# XOSPATA

Procedural steps taken and scientific information after the authorisation

| Application number | Scope | Opinion/ Notification [1] issued on | Commission Decision Issued [2] / amended on | Product Information affected [3] | Summary |
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| II/0007 | Submission of the report of an integrated analysis to demonstrate the safety of long term treatment with gilteritinib when all patients enrolled in studies 2215-CL-0101, 2215-CL-0102 and 2215-CL-0301 have completed at least 3 years of treatment with gilteritinib or have withdrawn prior to completing at least 3 years of treatment. The studies refer to: 1) study 2215-CL-0101: a phase 1/2 open-label, dose | 05/05/2022 | 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).

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| | escalation study investigating the safety, tolerability, pharmacokinetics, and pharmacodynamics of ASP2215 (gilteritinib) in patients with relapsed or refractory acute myeloid leukaemia (AML); 2) study 2215-CL-0102: a phase 1 open-label, dose escalation study investigating the safety, tolerability, pharmacokinetics, and pharmacodynamics of ASP2215 in Japanese patients with relapsed or refractory AML; 3) study 2215-CL-0301: a phase 3 open-label, multicentre, randomized study of ASP2215 versus salvage chemotherapy in patients with relapsed or refractory AML with FMS-like tyrosine kinase 3 (FLT3) mutation. The RMP (version 2.0) is updated in order to address the missing information regarding the safety of Xospata (gilteritinib).<br><br>C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required | | | | |
| PSUSA/10832 /202109 | Periodic Safety Update EU Single assessment - gilteritinib | 07/04/2022 | n/a | | PRAC Recommendation - maintenance |
| PSUSA/10832 /202103 | Periodic Safety Update EU Single assessment - gilteritinib | 28/10/2021 | n/a | | PRAC Recommendation - maintenance |
| IA/0006 | A.6 - Administrative change - Change in ATC | 13/08/2021 | 09/12/2021 | SmPC and PL | |

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| | Code/ATC Vet Code | | | | |
| PSUSA/10832 /202009 | Periodic Safety Update EU Single assessment - gilteritinib | 09/04/2021 | n/a | | PRAC Recommendation - maintenance |
| II/0003 | Update of section 4.4, 4.5 and 5.2 of the SmPC in order to update information about Transporter drug-drug interactions based on final results from in vitro transporter studies identified as recommendations by CHMP (REC003) during the initial approval. In addition, the MAH took the opportunity to perform minor corrections and editorial changes in the PI.<br><br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data | 03/12/2020 | 09/12/2021 | SmPC, Labelling and PL | SmPC new text<br>Sections 4.4 a warning is added for concominant administration of gilteritinib with medicinal products that are strong inhibitors of breast cancer resistant protein (BCRP)<br>Section 4.5<br>Interactions:"Strong inhibitors of BCRPP can increase gilteritinib plasma concentrations"<br>Effects of Xospata on other medicinal products: Effect of gliteritinib on medicinal products which are P-gp substrates is removed<br>Section 5.2 Transporter drug drug interactions;section is modified to reflect new data:<br>In vitro experiments demonstrated that gilteritinib is a substrate of P-gp and BCRP. Gilteritinib may potentially inhibit BCRP, and P gp, OATP1B1 in the small intestine, and OCT1 in the liver at clinically relevant concentrations (see section 4.5).<br>For more information, please refer to the Summary of Product Characteristics. |
| II/0001 | Submission of a pooled analysis report from studies 2215-CL-0101 (Phase 1/2), 2215-CL-0102 (Phase 1), 2215-CL-0301, 2215-CL-9100 (phase 3) listed as "Other forms of routine pharmacovigilance activities in section III.1 of the RMP". This is a pooled analysis to characterize gilteritinib-related differentiation | 26/11/2020 | n/a | | |

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| | syndrome, specifically incidence, observed signs and symptoms, duration, and response to intervention based on patient-level data from on-going trials in patients with acute myeloid leukemia.<br><br>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority | | | | |
| PSUSA/10832 /202003 | Periodic Safety Update EU Single assessment - gilteritinib | 29/10/2020 | n/a | | PRAC Recommendation - maintenance |