Bosulif - (100,500 mg; Tablet, Oral)

Generic Name	Bosutinib	**Innovator**	Pfizer
Dosage	100,500 mg; Tablet, Oral	**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**	Less Than 5
Final Approvals	Less Than 5	**Generic Launches**	None
Indication	Indicated for the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.		
Complexities	Yes		

Chronology Of Events

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Executive Summary

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Chronology Of Events

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Bosulif - (400 mg, tablet, oral)

Generic Name	Bosutinib	**Innovator**	Pfizer
Dosage	400 mg, tablet, oral	**Branded US Sales**	Less Than $1000 mn
Probable FTF	Less Than 5	**Known Para IV Filers**	Less Than 5
Other ANDA developers	Less Than 5	**Tentative Approvals**	Less Than 5
Final Approvals	Less Than 5	**Generic Launches**	Less Than 5
Indication	Indicated for the treatment of adult patients with newly-diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML) as well as for chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.		
Complexities	Yes		

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Bosulif - (50MG, 100MG ; Capsule)

Generic Name	Bosutinib	**Innovator**	PF PRISM CV
Dosage	50MG, 100MG ; Capsule	**Branded US Sales**	Less Than $1000 mn
Probable FTF	None	**Known Para IV Filers**	None
Other ANDA developers	None	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	BOSULIF is a kinase inhibitor indicated for the treatment of (1) adult and pediatric patients 1 year of age and older with chronic phase Ph+ chronic myelogenous leukemia (CML), newly diagnosed or resistant or intolerant to prior therapy. (2) Adult patients with accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy.		
Complexities	Yes		

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