



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 December 2014
EMA/733055/2014
Press Office

Press release

Experimental Ebola treatments still at early stage of development

For robust scientific assessment more information on safety and efficacy needed

At this point in time there is not enough evidence for any of the experimental therapies for Ebola Virus Disease to draw conclusions on their safety or efficacy when used in Ebola patients. This is the finding of an interim report published by the European Medicines Agency (EMA) that is continuing to review all Ebola treatments currently under development.

Any new information that becomes available will be added to the review to provide the best possible overview of data on medicinal treatments for Ebola.

"Treatments for patients infected with the Ebola virus are still in early stages of development," notes Marco Cavaleri, Head of Anti-infectives and Vaccines at the EMA. "We encourage developers to generate more information on the use of these medicines in the treatment of Ebola patients. We will review any new information as soon as it becomes available to support the response to this ongoing public health crisis."

The EMA review was started by the Agency's Committee for Medicinal Products for Human Use (CHMP) to support decision-making by health authorities. This first interim report includes information on seven experimental medicines intended for the treatment of people infected with the Ebola virus:

- BCX4430 (Biocryst);
- Brincidofovir (Chimerix);
- Favipiravir (Fujifilm Corporation/Toyama);
- TKM-100802 (Tekmira);
- AVI-7537 (Sarepta);
- ZMapp (Leafbio Inc.);
- Anti-Ebola F(ab')₂ (Fab'entech)



The amount of information available for the seven treatments is highly variable. For some compounds there is no data from use in human subjects available. A small number of treatments have been administered to patients in the current Ebola outbreak as compassionate use. Finally, there are also medicines included in this review that have already been studied in humans, albeit for the treatment of other viral diseases.

Vaccines to protect people against contracting the disease and treatments that do not directly target the Ebola virus have not been included in the review.

EMA's role in the Ebola outbreak

The review of experimental Ebola treatments is part of EMA's overall contribution to the global response to the Ebola outbreak in West Africa. The scale and complexity of this outbreak requires an unprecedented level of cooperation of the international health community. The Agency is working together with regulatory authorities around the world to support the World Health Organization and to advise on possible pathways for the development, evaluation and approval of medicines to fight Ebola.

Notes

1. This press release, together with all related documents, is available on the Agency's website at: <LINK>
2. The review is carried out under Art. 5(3) of Regulation (EC) No 726/2004. This procedure allows the Executive Director or the European Commission to ask the CHMP for a scientific opinion on any matter related to the evaluation of medicines.
3. Information on the European Medicines Agency's activities as part of the global response against the Ebola outbreak, is available on the Agency's website at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000624.jsp&mid=WC0b01ac0580841e30
4. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu