

FLT3

The EMA grants Rydapt® (midostaurin) approval for the treatment of newly diagnosed FLT3⁺ AML patients

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On 20th September 2017, the [European Commission](#) (EC) granted approval to Rydapt® (midostaurin) in combination with standard daunorubicin and cytarabine induction and high-dose cytarabine consolidation chemotherapy, and for patients in complete response followed by Rydapt® single agent maintenance therapy, for adults with newly diagnosed Acute Myeloid Leukemia (AML) who are *Fms Like Tyrosine Kinase 3 (FLT3)* mutation-positive (FLT3⁺).¹

This approval comes after the 'positive opinion' [recommendation](#) of Rydapt® by the [European Medicines Agency](#) (EMA) [Committee for Medicinal Products for Human Use](#) (CHMP) in July 2017 and the [U.S. Food and Drug Administration](#) (FDA) [approval](#) in April 2017.

The EC approval for Rydapt®, a FLT3 inhibitor, was based on results from the phase III RATIFY trial (NCT00651261), which was a randomized trial in 717 newly diagnosed FLT3⁺ AML patients (median age = 47.9 years, range 18–59 years). In this study, patients were randomly assigned to receive either placebo or Rydapt® 50 mg orally twice daily on days 8–21 of each cycle of induction and consolidation chemotherapy followed by continuous daily midostaurin for up to 12 cycles. Median Overall Survival (OS) in patients receiving Rydapt® and placebo were 74.7 and 25.6 months, respectively (HR for death = 0.78, *P* = 0.009).² More results of this study were reported [here](#).

The drug manufacturers, [Novartis](#), highlighted that Rydapt® “represents the first and only targeted therapy for FLT3-mutated AML” in the European Union (EU).

References

1. [GlobeNewswire](#): Novartis drug Rydapt® (midostaurin) receives EU approval for newly diagnosed FLT3-mutated acute myeloid leukemia (AML) and three types of advanced systemic mastocytosis (SM). 2017 Sep 20. <http://www.globenewswire.com/news-release/2017/09/20/1125006/0/en/Novartis-drug-Rydapt-midostaurin-receives-EU-approval-for-newly-diagnosed-FLT3-mutated-acute-myeloid-leukemia-AML-and-three-types-of-advanced-systemic-mastocytosis-SM.html>. [Accessed 2017 Sep 20].
2. [Stone R.M. et al.](#) Midostaurin plus Chemotherapy for Acute Myeloid Leukemia with a FLT3 Mutation. [N Engl J Med](#). 2017 Jun 23. DOI: [10.1056/NEJMoa1614359](https://doi.org/10.1056/NEJMoa1614359). [Epub ahead of print].

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