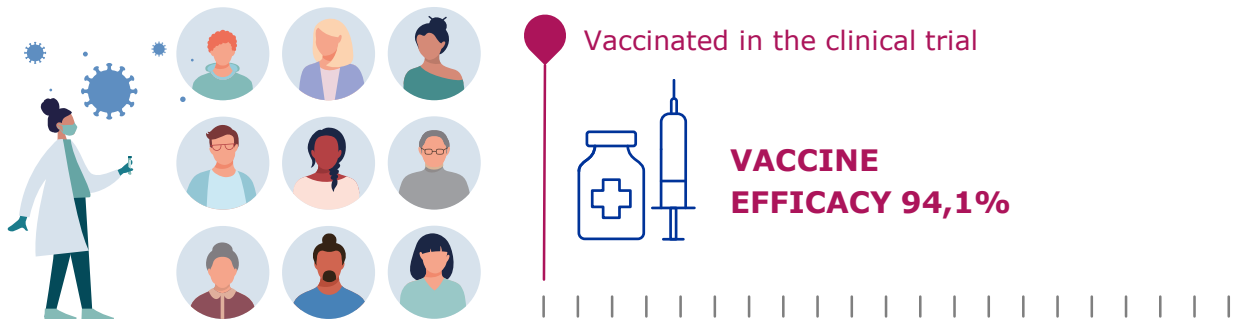
MAIN SIDE EFFECTS

- Most common side effects (**more than 1 in 10 people**) usually mild or moderate and temporary, including pain and swelling at injection site, tiredness, headache, muscle and joint pain, chills and fever
- Redness at the injection site and nausea occurred in **less than 1 in 10 people**
- Itching at the injection site, pain in the limb, enlarged lymph nodes, difficulty sleeping and feeling unwell were uncommon side effects (**less than 1 in 100 people**)
- Weakness in muscles on one side of face (acute peripheral facial paralysis or palsy) occurred rarely in **less than 1 in 1,000 people**
- **Very small number of cases of severe allergic reactions** (anaphylaxis) seen in vaccination campaigns

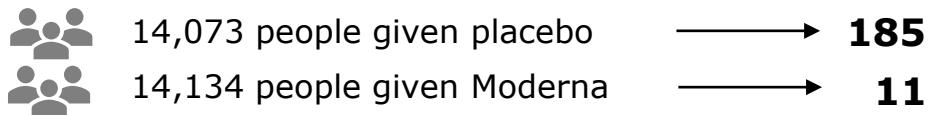
Full list of side effects for [Comirnaty](#)

BENEFITS AND RISKS FOR COMIRNATY AND COVID-19 VACCINE MODERNA

COVID-19 Vaccine Moderna – main benefit identified in study



How many people developed COVID-19 with symptoms?



Full information on the benefit-risk assessment for [COVID-19 vaccine Moderna](#)

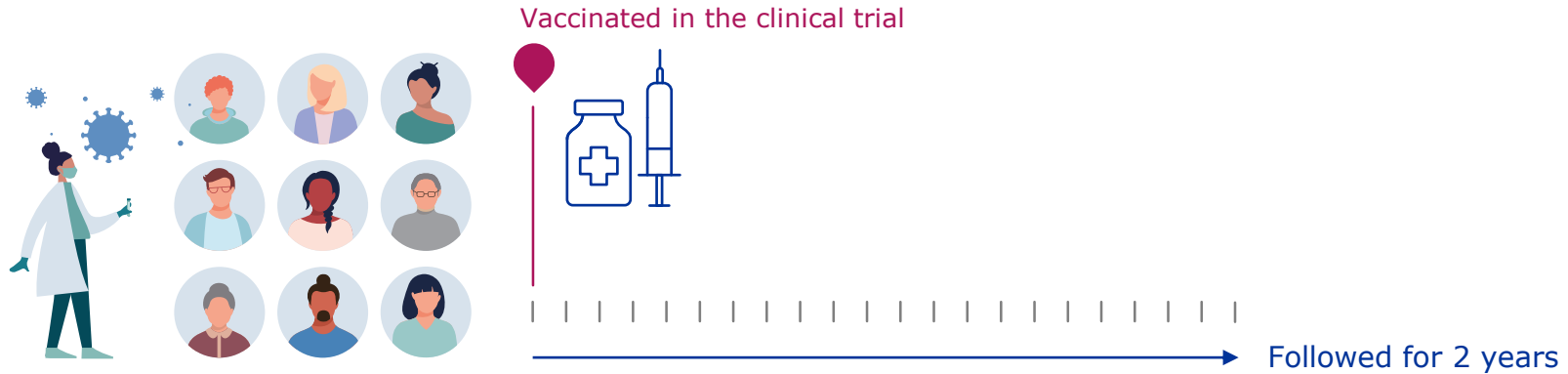
COVID-19 Vaccine Moderna – main side effects identified in study

MAIN SIDE EFFECTS

- Most common side effects (**more than 1 in 10 people**) usually mild or moderate and temporary, including pain and swelling at injection site, tiredness, chills, fever, swollen or tender lymph nodes under the arm, headache, muscle and joint pain, nausea and vomiting.
- Redness, hives and rash at the injection site and rash occurred in **less than 1 in 10 people**.
- Itching at the injection site occurred in **less than 1 in 100 people**.
- Swelling of the face, which may affect people who had facial cosmetic injections in the past, and weakness in muscles on one side of face (acute peripheral facial paralysis or palsy) occurred rarely (**less than 1 in 1000**).
- **Very small number of cases of severe allergic reactions** (anaphylaxis) seen in vaccination campaigns.

Full list of side effects for [COVID-19 vaccine Moderna](#)

How long does protection from the vaccines last?



- It is not currently known **how long protection given by the vaccines lasts**
- The people vaccinated in the clinical trial will **continue to be followed for 2 years** to gather more information on the duration of protection

Can the vaccines reduce transmission of the virus from one person to another?

- It is too soon to know the wider **impact of vaccination** with Comirnaty or Moderna vaccine on the spread of the SARS-CoV-2 virus in the community
- It is not yet known to which extent vaccinated people may still be able to carry and spread the virus – trials ongoing
- **The precautions must not be relaxed even after vaccination:** people should continue to **keep distance** from other people, **wear face masks and wash hands**
- It is important to **continue following national and regional guidelines**, which will be determined by the level of transmission locally



Can vaccines return us to normal life?



- **Immediate benefit** for people who will be protected against COVID-19 symptoms
- **If fewer people are getting sick** (develop symptoms of COVID-19), particularly among high risk individuals such as older people, this will also **alleviate the huge burden of COVID-19 disease on healthcare systems**
- COVID-19 vaccines that reduce symptomatic disease will be an **important step towards beating the pandemic**
- At least initially, vaccines alone will not allow us immediately to return to 'normal' life, and other public health measures such as **face masks and social distancing will remain essential**

Can people who have already had COVID-19 be vaccinated?



- **Not enough data from the trials** to conclude on how well the COVID-19 vaccines work for people who already had COVID-19
- **Trials included few people** who had previously had COVID-19
- There were no additional side effects in these people

Can children / immunocompromised patients be vaccinated?



- The vaccines are currently **not approved for younger children:**

- **Comirnaty** can be given above **16 years of age**
- **Moderna** can be given above **18 years of age**



- There are limited data on **immunocompromised people** (people with weakened immune systems):
 - Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19

Can pregnant or breast-feeding women be vaccinated?



- Data on the use of Comirnaty or COVID-19 Vaccine Moderna during pregnancy are **very limited**
- Non-clinical studies (e.g. animal studies) do not show any harmful effects in pregnancy
- Although there are no studies on breast-feeding, **no risk for breast-feeding is expected**
- The decision on whether to use the vaccine in pregnant women should be made in close consultation with a healthcare professional after considering the benefits and risks

How well do COVID-19 vaccines work for people of different ethnicities and genders?



- **The main trials** included people of different ethnicities and genders
- **High efficacy** levels were maintained across genders, racial and ethnic groups

Why are the vaccines approved in the EU?



- **The vaccines offer a high level of protection** (around 95%) against COVID-19 which is a critical need in the current pandemic
- **Most side effects are mild to moderate** in severity and are gone within a few days
- The Agency therefore decided that, for both vaccines, **the benefits are greater than its risks** and that they can be authorised for use in the EU
- The vaccines have been granted a conditional marketing authorisation
- This means that the company must provide more evidence which EMA will review

What information is still awaited for the COVID-19 vaccines?

- The companies that market COVID-19 vaccines will continue to provide results from the **main studies, which are ongoing for 2 years**
- This trial and additional studies will provide information on how long protection lasts, how well the vaccine prevents severe COVID-19, how well it protects immunocompromised people, children and pregnant women, and whether it prevents asymptomatic cases
- In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will also give more information on the **vaccine's long-term safety and benefit in the general population**
- The companies will also carry out studies to provide additional assurance on the pharmaceutical quality of the vaccine

Conclusions

- **First COVID-19 vaccines approved in the EU** – robust and efficient scientific assessment
- mRNA vaccines were **studied in large clinical trials**, involving many thousands of participants and including older people
- **Both vaccines show high efficacy** protecting against symptomatic COVID-19 disease and adequate safety profile
- It is still too soon to know the wider impact on preventing infection, asymptomatic transmission and viral spread in the community – until then measures like masks and social distancing are important
- **Vaccination is important** to prevent people getting sick with COVID-19 disease

