



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 November 2015
EMA/COMP/610640/2015
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Three chimeric human/murine monoclonal antibodies against the Ebola (Zaire) surface glycoprotein for the treatment for Ebola virus disease

On 9 October 2015, orphan designation (EU/3/15/1558) was granted by the European Commission to Dr Stefan Blesse, Germany, for three chimeric human/murine monoclonal antibodies against the Ebola (Zaire) surface glycoprotein (also known as ZMapp) for the treatment for Ebola virus disease.

What is Ebola virus disease?

Ebola virus disease is a severe disease caused by infection with viruses known as ebolaviruses. There are 5 known species of ebolavirus, 4 of which are known to cause the disease in humans. Zaire ebolavirus, sometimes referred to simply as 'ebola virus' or EBOV, is the cause of the largest outbreaks of the disease to date and has led to the most deaths.

Infection is caused by contact with the body fluids of an infected person. After infection there is an incubation period of between 2 to 21 days, following which the newly infected person starts to experience symptoms. The first symptoms typically are fever, headache, fatigue, muscle pain and sore throat. These are followed by other symptoms such as diarrhoea, vomiting, rash, kidney and liver problems and, in some cases, internal bleeding and bleeding from the gums, eyes, nose and ears. Patients are infectious once they start develop symptoms.

Ebola virus disease is a life-threatening condition that is frequently fatal due to fluid loss and severe bleeding.

What is the estimated number of patients affected by the condition?

At the time of designation, Ebola virus disease affected less than 0.01 in 10,000 people in the European Union (EU). This is below the ceiling for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and the knowledge of the Committee for Orphan Medicinal Products (COMP).

What treatments are available?

At the time of application for orphan designation, there were no satisfactory treatments authorised in the EU for treating Ebola virus disease. Different treatments were used to relieve the symptoms of the



disease, such as providing fluids by a drip into a vein and balancing electrolytes (body salts), maintaining oxygen supply to the body and blood pressure, and treating other infections if they develop.

How is this medicine expected to work?

This medicine is made of 3 monoclonal antibodies (type of proteins) that have been designed to recognise and attach to different parts of a protein on the ebolavirus surface. By attaching to the virus, the antibodies are expected to neutralise its action.

What is the stage of development of this medicine?

The effects of the medicine have been evaluated in experimental models.

At the time of submission of the application for orphan designation, a clinical trial with the medicine in patients with Ebola virus disease was ongoing.

At the time of submission, the medicine was not authorised anywhere in the EU for Ebola virus disease. Orphan designation of the medicine had been granted in the United States for this condition.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 3 September 2015 recommending the granting of this designation.

Opinions on orphan medicinal product designations are based on the following three criteria:

- the seriousness of the condition;
- the existence of alternative methods of diagnosis, prevention or treatment;
- either the rarity of the condition (affecting not more than 5 in 10,000 people in the EU) or insufficient returns on investment.

Designated orphan medicinal products are products that are still under investigation and are considered for orphan designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of quality, safety and efficacy is necessary before a product can be granted a marketing authorisation.

For more information

For details of the current sponsor of the orphan designation please refer to the information on the main web page of this Public Summary of Opinion.

For contact details of patients' organisations whose activities are targeted at rare diseases see:

- [Orphanet](#), a database containing information on rare diseases, which includes a directory of patients' organisations registered in Europe;
- [European Organisation for Rare Diseases \(EURORDIS\)](#), a non-governmental alliance of patient organisations and individuals active in the field of rare diseases.

Translations of the active ingredient and indication in all official EU languages¹, Norwegian and Icelandic

Language	Active ingredient	Indication
English	Three chimeric human/murine monoclonal antibodies against the Ebola (Zaire) surface glycoprotein	Treatment for Ebola virus disease
Bulgarian	Три химерни човешки/миши моноклонални антитела срещу повърхностен гликопротеин на Ебола (Заир)	Лечение на Ебола вирусно заболяване
Croatian	Tri kimerična ljudska/mišja monoklonska protutijela protiv površinskog glikoproteina Ebola virusa (Zair)	Liječenje Ebola virusne bolesti
Czech	Tři chimérické lidské/myší monoklonální protilátky proti povrchovému glykoproteinu viru Eboly (Zair)	Léčba Ebola virové choroby
Danish	Tre kimære humane/murine monoklonale antistoffer mod Ebola (Zaire) overfladeglycoprotein	Behandling af Ebola virus-sygdom
Dutch	Drie chimerische humaan/muriene monoklonale antilichamen tegen het oppervlakte-glycoproteïne van het (Zaïre) ebolavirus	Behandeling van Ebola virusziekte
Estonian	Kolm kimäärset Ebola (Zaire) viiruse pinnaglükoproteiini vastast inimese/hiire monoklonaalset antikeha	Ebola viiruse haiguse ravi
Finnish	Kolme kimeeristä ihmisen/hiiren monoklonaalista vasta-ainetta Ebola-viruksen (Zaire) vaipan glykoproteiinia vastaan	Ebola-viruksen aiheuttaman taudin hoito
French	Trois anticorps monoclonaux chimériques homme/souris contre la glycoprotéine de surface du virus Ebola (Zaïre)	Traitement de la maladie à virus Ebola
German	Drei chimäre humane/murine monoklonale Antikörper gegen das Oberflächen-Glykoprotein des (Zaire)-Ebolavirus	Behandlung der Ebola-Viruskrankheit
Greek	Τρία χιμαϊρικά ανθρώπινα/μυϊκά μονοκλωνικά αντισώματα κατά της επιφανειακής γλυκοπρωτεΐνης του Ebola (Ζαΐρ)	Θεραπεία της νόσου από τον ιό Έμπολα
Hungarian	A (Zaire-i) Ebola-vírus felületi glycoproteinjének három kíméra humán/egér eredetű monoklonális antitestje	Ebola vírus fertőzés kezelése
Italian	Tre anticorpi monoclonali chimerici umani/murini diretti contro la glicoproteina di superficie di Ebola (Zaire)	Trattamento della malattia da virus Ebola
Latvian	Trīs himēriskas cilvēka/peles monoklonālās antivielas pret Ebolas (Zairas) vīrusa virsmas glikoproteīnu	Ebolas vīrusa slimības ārstēšana
Lithuanian	Trys chimeriniai žmogaus/pelių monokloniniai antikūnai prieš Ebola (Zairo) paviršinių glikoproteiną	Ebola viruso sukeltos ligos gydymas
Maltese	Tliet antikorpi monoklonali kimeriċi umani/tal-ġrieden kontra l-glikoproteina tal-wiċċ ta' Ebola (Żaire)	Kura tal-marda mill-virus Ebola
Polish	Trzy humanizowane mysie chimeryczne przeciwciała monoklonalne skierowane przeciwko glikoproteinie powierzchniowej wirusa Ebola (forma Zair)	Leczenie choroby wywołanej przez wirus Ebola

¹ At the time of designation

Language	Active ingredient	Indication
Portuguese	Três anticorpos monoclonais humano/murino quiméricos contra a glicoproteína de superfície do vírus Ébola (Zaire)	Tratamento da doença por vírus Ébola
Romanian	Trei anticorpi monoclonali chimerici umani/murini împotriva glicoproteinei de suprafață a virusului Ebola (tulpina Zair)	Tratamentul bolii virale Ebola
Slovak	Tri chimérické humánne/myšacie monoklonálne protilátky proti povrchovému glykoproteínu vírusu Ebola (Zair)	Liečba Ebola vírusového ochorenia
Slovenian	Trihimerna človeška/mišja monoklonska protitelesa proti površinskemu glikoproteinu virusa Ebole (Zaire)	Zdravljenje Ebola virusne bolezni
Spanish	Tres anticuerpos monoclonales quiméricos humano/murino contra la glucoproteína de superficie del virus del Ébola (Zaire)	El tratamiento de la enfermedad viral de Ébola
Swedish	Tre kimeriska humaniserade/murina monoklonala antikroppar mot Ebola (Zaire) ytglykoprotein	Behandling av Ebolavirussjukdom
Norwegian	Tre kimeriske humane/murine monoklonale antistoffer mot ebola (Zaire) overflateglykoprotein	Behandling av ebolavirussykdom
Icelandic	Þrjú einklóna blendingsmótefni úr mönnum/músum gegn yfirborðsglýkópróteini Ebólu (Zaire)	Meðferð Ebóluveiru sjúkdóms