

## Kalydeco - (150 mg; Tablet, Oral)

<b>Generic Name</b>	Ivacaftor	<b>Innovator</b>	Vertex pharma
<b>Dosage</b>	150 mg; Tablet, 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>	None	<b>Generic Launches</b>	None
<b>Indication</b>	KALYDECO is indicated for the treatment CF in pediatric patients age 2-17 years of age who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation		
<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

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### Chronology Of Events

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## Kalydeco - (25, 50, 75 mg/packet ; Oral Granules)

<b>Generic Name</b>	Ivacaftor	<b>Innovator</b>	Vertex pharma
<b>Dosage</b>	25, 50, 75 mg/packet ; Oral Granules	<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>	Less Than 5	<b>Tentative Approvals</b>	Less Than 5
<b>Final Approvals</b>	None	<b>Generic Launches</b>	None
<b>Indication</b>	KALYDECO is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator indicated for the treatment of cystic fibrosis (CF) in patients age 2 years and older who have one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R and R117H.		
<b>Complexities</b>	Yes		

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