



EUROPEAN MEDICINES AGENCY
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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Bilayer engineered collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts for the treatment of partial deep dermal and full thickness burns

On 14 December 2015, orphan designation (EU/3/15/1596) was granted by the European Commission to Voisin Consulting S.A.R.L., France, for bilayer engineered collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts for the treatment of partial deep dermal and full thickness burns.

What are partial deep dermal and full thickness burns?

Partial deep dermal and full thickness burns are deep burns to the skin. Full thickness burns can also involve the layers of fat beneath the skin.

These types of burns are debilitating in the long term because of the scarring, disfigurement and disability that can follow. They are also life threatening because they can lead to serious infection.

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

At the time of designation, partial deep dermal and full thickness burns affected less than 2.9 in 10,000 people in the European Union (EU). This was equivalent to a total of fewer than 149,000 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?

At the time of the orphan designation, some products were authorised in the EU for wound care in patients with deep burns (e.g. povidone-iodine) and for removing dead tissue (e.g. NexoBrid).

The sponsor has provided sufficient information to show that this medicine might be of significant benefit for patients with partial deep dermal and full thickness burns. The product works in a different

^{*}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).



way to currently authorised treatments and early studies show that the medicine could be effective as a skin graft. 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 a graft containing cells known as fibroblasts and keratinocytes obtained from the patient's skin. Fibroblasts are normally present in the dermis, the lower layer of the skin, while keratinocytes are abundant in the epidermis, the upper layer. Both types of cells are arranged within a protein gel, with the fibroblasts within and the keratinocytes on top to form a product that mimics the skin and can be surgically implanted over the burn wound.

What is the stage of development of this medicine?

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

At the time of submission of the application for orphan designation, a clinical trial with this medicine including patients with partial deep dermal and full thickness burns was ongoing.

At the time of submission, the product was not authorised anywhere in the EU for partial deep dermal and full thickness burns 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 12 November 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

Sponsor's contact details:

Contact details of the current sponsor for this orphan designation can be found on EMA website, on the medicine's [rare disease designations page](#).

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	Bilayer engineered collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts	Treatment of partial deep dermal and full thickness burns
Bulgarian	Двупластов конструиран кожен имплантат, базиран на хидрогел и съставен от собствени кератиноцити и фибробласти	Лечение на частични дълбоки дермални и изгаряния на цялостната дебелина на кожата.
Croatian	Dvoslojni inženjeringom promijenjen kožni presadak baziran na kolagenskom hidrogelu sastavljen od autoložnih keratinocita i fibroblasta	Liječenje opekline djelomične debljine kože koje zahvaćaju duboki dermis i opekline cijele debljine kože
Czech	Dvojvrstva uměle vyrobeného hydrogel-kolagenu kožní štěpu složeného z autoložních keratinocytů a fibroblastů	Léčba parciálních hlubokých kožních a v plné šíři popálenin
Danish	Dobbeltlag manipuleret collagen hydrogel-baseret hudtransplantat sammensat af autologe keratinocytter og fibroblaster	Behandlingen af partielle, dybe dermale og fuld tykkelse brandsår
Dutch	Tweelagige kunstmatige collageen hydrogel-gebaseerde huidgreffe bestaande uit autologe keratinocyten en fibroblasten	Behandeling van partiële diepe en gehele dikte verbranding
Estonian	Kahekiline konstrueeritud kollageeni hüdrogeelil põhinev nahasiirik, mis koosneb autoloogsetest keratinotsüütidest ja fibroblastidest	Osalise sügava ja kogu naha paksust haarava nahapõletuse ravi
Finnish	Kaksikerroksinen kudosteknologian keinoin kasvatettu kollageeni ja hydrogeelipohjainen ihosiirre, joka koostuu autologisista keratinosyyteistä ja fibroblasteista	Osittaisten ja koko ihon syvyisten palovammojen hoito
French	Substitut cutané double couche produit artificiellement sous forme d'hydrogel de collagène composé de kératinocytes et fibroblastes autologues	Traitement des brûlures de deuxième degré profond et de troisième degré
German	Zweischichtiges künstlich hergestelltes auf einem Kollagenhydrogel basierendes Hauttransplantat bestehend aus autologen Keratinozyten und Fibroblasten	Behandlung von teilweise tiefen und vollschichtigen Verbrennungen
Greek	Διπλοστοιβάδα με βάση υδρογέλης κολλαγόνου, αποτελούμενη από αυτόλογα κερατινοκύτταρα και ινοβλάστες	Θεραπεία βαθέων δερματικών εγκαυμάτων μερικού ή ολικού πάχους
Hungarian	Autológ keratinocitákból és fibroblasztokból álló, kétrétegű mesterséges kollagén hidrogél alapú bőr graft	Részleges mély dermális és transzdermális égési sérülés kezelése
Italian	Trapianto cutaneo a doppio strato ingegnerizzato, basato su idrogel di collagene di tipo I contenente cheratinociti e fibroblasti autologhi	Trattamento da ustioni a profondità parziale e da ustione a pieno spessore

¹ At the time of designation

Language	Active ingredient	Indication
Latvian	Divslāņu inženierēts uz kolagēna hidrogēls balstīts ādas transplantāts, kas sastāv no autologiem keratinocītiem un fibroblastiem	Dalēja dziļa dermāla un pilna ādas biezuma apdeguma ārstēšana
Lithuanian	Dvisluoksnis kolageno hidrogelio pagrindu sukurtas odos transplantatas iš autologinių keratinocitų ir fibroblastų	Dalinio ir visų odos sluoksnių nudegimų gydymas
Maltese	Ġilda għat-trapjant maħduma b'żewġ saffi fuq idroġel ta' kollaġni magħmula minn keratinociti awtologi u fibroblasts	Kura ta' ħarġiet li jkunu parzjalment profondi fil-ġilda u fil-ħxuna kollha tal-ġilda
Polish	Dwuwarstwowy sztuczny przeszczep skóry na bazie kolagenowego hydrożelu składający się z autologicznych keratynocytów i fibroblastów	Leczenie częściowych i całkowitych głębokich skórnych oparzeń
Portuguese	Enxerto de pele bicamada de engenharia à base de hidrogel de colágeno composta por queratinócitos e fibroblastos autólogos	Tratamento de queimaduras profundas de espessura parcial e total
Romanian	Grefă cutanată dublu strat produsă artificial pe bază de hidrogel de colagen ce conține keratinocite și fibroblaste autologe	Tratamentul arsurilor dermale profunde parțiale și totale
Slovak	Dvojvrstvový umelovyrobený kožný transplantát pozostávajúci z kolagénoveho hydrogélu a autológnych keratinocytov a fibroblasto	Liečba kožných popálenín - čiastočných a v celej hrúbke kože
Slovenian	Dvoslojni, na osnovi kolagenskega hidrogela pridobljen kožni nadomestek, ki vsebuje avtologne keratocite in fibroblaste	Zdravljenje parcialne dermalne in subdermalne kožne opekline
Spanish	Injerto de piel bicapa ingeniería a base de hidrogel de colágeno compone de queratinocitos y fibroblastos autólogos	Tratamiento de quemaduras profundas parciales o totales de la piel
Swedish	Dubbelskiktigt konstruerad kollagen-hydrogel-baserade hudtransplantat bestående av autologa keratinocyter och fibroblaster	Behandling av djupa brännskador i huden, både partiella och full tjockleksskador
Norwegian	Bilaget konstruert kollagen hydrogel -baserte hud pode sammensatt av autologe keratinocytter og fibroblaster	Behandling av dype brannskader i huden, både dermale og subdermale skader
Icelandic	Tveggja laga samsett kollagen hýdrógel húðgræðlingur sem samanstendur afsamgena hymisfrumum og trefjakímfrumum	Meðhöndlun á djúpum fullþykktar húðbruna