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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Ovine specific immunoglobulin (Fab) fragments raised against *Vipera berus* venom for the treatment of snakebite envenomation

On 9 October 2015, orphan designation (EU/3/15/1548) was granted by the European Commission to MicroPharm Limited, United Kingdom, for ovine specific immunoglobulin (Fab) fragments raised against *Vipera berus* venom for the treatment of snakebite envenomation.

What is snakebite envenomation?

Snakebite envenomation is poisoning from the bite of a snake. Symptoms depend on the species of snake, where it bites on the body and the amount of poison entering the body.

Vipera berus (common adder) is the most widespread poisonous snake in Western Europe. Symptoms of poisoning from an adder bite usually include local swelling and pain, feeling sick, fainting, and difficulty swallowing or breathing.

Snakebite envenomation is a debilitating condition that can be life-threatening because it may lead to failure of multiple organs.

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

At the time of designation, snakebite envenomation affected less than 0.5 in 10,000 people in the European Union (EU). This was equivalent to a total of fewer than 26,000 people[*], and 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?

Treatment of snakebite envenomation is usually guided by the species of snake and the severity of the symptoms. Less severe poisoning can be treated with first-aid measures such as applying pressure to the wound (to prevent the poison reaching vital organs), while for more severe bites, antivenom is the

[*]Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union (EU 28), Norway, Iceland and Liechtenstein. This represents a population of 512,900,000 (Eurostat 2015).

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only effective treatment. At the time of designation, several antivenom medicines were authorised for the condition in EU some countries.

The sponsor has provided sufficient information to show that the medicine might be of significant benefit for patients affected by snakebite envenomation because early studies in experimental models indicate that it might be more effective than existing treatments. This assumption will need to be confirmed at the time of marketing authorisation, in order to maintain the orphan status.

How is this medicine expected to work?

This medicine is made of antibody fragments. Antibodies are proteins that attach to a specific target in the body and can help to fight infections and other diseases. The antibody fragments in the medicine are expected to attach to the venom of *Vipera berus* and neutralise its effects.

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, no clinical trials with the medicine in patients with snakebite envenomation had been started by the sponsor.

At the time of submission, the medicine was not authorised anywhere in the EU for snakebite envenomation or designated as an orphan medicinal product elsewhere 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.

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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 languages[1], Norwegian and Icelandic

Language	Active ingredient	Indication
English	Ovine-specific immunoglobulin (Fab) fragments raised against *Vipera berus* venom	Treatment of snakebite envenomation
Bulgarian	Fab фрагменти от овчи имуноглобулин срещу отрова на *Vipera berus*	Лечение при ухапване от отровна змия
Croatian	Fab-fragmenti ovčjeg imunoglobulina, uzgojeni protiv otrova *Vipera berus*	Liječenje otrovanja nakon ugriza zmije
Czech	Ovčí speicifcký imunoglobuinový fragment (Fab) proti jedu Vipera berus	Protijed proti hadímu ušknutí
Danish	Får-specifikke immunglobulin (FAB) fragmenter rejst mod hugorm (*Vipera berus)* gift	Behandling af slangebidsforgiftning
Dutch	Schaap-specifieke immunoglobuline (Fab) fragmenten bekomen tegen *Vipera berus* gift	Behandeling van slangenbeetvergiftiging
Estonian	Lamba-spetsiifilise immuunglobuliini (FAB) fragmendid kasvatatud *Vipera berus* mürgi vastu	Maohammustusest tingitud mürgistuse ravi
Finnish	Spesifiset lampaan immunoglobuliinin (Fab) fragmentit kyyn myrkkyä vastaan	Käärmeenpuremasta aiheutuneen myrkytyksen hoito
French	Fragments d'immunoglobuline spécifique ovine (Fab) dirigés contre le venin de *Vipera berus*	Traitement de l'envenimation par morsure de serpent
German	Schaf Immunglobulin (Fab) Fragmente gegen das Vipera berus Gift	Behandlung von Schlangenbissvergiftungen
Greek	Θραύσματα ανοσοσφαιρίνης (Fab) ειδικής για αιγοπρόβατα κατά της τοξίνης από *Vipera berus*	Θεραπεία της έγχυσης δηλητηρίου από δάγκωμα φιδιού
Hungarian	Vipera berus venom-ellenes juh-specifikus immunoglobulin (Fab) fragmentumok	Mérgeskígyó-marás kezelése
Italian	Frammenti d'immunoglobuline specifiche ovine (Fab) diretti contro il veleno di *Vipera berus*	Trattamento dell'avvelenamento da ofidi
Latvian	Aitas specifiskā imunoglobulīna (Fab) fragmenti, kas vērsti prec *Vipera berus* indi	Čūskas kodiena izraisītas intoksikācijas ārstēšana
Lithuanian	Avies specifinis imunoglobulino (Fab) fragmentai prieš *Vipera berus* nuodus	Nuodingo gyvatės įkandimo gydymas
Maltese	Frammenti (Fab) tal-immunoglobulina speċifiċi għan-nagħaġ iġġenerati kontra velenu ta' *Vipera berus*	Kura ta' avvelenament minn gdim ta' sriep
Polish	Specyficzne dla owcy fragmenty przeciwciał (Fab) wytworzone przeciwko jadowi *Vipera berus*	Leczenie zatrucia jadem po ukąszeniu węża
Portuguese	Fragmentos (Fab) de imunoglobulina ovina especifica contra o veneno de *Vipera berus*	Tratamento de envenenamento por mordedura de serpente
Romanian	Fragmente de imunoglobuline (Fab) specific pentru ovine îndreptate împotriva veninului de *Vipera berus*	Tratamentul intoxicaţiei cu venin prin muşcătură de şarpe

[1] At the time of designation

Language	Active ingredient	Indication
Slovak	Ovčie špecifické imunoglubulínové (Fab) fragmenty vytvorené proti jedu *Vipera berus*	Liečba otravy po uštipnutí hadom
Slovenian	Specifični fragmenti ovinega imunoglobulina (Fab) proti strupu Vipera berusa	Zdravljenje zastrupitev s kačjim strupom
Spanish	Inmunoglobulina ovina (fragmento Fab) específica contra el venoma de *Vipera berus*	Tratamiento del envenenamiento por mordedura de serpiente
Swedish	Får-immunoglobulin (Fab) fragment mot *Vipera berus* gift	Behandling av förgiftning vid ormbett
Norwegian	Sauer spesifikke immunglobulin (FAB) fragmenter reist mot Hoggorm gift	Behandling av slangebittforgiftning
Icelandic	Sauðfjár sértækt ónæmisglóbúlín (FAB) brot beint gegn Vipera berus eitri	Behandling av forgiftning etter slangebitt