



## Common Drug Review

### Project Status Report

<b>Brand Name:</b>	Ravicti		
<b>Non-proprietary Name:</b>	glycerol phenylbutyrate		
<b>Applicant:</b>	Horizon Therapeutics Canada / Horizon Pharma Ireland Ltd.		
<b>Indication(s):</b>	Urea cycle disorders		
<b>Project Type:</b>	Submission	<b>Date NOC Issued<sup>1</sup>:</b>	2016-Mar-18
<b>Date Received:</b>	2016-Aug-30	<b>Application Fee Schedule<sup>2</sup>:</b>	Schedule A

Key Milestone <sup>3</sup>	Target Date	Actual Date	Comments
Application accepted for review	2016-Sep-14	2016-Sep-14	- Review has been initiated 2016-Sep-15
Patient group input received <sup>4</sup>	2016-Sep-21	2016-Sep-21	- Call for patient input posted on 2016-Aug-02 - Patient group input deadline: 2016-Sep-21 - Patient input submission received
Patient group comments on input summary received	2016-Oct-17	2016-Oct-17	- Patient input summary sent for review on 2016-Oct-06 - Patient input summary feedback deadline: 2016-Oct-17 - Patient input summary feedback received
Draft CDR review report(s) sent to applicant	2016-Nov-29	2016-Dec-14	- New target date: 2016-Dec-13 - New target date: 2016-Dec-14
Comments from applicant on draft CDR review report(s) received by CADTH	2016-Dec-08	2017-Jan-04	- New target date: 2016-Dec-22 - New target date: 2016-Dec-23 - New target date: 2017-Jan-04
Redaction requests from applicant on draft CDR review report(s) received by CADTH	2016-Dec-15	2017-Jan-09	- New target date: 2017-Jan-06 - New target date: 2017-Jan-09
CDR review team's comments on draft CDR review report(s) sent to applicant	2017-Feb-03	2017-Feb-03	
Canadian Drug Expert Committee (CDEC) meeting	2017-Feb-15	2017-Feb-15	
CDEC recommendation & redacted CDR review report(s) sent to drug plans and applicant	2017-Feb-28 to 2017-Mar-02	2017-Feb-28	
Embargo period <sup>5</sup> and validation of redacted CDR review report(s)	2017-Mar-14	2017-Mar-14	
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-Mar-21	2017-Mar-21	
CDEC Final Recommendation posted <sup>6</sup>	2017-Mar-23	2017-Mar-23	
Final CDR review report(s) <sup>6</sup> and patient input posted		2017-Apr-04	

<sup>1</sup> 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.

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

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

<sup>4</sup> The call for patient group input is posted 20 business days in advance 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.

<sup>5</sup> 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*).

<sup>6</sup> 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.**