Update on treatments and vaccines against COVID-19 under development

Supporting the rapid development and approval of effective and safe treatments for and vaccines against COVID-19 is EMA's top priority to help save lives during the pandemic. Over recent weeks and months, the Agency has engaged with many developers of therapeutic medicines and there are a number of developments underway. However, at this point, on the basis of the preliminary data presented to the Agency, no medicine has yet demonstrated efficacy in treating COVID-19.

EMA's COVID-19 response team has been in contact with developers of around 40 therapeutic medicines, allowing better understanding of potential treatments.

Among the potential treatments for COVID-19 that are undergoing clinical trials to assess their safety and efficacy against the disease are:

- remdesivir (investigational)
- lopinavir/ritonavir (currently authorised as an anti-HIV medicine)
- chloroquine and hydroxychloroquine (currently authorised at national level as treatments against malaria and certain autoimmune diseases such as rheumatoid arthritis)
- systemic interferons and in particular interferon beta (currently authorised to treat diseases such as multiple sclerosis)
- monoclonal antibodies with activity against components of the immune system

EMA welcomes the launch of large clinical trials as they are necessary to generate the robust data needed to establish evidence for which medicines do work and thus to give appropriate advice to healthcare professionals and patients and enable regulatory decision-making, as advised by EMA's human medicines committee (CHMP).

The Agency has also had discussions with developers of a dozen potential COVID-19 vaccines. Two vaccines have already entered phase I clinical trials, which are the first trials needed and are carried out in healthy volunteers. In general, timelines for the development of medicinal products are difficult to predict. Based on the information currently available and past experience with vaccine development timeframes, EMA estimates that it might take at least one year before a vaccine against COVID-19 is ready for approval and available in sufficient quantities to enable widespread use. Adequate supply of doses to meet the needs of all EU countries has to be proactively forecast.

EMA's response team will continue to interact with developers of potential therapeutics or vaccines against COVID-19. The aim is to provide advice on regulatory requirements so that any promising medicinal product can be made available as rapidly as possible to patients, initially in the clinical trial setting and then, once authorised, on the market.

Notes:

1. This press release, together with all related documents, is available on the Agency's website.

2. EMA has a range of support measures that can help to facilitate and speed up the development of medicines, which in addition to fast-track scientific advice includes the PRIME scheme, the accelerated assessment, and conditional marketing authorisation procedures.

3. Developers working on medicinal products or vaccines that could be used for treatment or prevention of COVID-19 are encouraged to contact the Agency and discuss their strategy for evidence generation as soon as possible by sending an email to 2019-nCoV@ema.europa.eu. EMA will review the received proposals and will contact developers with the most relevant proposals for an initial discussion.

4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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