IMKELDI - (80MG/1ML ; Solution)

Generic Name	IMATINIB MESYLATE	**Innovator**	SHORLA ONCOLOGY
Dosage	80MG/1ML ; Solution	**Branded US Sales**	Less Than $1000 mn
Probable FTF	None	**Known Para IV Filers**	None
Other ANDA developers	Less Than 5	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	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		
Complexities	Yes		

Chronology Of Events

Please Contact contact@researchdelta.com to get Detailed Information.

Executive Summary

Please Contact contact@researchdelta.com to get Detailed Information.

Patent Status

Please Contact contact@researchdelta.com to get Detailed Information.

Launch Timelines and Competition

Please Contact contact@researchdelta.com to get Detailed Information.

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