



# POLICY ON COMPASSIONATE USE

INCY.CU.01-2

REGION: GLOBAL  
LOCAL POLICY: N/A  
ISSUE DATE: FEBRUARY 14, 2017

This Policy applies to the provision of Incyte investigational products to individual patients on humanitarian grounds. If you have any questions as to the applicability of this Policy for whatever reason, please contact Compliance at [compliance@incyte.com](mailto:compliance@incyte.com) or contact a member of the Compliance team.

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## 1. INTRODUCTION

Incyte believes that conducting clinical trials for review by regulatory authorities around the world to obtain the necessary approvals provides patients with the optimal mechanism for broad access to medicines as prescribed by qualified healthcare professionals. Incyte recognizes that some patients with serious or immediately life threatening diseases or conditions may not be eligible for participation in a clinical trial or may not otherwise have other options. Subject to appropriate internal review and approval based on the conditions set forth below, Incyte in its sole discretion may choose to provide individual patients with access to an unapproved or investigational product outside of a clinical trial setting. Such situations are often referred to as compassionate use but can also be known as single patient access or emergency use.

## 2. SCOPE

This Policy applies to all Incyte personnel, including contractors, consultants, or vendors, who have received an inquiry and/or are involved in the evaluation or provision of an investigational Incyte product for Compassionate Use.

## 3 DEFINITION

- **Compassionate Use:** Providing an unapproved investigational product for an individual patient's use outside of a clinical trial under the care and supervision of the patient's physician.

## 4. POLICY

- **Requirements for Compassionate Use:** Incyte will consider providing an individual patient access to an investigational product outside of a clinical trial when all of the following criteria are met:
  - The investigational product is under active clinical development by Incyte.
  - Clinical development of the investigational product is not affected by granting a patient access to the product.
    - Granting access to the investigational product does not adversely affect initiation of clinical trials or delay the completion of clinical trials involving the investigational product that could support a regulatory approval of the product or otherwise compromise the potential development of the investigational product.
  - There is sufficient evidence that the investigational product and an appropriate dose may benefit the patient.
    - Scientific data from clinical trials must show that the potential benefits to the patient seeking the investigational product outweigh the potential risks and those potential risks are not unreasonable in the context of the disease or condition.
    - Patients with underlying medical conditions that may pose safety risks that have not been sufficiently studied would not be able to receive the investigational product.

- A formal request is made by the patient's physician, unsolicited by Incyte or any other individual or organization.
  - The physician must be responsible for the patient's care and understand the risks and potential benefits of the investigational treatment.
  - The physician must comply with all regulatory authority requirements and be willing to conduct all necessary medical monitoring, safety reporting and data collection.
- Compassionate Use is permitted/approved in the country, region and/or state in which the investigational product will be administered.
- An adequate supply of the investigational product exists to support both the ongoing clinical trials and approved Compassionate Use, until and if the product becomes commercially available.
- **Patient Requirements:** To be eligible for access to an investigational or unlicensed product, a patient must meet the following criteria:
  - Have a serious or life-threatening disease or condition.
  - Have undergone appropriate standard treatments, such as standard of care, without clinical success and there is no comparable or satisfactory alternative therapy to treat the disease or condition.
  - Is ineligible for participation in any ongoing Incyte-sponsored clinical trial of the investigational product, including lack of access due to geographic limitations.
  - Be informed (or the patient's guardian or caregiver be informed) of the potential risks and benefits of the investigational treatment, provide informed consent and agree to comply with the safety and monitoring requirements defined by Incyte.
- If all the above requirements are met, Incyte will consider Compassionate Use requests subject to applicable laws and regulations.
  - Any access to an unapproved, investigational product must comply with the applicable country-specific laws and regulations including medicine importation requirements and approvals from applicable regulatory bodies and applicable Institutional Review Board or Ethics Committee.
- All requests for Compassionate Use will be acknowledged and evaluated promptly in a fair and unbiased manner.
  - Patients with exceptional safety risks that have not been sufficiently studied would be excluded.
- Incyte affiliates create and adhere to country and/or region specific laws, regulations and procedures regarding Compassionate Use/single patient access for investigational products.
  - Such procedures must be consistent with this Policy.

- In the U.S., requests for Compassionate Use can be directed to Medical Information at Incyte: 1-855-463-3463 or [www.incytemi.com](http://www.incytemi.com). Clinical trial records for an investigational product can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) by searching for that investigational product.