CADTH

Common Drug Review

Project Status Report

Brand Name: Ocaliva

Non-proprietary Name: obeticholic acid (OCA)

Applicant: Intercept Pharma Canada, Inc.

Indication(s): Primary Biliary Cholangitis

Project Type: Submission

Date Received: 2016-Dec-22

Date NOC Issued[1]: 2017-May-25

Application Fee Schedule[2]: Schedule A

Key Milestone[3]	Target Date	Actual Date	Comments
Application accepted for review	2017-Jan-13	2017-Jan-13	- Review has been initiated 2017-Jan-16
Patient group input received[4]	2017-Jan-20	2017-Jan-20	- Call for patient input posted on 2016-Nov-24 - Patient group input deadline: 2017-Jan-20 - Patient input submission received
Patient group comments on input summary received	2017-Feb-10	2017-Feb-10	- Patient input summary sent for review on 2017-Feb-03 - Patient input summary feedback deadline: 2017-Feb-10 - Patient input summary feedback received
Draft CDR review report(s) sent to applicant	2017-Mar-30	2017-Mar-30	
Comments from applicant on draft CDR review report(s) received by CADTH	2017-Apr-10	2017-Apr-10	
Redaction requests from applicant on draft CDR review report(s) received by CADTH	2017-Apr-18	2017-Apr-18	- Manufacturer waived the opportunity to request redactions
CDR review team's comments on draft CDR review report(s) sent to applicant	2017-May-05	2017-May-05	
Canadian Drug Expert Committee (CDEC) meeting	2017-May-17	2017-Jun-21	- Deferred to the 21-Jun-2017 CDEC meeting
CDEC recommendation & redacted CDR review report(s) sent to drug plans and applicant	2017-May-30 to 2017-Jun-01	2017-Jul-04	- New target date: 4-July-2017 to 6-July-2017
Embargo period[5] and validation of redacted CDR review report(s)	2017-Jul-18	2017-Jul-18	
CDEC Final Recommendation issued to drug plans and applicant if: - no request for clarification is made AND - no request for reconsideration is made AND - no request for resubmission based on a reduced price during embargo period is made	2017-Jul-25	2017-Jul-25	
CDEC Final Recommendation posted[6]		2017-Jul-27	
Final CDR review report(s)[6] and patient input posted		2017-Aug-16	

[1] CDR applications for submissions can be filed on a pre-NOC basis. When such a submission is received, this field will indicate 'pending' until the NOC (or NOC/c) is issued by Health Canada.

[2] Refer to Appendix 1 of the *Procedure for the CADTH Common Drug Review* (https://www.cadth.ca/media/cdr/process/CDR_Procedure.pdf) for details regarding CDR application fee schedules.

[3] Please refer to the *Procedure for the CADTH Common Drug Review* (https://www.cadth.ca/media/cdr/process/CDR_Procedure.pdf) for complete details regarding the CDR process and targeted time frames for key milestones.

[4] The call for patient group input is posted 20 business days inadvance of the applicant's anticipated date of filing the CDR application. Patient groups have a total of 35 business days for preparing and submitting patient input.

[5] The embargoed CDEC recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of *CDEC Final Recommendation.* The applicant may make a request for reconsideration or resubmission based on reduced price during the embargo period, and the drug plans may make a request for clarification, as applicable (see section 8 of the *Procedure for the CADTH Common Drug Review)* .

[6] The timing for posting the *CDEC Final Recommendation* and CDR review report(s) depends on several factors including the need for consultation with the applicant regarding redaction issues.

This CDR Project Status Report is posted every other week, reflecting status as of the end of day Wednesday (4:00 pm ET) of that week.