

## IMKELDI - (80MG/1ML ; Solution)

<b>Generic Name</b>	IMATINIB MESYLATE	<b>Innovator</b>	SHORLA ONCOLOGY
<b>Dosage</b>	80MG/1ML ; Solution	<b>Branded US Sales</b>	Less Than \$1000 mn
<b>Probable FTF</b>	None	<b>Known Para IV Filers</b>	None
<b>Other ANDA developers</b>	Less Than 5	<b>Tentative Approvals</b>	None
<b>Final Approvals</b>	None	<b>Generic Launches</b>	None
<b>Indication</b>	<p>Imkeldi is a kinase inhibitor indicated for the treatment of: • Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. • Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy. • Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). • Pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy. • Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements. • Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown. • Adult patients with hypereosinophilic syndrome</p>		
<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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