

## CADTH REIMBURSEMENT REVIEW

# Stakeholder Feedback on Draft Recommendation

entrectinib (Rozlytrek) Hoffmann-La Roche Ltd.

Indication: Extracranial solid tumours with NTRK gene fusion

October 21, 2022

**Disclaimer:** The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CADTH and do not necessarily represent or reflect the view of CADTH. No endorsement by CADTH is intended or should be inferred.

By filing with CADTH, the submitting organization or individual agrees to the full disclosure of the information. CADTH does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no identifying personal information or personal health information is included in the submission. The name of the submitting stakeholder group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.



## CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder						
information						
CADTH project number	PC0278-000					
Brand name (generic)	Rozlytrek (entrectinib)					
Indication(s)	For the treatment of adult patients with unresectable locally advanced or metastatic extracranial solid tumours, including bra metastases, that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, and with no satisfactory treatment options.					
Organization	Ontario Health (Cancer Care Ontario) Gastrointestinal D Advisory Committee	rug				
Contact information <sup>a</sup>	Name: Dr. Erin Kennedy					
Stakeholder agreement	with the draft recommendation					
1 Doop the stakeholder	agree with the committee's recommendation	Yes	$\boxtimes$			
1. Does the stakeholder	agree with the committee's recommendation.	No				
Whenever possible, pleas Expert committee consi	Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale. Expert committee consideration of the stakeholder input					
	ation demonstrate that the committee has nolder input that your organization provided to	Yes No	$\boxtimes$			
If not, what aspects are m	nissing from the draft recommendation?					
Clarity of the draft recor	nmendation					
3. Are the reasons for th	e recommendation clearly stated?	Yes No	$\boxtimes$			
If not, please provide details regarding the information that requires clarification.						
4. Have the implementat addressed in the reco	ion issues been clearly articulated and adequately mmendation?	Yes No				
If not, please provide deta	ails regarding the information that requires clarification.	·				
	eimbursement conditions clearly stated and the itions provided in the recommendation?	Yes No	$\square$			
If not, please provide deta	ails regarding the information that requires clarification.	1				

<sup>a</sup> CADTH may contact this person if comments require clarification.

## Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.
- For conflict of interest declarations:
  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
1. Did you receive help from outside your clinician group to complete this submission?	No	
	Yes	$\boxtimes$
If yes, please detail the help and who provided it.		
OH-CCO provided secretariat support.		
2. Did you receive help from outside your clinician group to collect or analyze any	No	$\boxtimes$
information used in this submission?	Yes	
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was	No	
submitted at the outset of the CADTH review and have those declarations remained	Yes	$\times$
unchanged? If no, please complete section C below.		
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
Clinician 1		
Clinician 2		
Add additional (as required)		

#### C. New or Updated Conflict of Interest Declarations

Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)
	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

	Check Appropriate Dollar Range			
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name				
Add company name				
Add or remove rows as required				

Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)
	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

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	Check Appropriate Dollar Range			
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name				
Add company name				
Add or remove rows as required				

new or op	dated Declaration for Clinician	3			
Name	Please state full name				
Position	Please state currently held position				
Date	Please add the date form was completed (DD-MM-YYYY)				
$\boxtimes$	I hereby certify that I have the matter involving this clinician or place this clinician or clinician g	clinician group	with a company,	organization, or e	entity that may
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New or Up	dated Declaration for Clinician 4				
Name	Please state full name				
Position	Please state currently held position				
Date	Please add the date form was completed (DD-MM-YYYY)				
	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.				
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Add company name					
Add company name					
Add or rem	nove rows as required				

New or Up	dated Declaration for Clinician	5			
Name	Please state full name				
Position	Please state currently held position				
Date	Please add the date form was completed (DD-MM-YYYY)				
	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.				
Conflict of	Interest Declaration				
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# CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information				
CADTH project number	PC0278-000			
Brand name (generic)	Entrectinib (Rozlytrek)			
Indication(s)	For the treatment of adult patients with unresectable locally advance			
	metastatic extracranial solid tumours, including brain metastas			
	have a neurotrophic tyrosine receptor kinase (NTRK) gene fu			
	without a known acquired resistance mutation, and with no satis			
_	treatment options.			
Organization	Ontario Health Lung Cancer Drug Advisory Committee			
Contact information <sup>a</sup>	Name: Dr. Donna Maziak			
Stakeholder agreement w	ith the draft recommendation			
1 Doos the stakeholder a	gree with the committee's recommendation.	Yes	$\boxtimes$	
		No		
[Consideration for continuat	tion or renewal of therapy]			
achieved, then every 6 mor renewal should be a clinica The DAC would like to advo	oths. CT scan or chest x-ray is preferred over PET scan. The de I decision rather than a radiology decision. Decate switching for toxicity that might be drug specific but not cl a specific intolerances and patient would benefit from switching	ass	for	
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## Appendix 2. Conflict of Interest Declarations for Clinician Groups

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  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
1. Did you receive help from outside your clinician group to complete this submission?	No	
	Yes	$\boxtimes$
Ontario Health provided secretariat function to the DAC.		
	No	$\boxtimes$
information used in this submission?	Yes	
B. Previously Disclosed Conflict of Interest		
	No	
submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	Yes	$\boxtimes$
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
Dr. Stephanie Brule		
Dr. Natasha Leighl		
Dr. Sara Kuruvilla		

# **CADTH Reimbursement Review**

# **Feedback on Draft Recommendation**

Stakeholder information	
CADTH project number	PC0278
Name of the drug and	Entrectinib (Rozlytrek) for extracranial solid tumours with NTRK
Indication(s)	gene fusion
Organization Providing	PAG
Feedback	

<b>1. Recommendat</b> Please indicate if the recommendation.	<b>ion revisions</b> ne stakeholder requires the expert review committee to reconsider or clari	fy its			
Request for	Major revisions: A change in recommendation category or patient population is requested				
Reconsideration         Minor revisions: A change in reimbursement conditions is requested					
No Request for	Editorial revisions: Clarifications in recommendation text are requested	х			
Reconsideration	No requested revisions				

2. Change in recommendation category or conditions

Complete this section if major or minor revisions are requested None.

**3. Clarity of the recommendation** Complete this section if editorial revisions are requested for the following elements

#### a) Recommendation rationale

None.

#### b) Reimbursement conditions and related reasons

In Table 1. Reimbursement Conditions and Reasons, under the section "Initiation" PAG is requesting the following addition in 1.2 NTRK gene fusion "*without a known acquired resistance mutation*" to align with NOC and Larotrectinib.

#### c) Implementation guidance

None.



# **CADTH Reimbursement Review**

## **Feedback on Draft Recommendation**

Stakeholder information					
CADTH project number	PC0278-000				
Brand name (generic)	Entrectinib (Rozlytrek)				
Indication(s)	For the treatment of adult patients with unresectable locally a	dvance	ed or		
	metastatic extracranial solid tumours, including brain metastases, that				
	have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion				
	without a known acquired resistance mutation, and with no satisfactory				
	treatment options				
Organization	Lung Cancer Canada – Patient and Clinician Groups				
Contact information <sup>a</sup>	Name: Shem Singh				
Stakeholder agreement wi	ith the draft recommendation				
1 Doos the stakeholder as	gree with the committee's recommendation.	Yes	X		
. Does the stakeholder at		No			
Lung Cancer Canada is plea	ased with pERC's positive recommendation of entrectinib for p	atients	with		
	rationale for recommendation states the reason for recommend		and		
	group input has been adequately referenced in consideration for				
	e the recommendation is fair and comprehensive, and have no	othing t	0		
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	orts conversion to final recommendation.	Ū	-		
add at this time. LCC suppo	orts conversion to final recommendation.	Ū	-		
add at this time. LCC suppo Lung Cancer Canada's Clin	rts conversion to final recommendation. ician Group and Medical Advisory Committee also agrees with	Ū	-		
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<sup>a</sup> CADTH may contact this person if comments require clarification.

### **Appendix 1. Conflict of Interest Declarations for Patient Groups**

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the <u>Procedures for CADTH Drug Reimbursement Reviews</u> for further details.

A. Patient	Group Information					
Name	Shem Singh					
Position	Executive Director					
Date	October 21, 2022					
$\boxtimes$	I hereby certify that I have the a matter involving this patient gro patient group in a real, potential	up with a comp	any, organizatio	on, or entity that m		
B. Assista	nce with Providing Feedback					
					No	$\boxtimes$
1. Did yo	u receive help from outside you	ir patient grou	p to complete y	our feedback?	Yes	
2. Did vo	u receive help from outside vou	r patient grou	p to collect or a	analvze anv	No	$\boxtimes$
inform	u receive help from outside you ation used in your feedback? se detail the help and who provide		p to collect or a	analyze any	No Yes	
inform If yes, plea	ation used in your feedback?	ed it.	p to collect or a	analyze any		
inform If yes, plea C. Previou 1. Were	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interes conflict of interest declarations	ed it. St provided in pa	tient group inp	but that was	Yes	
inform If yes, plea C. Previou 1. Were of submi	se detail the help and who provide se <b>Jusclosed Conflict of Interes</b>	ed it. st provided in pa review and ha	tient group inp	but that was	Yes	
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inform If yes, plea C. Previou 1. Were of submi uncha D. New or 3. List ar	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interes conflict of interest declarations tted at the outset of the CADTH nged? If no, please complete se	ed it. provided in pa review and ha oction D below claration hat have provi	itient group inp ive those decla ided your grou	out that was rations remained p with financial p	Yes d No Yes	
inform If yes, plea C. Previou 1. Were of submi uncha D. New or 3. List ar	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interest conflict of interest declarations p tted at the outset of the CADTH nged? If no, please complete se Updated Conflict of Interest Dec by companies or organizations t	ed it. provided in pa review and ha oction D below claration hat have provi	itient group inp ive those decla ided your grou	out that was rations remained p with financial p	Yes d No Yes oayment ew.	
inform If yes, plea C. Previou 1. Were o submi uncha D. New or 3. List ar past ty	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interest conflict of interest declarations p tted at the outset of the CADTH nged? If no, please complete se Updated Conflict of Interest Dec by companies or organizations t	ed it. provided in pa review and ha oction D below claration hat have provi	itient group inp ive those decla ided your grou	out that was rations remained p with financial p drug under revio	Yes d No Yes oayment ew.	over the
inform If yes, plea C. Previou 1. Were of submi uncha D. New or 3. List ar past tw Company	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interest conflict of interest declarations p tted at the outset of the CADTH nged? If no, please complete se Updated Conflict of Interest Dec ny companies or organizations t wo years AND who may have dir	ed it. provided in pa review and ha oction D below claration hat have provi	itient group inp ive those decla ided your grou t interest in the <u>Check Appro</u> \$5,001 to	put that was rations remained p with financial p drug under revio priate Dollar Rat \$10,001 to	Ves No Yes Dayment ew. nge In Exces \$50,000	over the
inform If yes, plea C. Previou 1. Were o submi uncha D. New or 3. List ar	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interest conflict of interest declarations p tted at the outset of the CADTH nged? If no, please complete se Updated Conflict of Interest Dec ny companies or organizations t wo years AND who may have dir	ed it. provided in pa review and ha oction D below claration hat have provi ect or indirect \$0 to 5,000	itient group inp ve those decla ided your grou t interest in the <u>Check Appro</u> \$5,001 to 10,000	put that was rations remained p with financial p drug under revio priate Dollar Rat \$10,001 to 50,000	A Yes No Yes Dayment ew. nge In Exces \$50,000	over the

### Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the <u>Procedures for CADTH Drug Reimbursement Reviews</u> for further details.
- For conflict of interest declarations:
  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	$\boxtimes$
	Yes	
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any	No	$\boxtimes$
information used in this submission?	Yes	
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was	No	
submitted at the outset of the CADTH review and have those declarations remained	Yes	$\boxtimes$
unchanged? If no, please complete section C below.		
<ul> <li>If yes, please list the clinicians who contributed input and whose declarations have not changed:</li> <li>Dr. Paul Wheatley-Price (lead)</li> </ul>		
<ul> <li>Dr. Shaqil Kassam</li> </ul>		
<ul> <li>Dr. Stephanie Snow</li> </ul>		
Dr. David Dawe		
Dr. Callista Phillips		
Dr. Sunil Yaday		
Dr. Catherine Labbé		
Dr. Nicole Bouchard		
Dr. David Stewart		
Dr. Kevin Jao		
Dr. Jeffery Rothenstein		
Dr. Zhaolin Xu		
Dr. Randeep Sangha		
Dr. Cheryl Ho		
Dr. Quincy Chu		
Dr. Silvana Spadafora		
Dr. Normand Blais		

- Dr. Rosalyn Juergens
- Dr. Geoffrey Liu
- Dr. Ron Burkes
- Dr. Barbara Melosky

## C. New or Updated Conflict of Interest Declarations

New or Up	New or Updated Declaration for Clinician 1				
Name	Please state full name				
Position	Please state currently held posi	tion			
Date	Please add the date form was o	completed (DD-	MM-YYYY)		
	I hereby certify that I have the matter involving this clinician or place this clinician or clinician g	clinician group	with a company,	organization, or e	entity that may
Conflict of	Interest Declaration				
	mpanies or organizations that hav who may have direct or indirect i				r the past two
			Check Approp	oriate Dollar Rang	ge
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name					
Add company name					
Add or rem	ove rows as required	П	П	П	

New or Updated Declaration for Clinician 2					
Name	Please state full name				
Position	Please state currently held posi	ition			
Date	Please add the date form was o	completed (DD-	MM-YYYY)		
	I hereby certify that I have the matter involving this clinician or place this clinician or clinician g	clinician group	with a company,	organization, or e	entity that may
Conflict of	Interest Declaration				
	npanies or organizations that hav who may have direct or indirect i				er the past two
			Check Approp	riate Dollar Ranç	ge
Company	Company \$0 to 5,000 \$5,001 to \$10,001 to In Excess of 10,000 50,000 \$50,000				
Add compa	Add company name				
Add compa	Add company name				
Add or rem	ove rows as required				

#### New or Updated Declaration for Clinician 3

Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)
	<b>I hereby certify</b> that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

#### **Conflict of Interest Declaration**

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

	Check Appropriate Dollar Range				
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000	
Add company name					
Add company name					
Add or remove rows as required					

New or Up	New or Updated Declaration for Clinician 4				
Name	Please state full name				
Position	Please state currently held posi	tion			
Date	Please add the date form was o	completed (DD-	ΜΜ-ΥΥΥΥ)		
	I hereby certify that I have the matter involving this clinician or place this clinician or clinician g	clinician group	with a company,	organization, or e	entity that may
Conflict of	Interest Declaration				
	npanies or organizations that hav who may have direct or indirect i				r the past two
			Check Approp	riate Dollar Rang	je
Company					
Add compa	Add company name				
Add company name					
Add or rem	ove rows as required				

New or Up	New or Updated Declaration for Clinician 5				
Name	Please state full name				
Position	Please state currently held position				
Date	Please add the date form was completed (DD-MM-YYYY)				
	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.				
Conflict of	Conflict of Interest Declaration				

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

	Check Appropriate Dollar Range				
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000	
Add company name					
Add company name					
Add or remove rows as required					