



## Common Drug Review

### Project Status Report

<b>Brand Name:</b>	Otezla
<b>Non-proprietary Name:</b>	apremilast
<b>Applicant:</b>	Celgene Inc.
<b>Indication(s):</b>	Arthritis, psoriatic
<b>Project Type:</b>	Submission
<b>Date Received:</b>	2015-Jun-08
<b>Date NOC Issued<sup>1</sup>:</b>	2015-Jun-10
<b>Application Fee Schedule<sup>2</sup>:</b>	Schedule B

Key Milestone <sup>3</sup>	Target Date	Actual Date	Comments
Application accepted for review	2015-Jun-22	2015-Jun-22	- Review has been initiated 2015-Jun-23
Patient group input received <sup>4</sup>	2015-May-21	2015-May-21	- Call for patient input posted on 2015-Mar-31 - Patient group input deadline: 2015-May-21 - Patient input submission received
Patient group comments on input summary received	2015-Jul-08	2015-Jul-08	- Patient input summary sent for review on 2015-Jun-30 - Patient input summary feedback deadline: 2015-Jul-08 - Patient input summary feedback received
Draft CDR review report(s) sent to applicant	2015-Sep-08	2015-Oct-05	- New target date: 2015-Oct-01 - New target date: 2015-Oct-05
Comments from applicant on draft CDR review report(s) received by CADTH	2015-Sep-17	2015-Oct-15	- New target date: 2015-Oct-13 - New target date: 2015-Oct-15
Redaction requests from applicant on draft CDR review report(s) received by CADTH	2015-Sep-24	2015-Oct-22	- New target date: 2015-Oct-20 - New target date: 2015-Oct-22
Canadian Drug Expert Committee (CDEC) meeting	2015-Nov-18	2015-Nov-18	
CDEC recommendation & redacted CDR review report(s) sent to drug plans and applicant	2015-Nov-25 to 2015-Nov-27	2015-Nov-26	
Embargo period <sup>5</sup> and validation of redacted CDR review report(s)	2015-Dec-10	2015-Dec-10	
<i>CDEC Final Recommendation</i> 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	2015-Dec-17	2015-Dec-17	- Notice of final recommendation issued
<i>CDEC Final Recommendation</i> posted <sup>6</sup>	2015-Dec-21	2015-Dec-21	
Final CDR review report(s) <sup>6</sup> and patient input posted		2018-Dec-05	

<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.**