



EUROPEAN MEDICINES AGENCY
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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Olaparib for the treatment of ovarian cancer

First publication	1 July 2008
Rev.1: administrative update	21 June 2010
Rev.2: sponsor's change of address	1 October 2014
Rev.3: information about Marketing Authorisation	3 March 2015
Disclaimer Please note that revisions to the Public Summary of Opinion are purely administrative updates. Therefore, the scientific content of the document reflects the outcome of the Committee for Orphan Medicinal Products (COMP) at the time of designation and is not updated after first publication.	

On 6 December 2007, orphan designation (EU/3/07/501) was granted by the European Commission to AstraZeneca AB, Sweden, for olaparib for the treatment of ovarian cancer.

What is ovarian cancer?

Tumours that begin in the ovaries are known as ovarian tumours. Tumours that have the potential to grow rapidly and invade surrounding healthy tissues are called ovarian cancers. Due to the absence of symptoms in early stages of the disease, the majority of patients are diagnosed when the tumours have spread locally or to distant parts of the body. Ovarian cancer is a life-threatening condition.

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

At the time of designation, ovarian cancer affected approximately 2.9 in 10,000 people in the European Union (EU). This was equivalent to a total of around 145,000 people*, and is below the threshold 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).

*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 27), Norway, Iceland and Liechtenstein. At the time of designation, this represented a population of 500,300,000 (Eurostat 2007).



What treatments are available?

Several medicinal products were authorised for the condition in the Community at the time of submission of the application for orphan designation. Although a significant percentage of patients respond to the initial chemotherapy (drugs used to kill cancer cells), most ovarian cancers grow again and respond moderately or poorly to subsequent chemotherapy.

Olaparib might be of potential significant benefit for the treatment of ovarian cancer. This assumption will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

How is this medicine expected to work?

This protein helps repair damaged DNA (the genetic material in the cells); if PARP is blocked by olaparib, the damaged DNA in the tumour cell cannot be repaired, and the cell dies as a result. This is expected to reduce or block tumour growth.

What is the stage of development of this medicine?

The effects of olaparib were evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials in patients with ovarian cancer were ongoing.

Olaparib was not authorised anywhere in the world for ovarian cancer, or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 10 October 2007 recommending the granting of this designation.

Update: olaparib (Lynparza) has been authorised in the EU since 16 December 2014. Lynparza is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.

More information on Lynparza can be found in the European public assessment report (EPAR) on the Agency's website: [ema.europa.eu/Find_medicine/Human_medicines/European Public Assessment Reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports)

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 European Union) 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:

AstraZeneca AB
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Tel. +44 1625 514 776 (AstraZeneca UK Limited)
E-mail: Olaparib@astrazeneca.com

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	Olaparib	Treatment of ovarian cancer
Bulgarian	Олапариб	Лечение на рак на яйчниците
Czech	Olaparib	Léčba karcinomu vaječníků
Danish	Olaparib	Behandling af ovarie cancer
Dutch	Olaparib	Behandeling van ovariumkanker
Estonian	Olapariib	Munasarjavähi ravi
Finnish	Olaparibi	Munasarjasyövän hoito
French	Olaparib	Traitement du cancer de l'ovaire
German	Olaparib	Behandlung des Ovarialkarzinoms
Greek	Ολαπαρίμπη	Θεραπεία του καρκίνου των ωοθηκών
Hungarian	Olaparib	Petefészekrák kezelése
Italian	Olaparib	Trattamento del carcinoma dell'ovaio
Latvian	Olaparībs	Olnīcu vēža ārstēšanai
Lithuanian	Olaparibas	Kiaušidžių vėžio gydymas
Maltese	Olaparib	Kura tal-kanċer ta' l-ovarji
Polish	Olaparyb	Leczenie raka jajnika
Portuguese	Olaparib	Tratamento do cancro do ovário
Romanian	Olaparib	Tratamentul cancerului ovarian
Slovak	Olaparib	Liečba rakoviny vaječníkov
Slovenian	Olaparib	Zdravljenje raka na jajčnikih
Spanish	Olaparib	Tratamiento del cáncer de ovario
Swedish	Olaparib	Behandling av ovarialcancer
Norwegian	Olaparib	Behandling av eggstokkreft
Icelandic	Ólaparíb	Meðferð eggjastokkakrabbameins

¹ At the time of designation