

## **Product Sheet Gilteritinib**

### **1. General Product Information**

- Drug used in the treatment of acute myeloid leukemia (AML), a form of cancer that affects blood and bone marrow cells.
- Belongs to the tyrosine kinase inhibitor family.
- Blocks abnormal proteins found in cancer cells, helping to slow or stop the growth of these cells.
- Route of administration: Oral, once daily.

### **2. Therapeutic Indications**

- For patients with AML who have a specific mutation in the FLT3 gene, known as FLT3-ITD or FLT3-TKD mutation.

### **3. Evidence**

- The clinical trial supporting the efficacy of gilteritinib is the ADMIRAL trial (Assessment of the Differentiation of AML Therapy). This study evaluated the efficacy and safety of gilteritinib in patients with AML who had a specific mutation in the FLT3 gene (FLT3-ITD or FLT3-TKD) and had relapsed after previous treatment or were refractory to initial treatment.
- The results of the trial showed that gilteritinib significantly improved overall survival compared to conventional chemotherapy in this patient group.
- Patients treated with Gilteritinib had a median overall survival of 9.3 months, while those treated with conventional chemotherapy had a median overall survival of 5.6 months.
- Gilteritinib is the only FLT3 inhibitor approved by both the NCCN guidelines and the European guidelines for patients with FLT3+ AML in relapse or refractory conditions.

### **4. Additional Benefits**

- Additionally, more than 25% of the patients included in the trial received a bone marrow transplant, demonstrating the versatility and compatibility of Gilteritinib with other treatments.
- More than double the remission rate.

## **Questions for Exploration:**

- How do you currently treat patients with AML?
- What are your most significant treatment challenges?

- What has been your experience with agents like Midostaurin, Venetoclax in terms of Overall Survival?
- What are your most important treatment goals?
- Besides clinical outcomes, what is important for your patients in their daily lives?

**Value Dialogue Against the Competition:** Absolutely, I understand your interest in exploring more options for your patients. Gilteritinib offers a significant advantage over rescue chemotherapy, demonstrating notable improvements in overall survival in patients with FLT3+ AML. Compared to Venetoclax, Gilteritinib is the only FLT3 inhibitor approved by both the NCCN and European guidelines, backed by the ADMIRAL trial with outstanding survival results. Additionally, its versatility is evidenced by its compatibility with bone marrow transplantation and higher remission rates. Would you like more information on how Gilteritinib can benefit your patients?