**CPI-613® (devimistat): INDIVIDUAL PATIENT COMPASSIONATE USE REQUEST FORM**

**IND Number** (for eligible patients)**:**

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| **Purpose of this Document:*** *This document is to request individual patient access to CPI-613® (devimistat)*
* *Patient information is required for medical review of the eligibility of patients based on clinical criteria gathered from the questions below*
* *The following information is for enrollment purposes only and will be kept confidential in accordance with Rafael Pharmaceuticals privacy policy*
* *This document also describes individual access under the federal “Right to Try” law*
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| **Primary Eligibility Criteria:****Compassionate Use***Compassionate use requests are limited to patients with cancers where there is clinical data to suggest that it is safe to administer CPI-613® (devimistat) and that there may be a benefit. CPI-613® (devimistat) has not been approved by the Food and Drug Administration to treat any disease. Compassionate use requests are limited to the following:*1. ***Metastatic adenocarcinoma of the pancreas*** *not previously treated and able to tolerate FOLFIRINOX therapy in the opinion of the treating oncologist*
2. ***Acute Myeloid Leukemia*** *that has relapsed following or been refractory to at least one line of previous therapy and able to tolerate high dose cytarabine and mitoxantrone in the opinion of the treating oncologist*
3. ***Myelodysplastic syndrome*** *having failed at least one previous therapy*
4. ***T-Cell Non-Hodgkin's lymphoma*** *having failed at least one previous line of therapy and able to tolerate bendamustine in the opinion of the treating oncologist.*

*Additionally, patients must not be eligible for any open clinical that uses CPI-613® (devimistat) in their disease type. Meeting these criteria is not a guarantee of approval. All requests will be evaluated on a case by case basis.***Right to Try**Under the Right to Try laws, the patient must: (1) be diagnosed with a severely-debilitating or life-threatening disease; (2) have no approved treatment options and be unable to participate in a clinical trial involving CPI-613® (devimistat); and (3) provide written informed consent to the treating physician regarding CPI-613® (devimistat). |

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| **GENERAL INFORMATION:** |
| **Patient Initials:** |
| **Age (years):** | **Weight (kg):** |
| **Height (cm):** | **Body Surface Area (m2):** |
| **Pregnancy Status (in case of female patients):** | **Lactation Status (in case of female patients):** |

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

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

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| **Study specific protocol to be followed for this patient:** **(Note: Please specify the therapy/standard of care (SOCs) that will be administered along with CPI-613® (devimistat)).** |

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| **OTHER TREATMENT HISTORY:** |

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| **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:** |
| ****Albumin**** |  |  |  |  |
| ****Total Protein**** |  |  |  |  |
| ****Alanine Transaminase**** |  |  |  |  |
| ****Aspartate Transaminase**** |  |  |  |  |
| ****Alkaline Phosphatase**** |  |  |  |  |
| ****Bilirubin**** |  |  |  |  |
| ****Prothrombin Time**** |  |  |  |  |
| **Kidney Function Tests:** |
| **Blood Urea Nitrogen** |  |  |  |  |
| **Creatinine – Blood** |  |  |  |  |
| **Creatinine Clearance** |  |  |  |  |
| **Others:** |
| **Prothrombin Ratio (PT)** |  |  |  |  |
| ****Partial Thromboplastin Time (PTT)**** |  |  |  |  |
| **Left Ventricular Ejection Fraction** |  |  |  |  |

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| **OTHER MEDICAL CONDITIONS:** |

**Does the patient have any acute, non-hematological, non-infectious toxicities of any prior treatment with cytotoxic drugs? (Yes/No):**

**Does the patient have any persisting, non-hematologic, non-infectious toxicities from prior treatment? (Yes/No):**

**If ‘Yes’, grade of the toxicity and detailed description:**

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| **PHYSICIAN INFORMATION** |
| **First Name:** | **Last Name:** |
| **Institution Name:** |
| **Address:** |
| **City:** | **State/Country:** | **ZIP Code:** |
| **Office Phone:** | **Office Fax:** |
| **Email:** | **Affiliation:** |
| **Preferred form of Contact: (Office phone/ Office fax/ Email/ Other)** |

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| **PRIMARY PATIENT COORDINATOR*****(person responsible for patient services, including: Enrolment, reimbursement and coordination of infusions)*** |
| **First Name:** | **Last Name:** |
| **Office Phone:** | **Office Fax:** |
| **Email:** | **Affiliation:** |

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

**Right to Try**

In addition to the above information, the physician must sign the following certification.

***I hereby certify that this patient has been diagnosed with a severely-debilitating or life-threatening disease as defined at 21 C.F.R. § 312.81; has exhausted all approved treatment options and is unable to participate in a clinical trial involving CPI-613® (devimistat); and has provided written informed consent regarding CPI-613® (devimistat) to me.***

Signature of physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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