

New Drug Manufacturer Report

Section	Data element	Field type	Drug #1
1.	Drug identification	National drug code (11-digit NDC)	Numeric 50881-0006-03
		Drug name	Text Zynyz 500mg/20ml Injection
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 To market Zynyz, Incyte designed activities to increase awareness and understanding with healthcare providers about the product. Marketing activities will include education and training provided by our sales force. Consumer-directed communications to educate patients on the disease state and Zynyz are planned. At Incyte, we are driven by rigorous science and committed to ensuring patients have access to our innovative medicines. We responsibly price our drugs by balancing the value of the outcomes and innovation they bring to patients and the health care system within market and societal expectations. Zynyz is indicated for the treatment of metastatic or recurrent locally advanced merkel cell carcinoma (MCC).
		Estimated volume of patients who may be prescribed the drug	Numeric 1,000: MCC is a rare and aggressive type of skin cancer and impacts less than 1 per 100,000 people in the U.S., but incidence rates are rapidly rising, especially in adults over the age of 65. There are ~1,000 estimated patients per year with locally advanced or metastatic MCC disease.
		Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text Zynyz was granted Fast Track, Accelerated Approval and Priority Review statuses
		Date and price of acquisition if the drug was not developed by the manufacturer	Text NA - product not acquired