

New Drug Manufacturer Report

Section	Data element	Field type	Drug #1	Drug #2
1. Drug identification	National drug code (11-digit NDC)	Numeric	45629-0089-01	45629-0134-01
	Drug name	Text	Fotivada	Fotivada
2. Drug Launch Information	Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	Text	<p>Marketing Plan: Fotivada is a treatment for relapsed or refractory advanced renal cell carcinoma (RCC) in adult patients. Aveo's marketing approach will focus on educating health care providers on how to diagnose and treat patients efficiently to relieve symptoms for patients. Educational materials will be provided across the patient journey, to both HCPs and to families, and highlight access and affordability support for Fotivada to ensure rapid access to therapy.</p> <p>Pricing Plan: Fotivada has been developed for the treatment of relapsed or refractory advanced renal cell carcinoma (RCC). Fotivada provides an option to deliver a safe, effective treatment that reduces the symptoms in patients. Fotivada is priced responsibly compared to similar oncology agents with significant clinical benefit and disease modification. Pricing accounts for development costs, complexity of manufacturing, distribution, and storage. Aveo demonstrates a strong commitment to patients and their ability to get access to care with support programs that leaves no patient behind.</p>	<p>Marketing Plan: Fotivada is a treatment for relapsed or refractory advanced renal cell carcinoma (RCC) in adult patients. Aveo's marketing approach will focus on educating health care providers on how to diagnose and treat patients efficiently to relieve symptoms for patients. Educational materials will be provided across the patient journey, to both HCPs and to families, and highlight access and affordability support for Fotivada to ensure rapid access to therapy.</p> <p>Pricing Plan: Fotivada has been developed for the treatment of relapsed or refractory advanced renal cell carcinoma (RCC). Fotivada provides an option to deliver a safe, effective treatment that reduces the symptoms in patients. Fotivada is priced responsibly compared to similar oncology agents with significant clinical benefit and disease modification. Pricing accounts for development costs, complexity of manufacturing, distribution, and storage. Aveo demonstrates a strong commitment to patients and their ability to get access to care with support programs that leaves no patient behind.</p>
	Estimated volume of patients who may be prescribed the drug	Numeric	48,000 potential patients in US > 104 in NH	48,000 potential patients in US > 104 in NH
	Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text	No	No
	Date and price of acquisition if the drug was not developed by the manufacturer	Text	N/A	N/A