ERC1671: INDIVIDUAL PATIENT RIGHT-TO-TRY REQUEST FORM

IND Number 15430

Purpose of this document:

- This document is to request individual patient access to ERC1671;
- Eligible physician information is required for consideration of an individual patient request;
- Patient information is required for clinical review of patient eligibility based upon criteria established for the ERC1671 Right-to-Try program;
- Necessary information will be gathered from the questions below;
- The following information is for review purposes only and will be kept confidential in accordance with ERC privacy policy.

Primary Eligibility Criteria:

Right-to-Try requests are limited to patients with cancers where there is clinical data to suggest that it is safe to administer ERC1671 and the potential for clinical benefit exists. ERC1671 has not been approved by the Food and Drug Administration to treat any disease. Right-to-Try requests are limited to adult patients with a confirmed diagnosis of glioblastoma or gliosarcoma (WHO grade IV glioma), who have failed radiation and temozolomide.

Additionally, patients must not be eligible for, or able to participate in, any open clinical trial that uses ERC1671. Meeting primary eligibility criteria is not a guarantee of approval. All requests will be evaluated on a case by case basis.

Cost of Participation:

Right-to-Try Law is silent on, and FDA regulations do not consider whether patients may be charged for investigational products in Right-to-Try cases. ERC believes that it can recover reasonable direct manufacturing, storage and handling of investigational products made available for Right-to-Try. Similarly, ERC may charge patients for fees paid to third parties who support this program. Patients and/or their third-party payer (for e.g. insurance) will be billed for these costs.

GENERAL INFORMATION:	
Patient Initials:	
Age (years):	Weight (kg):
Height (cm):	Body Surface Area (m^2):
Pregnancy Status (in case of female patients):	Lactation Status (in case of female patients):

INFORMATION RELATED TO CURRENT MEDICAL CONDITION:	
Diagnosis:	Date of Diagnosis:
# of relapses:	
Stage of Cancer (if applicable):	ECOG Performance Status:
Metastatic Sites (if applicable):	
Histology:	

PRIOR Treatments:	
Prior surgery (please select). Y/N	Describe whether biopsy, partial resection, or full surgical resection
Date of surgery (DD/MM/YYYY)	

No.	Drugs/ Radiation Therapy	Dose	Treatment Start Date (DD/MM/YYYY)	No. of Cycles	Adverse Events	Response
1						
2						
3						
4						
5						
6						

OTHER TREATMENT HISTORY:

LATEST LABORATORY VALUES:				
Measurement	Value	Unit	Range	Date of Measurement (YYYY/MM/DD)
Complete Blood Count (CBC):				
Red Blood Cell Count				
White Blood Cell Count				
Hemoglobin				
Hematocrit				
Platelet Count				
Neutrophils				
Liver Function Tests:				
Bilirubin				
Kidney Function Tests:				
Creatinine - Blood				
Creatinine Clearance				

MRI RECORD:
Date of MRI (DD/MM/YYYY):
OTHER MEDICAL CONDITIONS:

ELIGIBLE PHYSICIAN INFORMATION		
First Name:	Last Name:	
Physician Degree(s):		
Institution:	Title:	
License (State/Province/Country):	Expiry Date:	
Board Certification (Type):	Expiry Date:	
Address:		
City:	State:	ZIP Code:
Office Phone:	Email:	
Preferred form of Contact: (Office phone/ Office fax/ Email/ Other)		
Prior audit by FDA? Y ☐ N ☐	Received FDA 483? Y ☐ N ☐	Received FDA Warning Letter? Y ☐ N ☐
FDA Debarred? Y ☐ N ☐		

INSTITUTION OFFICIAL (Signatory e.g. for CDA)	
Contact First Name:	Contact Last Name:
Job Title:	
Office Phone:	Email:

SURGEON CONTACT INFORMATION (tissue collection required for manufacturing)	
☐ Tick to indicate if tissue for this request has already been provided to ERC.	
First Name:	Last Name:
Physician Degree(s):	
Institution:	Title:
License (State/Province/Country):	Expiry Date:
Board Certification (Type):	Expiry Date:
Address:	

City:	State:	ZIP Code:
Office Phone:	Email:	

INSTITUTIONAL ETHICS COMMITTEE – IEC/IRB	
Site willing to use a central IRB? Y ☐ N ☐	
Independent IRBs accepted (please list, if applicable)	
Local IEC/IRB Information	
IEC/IRB Name:	
IRB Contact First Name:	IRB Contact Last Name:
Office Phone:	Email:

PRIMARY PATIENT COORDINATOR (person responsible for patient services, including: Enrolment, reimbursement and coordination of product administration)	
First Name:	Last Name:
Office Phone:	Email:

PRIMARY PHARMACY CONTACT (person responsible for ordering and inventory management)	
First Name:	Last Name:
Office Phone:	Email:

Once the form is completed, please submit the form to compassionateuse@anovaevidence.com

IMPORTANT NOTICE
When emailing this form, please do not cc any other email addresses as this form contains patient information.