VIJOICE - (50MG, 125MG, 200MG ; Tablet)

Generic Name	ALPELISIB	**Innovator**	Novartis
Dosage	50MG, 125MG, 200MG ; Tablet	**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	VIJOICE is a kinase inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CARelated Overgrowth Spectrum (PROS) who require systemic therapy.		
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.

Chronology Of Events

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VIJOICE - (50MG/PACKET ; Granules)

Generic Name	ALPELISIB	**Innovator**	Novartis
Dosage	50MG/PACKET ; Granules	**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	VIJOICE is a kinase inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CARelated Overgrowth Spectrum (PROS) who require systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.		
Complexities	Yes		

Chronology Of Events

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