Tafinlar - (50 mg and 75 mg ; Capsule)

Generic Name	Dabrafenib Mesylate	**Innovator**	Novartis
Dosage	50 mg and 75 mg ; Capsule	**Branded US Sales**	Less Than $1000 mn
Probable FTF	Less Than 5	**Known Para IV Filers**	Less Than 5
Other ANDA developers	More Than 5	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	TAFINLAR is a kinase inhibitor indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. TAFINLAR is indicated, in combination with trametinib, for: • the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. • the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. • the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. • the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. • the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.		
Complexities	Yes		

Chronology Of Events

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

Executive Summary

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Patent Status

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Launch Timelines and Competition

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Chronology Of Events

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Tafinlar - (10MG ; TABLET,FOR SUSPENSION)

Generic Name	Dabrafenib Mesylate	**Innovator**	Novartis
Dosage	10MG ; TABLET,FOR SUSPENSION	**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	TAFINLAR is a kinase inhibitor indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. TAFINLAR is indicated, in combination with trametinib, for: • the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. • the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. • the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. • the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. • the treatment of adult and pediatric patients 6 years of age and older with unresectable or		
Complexities	Yes		

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