10 June 2022
EMA/PRAC/68282/2022 Rev 1

Timetable for the procedure

Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data

Janus Kinase inhibitors (JAKi)

Xeljanz EMEA/H-A20/1517/C/004214/0048

Cibinqo EMEA/H-A20/1517/C/005452/0003

Olumiant EMEA/H-A20/1517/C/004085/0032

Rinvoq EMEA/H-A20/1517/C/004760/0017

Jyseleca EMEA/H-A20/1517/C/005113/0014

Procedural step:	**Date**
Notification:	28 January 2022
Start of the procedure (PRAC[1]):	February 2022, PRAC
List of questions:	10 February 2022
Submission of responses:	17 March 2022
Re-start of the procedure:	07 April 2022
Overall Rapporteur and Co-Rapporteurs' assessment reports circulated to PRAC and to CHMP[2]	19 May 2022
Comments:	25 May 2022

[1] Pharmacovigilance Risk Assessment Committee
[2] Committee for Medicinal Products for Human Use

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

© European Medicines Agency, 2022. Reproduction is authorised provided the source is acknowledged.

Procedural step:	**Date**
Updated overall Rapporteur and Co-Rapporteurs' assessments report circulated to PRAC and to CHMP	03 June 2022
PRAC list of outstanding issues:	10 June 2022
Submission of responses:	11 August 2022
Re-start of the procedure:	1 September 2022
Rapporteur/co-rapporteurs joint assessment report circulated to PRAC and to CHMP	9 September 2022
Ad hoc expert group (AHEG):	To be confirmed
Comments:	30 September 2022
Updated Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP	17 October 2022
PRAC recommendation to CHMP:	November 2022, PRAC