

## Rydapt - (25 mg; Capsule, Oral)

<b>Generic Name</b>	Midostaurin	<b>Innovator</b>	Novartis
<b>Dosage</b>	25 mg; Capsule, Oral	<b>Branded US Sales</b>	Less Than \$1000 mn
<b>Probable FTF</b>	Less Than 5	<b>Known Para IV Filers</b>	Less Than 5
<b>Other ANDA developers</b>	More Than 5	<b>Tentative Approvals</b>	Less Than 5
<b>Final Approvals</b>	Less Than 5	<b>Generic Launches</b>	None
<b>Indication</b>	RYDAPT is a kinase inhibitor indicated for the treatment of adult patients with: • Newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutationpositive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation (1.1). Limitations of Use: RYDAPT is not indicated as a single-agent induction therapy for the treatment of patients with AML. • Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). (1.2)		
<b>Complexities</b>	Yes		

### Chronology Of Events

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Executive Summary

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Patent Status

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Launch Timelines and Competition

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

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