Lynparza

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IA /	A. ADMINISTRATIVE CHANGES - A.4 Change	17/11/2025	N/A		

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000312766	in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
Variation type II / EMA/VR/0000287658	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to add paediatric information based on final results from study D0816C00025, a PIP study and submitted in accordance with Article 46 of Regulation (EC) No 1901/2006. This is a Phase I, Open-label, Parallel Group Study to Investigate Olaparib Safety and Tolerability, Efficacy and Pharmacokinetics in Paediatric Patients with Solid Tumours. In addition, the MAH is taking the opportunity to correct errors in CSR Addendum 1 for Lynparza study D081CC00006 (OlympiA).	09/10/2025		SmPC	SmPC new text For more information, please refer to the Summary of Product Characteristics. Sections 4.2, 4.8, 5.1 and 5.2 of the SmPC have been updated to describe the efficacy, safety and pharmacokinectis results of study D0816C00025, a Phase 1, open-label, multicentre study to investigate the safety, tolerability, pharmacokinetic, pharmacodynamics and preliminary efficacy of Lynparza monotherapy in paediatric patients from ≥ 6 months to < 18 years with relapsed or refractory solid or primary central nervous system (CNS) tumours (excluding lymphoid malignancies) for whom there were no standard treatment options. The study enrolled 16 patients aged ≥ 6 years to < 18 years with a homologous recombination repair (HRR) deficiency or HRR gene mutation via local test or gBRCA mutation via central test. Lynparza was administered as a single dose on day 1, followed by twice daily in a continuous schedule. Of the 16 patients enrolled, 13 patients aged ≥ 12

					years to < 18 years received 300 mg of olaparib tablet twice daily and 3 patients aged ≥ 6 years to < 12 years received 200 mg of olaparib tablet twice daily until disease progression or unacceptable toxicity. There was no objective response observed in the 12 participants enrolled with measurable disease at baseline. In summary, the results of the study did not allow to conclude that the benefits of Lynparza in children and adolescents outweigh the risks. The safety and efficacy of Lynparza in children and adolescents aged less than 18 years has not been established
Variation type II / EMA/VR/0000252324	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 5.1 of the SmPC to include the results of a descriptive analysis of Overall Survival at five years last subject randomised from study D081CC00006 (OlympiA); a randomised, double-blind, parallel group, placebo-controlled multi-centre phase III study to assess the efficacy and safety of olaparib versus placebo as adjuvant treatment in patients with Germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and	05/06/2025		SmPC	Adjuvant treatment of germline BRCA-mutated high risk early breast cancer OlympiA [...] The study met its primary endpoint demonstrating a statistically significant improvement in IDFS in the olaparib arm compared with the placebo arm. Two hundred and eighty-four (284) patients had IDFS events, this represented 12% of patients in the olaparib arm (distant 8%, local/regional 1.4%, contralateral invasive breast cancer 0.9%, non-breast second primary malignancies 1.2%, death 0.2%) and 20% of patients in the placebo arm (distant 13%, local/regional 2.7%, contralateral invasive breast cancer 1.3%, non-breast second primary malignancies 2.3%, death 0%). A statistically significant improvement in DDFS in the olaparib arm compared with the placebo arm was also observed. At the primary OS analysis (10% maturity, DCO 12 July 2021), a statistically significant improvement in OS was observed in the

	neoadjuvant or adjuvant chemotherapy.				olaparib arm compared with the placebo arm (HR=0.68 [98.5% CI 0.47, 0.97], p value=0.0091). In a prespecified analysis performed approximately five years after the last patient was randomised, with a median follow–up of 6.2 years in the olaparib arm and 6.1 years in the placebo arm, olaparib continued to demonstrate improved OS compared to placebo. Efficacy results in the FAS are presented in Table 11 and Figures 9 and 10. For more information, please refer to the Summary of Product Characteristics.
Variation type II / EMA/VR/0000246964	This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted A. ADMINISTRATIVE CHANGES - A.z Other variation - Accepted A grouped application comprising of a Type II variation and a Type I variation, as follows: Type II (C.I.4): Update of sections 4.4 and 4.8 of the SmPC in order to update the warning on 'Pneumonitis' and add it to the list of adverse drug reactions (ADRs) with frequency 'uncommon', based on a	15/05/2025		SmPC and PL	4.4 Special warnings and precautions for use […] Myelodysplastic syndrome/Acute myeloid leukaemia Myelodysplastic syndrome (MDS)/acute myeloid leukaemia (AML) has occurred in patients treated with Lynparza (see section 4.8). The majority of events had a fatal outcome. Patients with BRCAm platinum-sensitive relapsed ovarian cancer who had received at least two prior lines of platinum chemotherapy were at higher risk to experience MDS/AML. The duration of therapy with olaparib in patients who developed MDS/AML varied from < 6 months to > 4 years. […] Pneumonitis Pneumonitis, including events with a fatal outcome, has been reported in patients treated with Lynparza in clinical studies (see section 4.8). If patients present with new or worsening respiratory symptoms such as dyspnoea, cough and fever, or an abnormal chest radiologic finding is observed, Lynparza treatment should be interrupted and prompt investigation initiated. If pneumonitis is confirmed, Lynparza

	safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. Type I (A.z): the Package Leaflet is updated to reflect the higher incidence of Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukaemia (AML) observed during long-term follow up of patients in clinical trials, in order to align with the current information in section 4.4 of the SmPC.				treatment should be discontinued and the patient treated appropriately. For more information, please refer to the Summary of Product Characteristics.
PSUR / EMA/PSUR/0000257846	- -	10/07/2025	N/A		Maintenance