New Drug Manufacturer Report

Section		Data element	Field type	Drug #1
1.	**Drug identification**	National drug code (11-digit NDC)	Numeric	73776-0001-11
		Drug name	Text	AMTAGVI™ (lifileucel)
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	AMTAGVI™ was approved by FDA on 2/16/2024 and is a first-in-class autologous cell therapy used to treat patients with advanced melanoma who've progressed on or after prior anti-PD-1/PD-L1 therapy and targeted therapy. Marketing plans consist of items and activities for educating health care providers (HCPs) based in authorized treatment centers (ATCs) which, includes focused websites, electronic and printed materials, educational events conducted by dedicated sales professionals and sponsorships and exhibits for medical congresses. Iovance, Inc., will provide support for access and patient assistance programs for economically disadvantaged patients: www.iovancecares.com/#patient. AMTAGVI™ pricing was established to balance the need for patient access to the relatively small (~6200) patient population and a need to allow for business sustainability in the first cell therapy approved for solid tumors. The FDA granted both orphan and breakthrough status to Iovance's product along with priority review. The cost elements related to the individualization of therapy (produced by the patient's own tumor cells), the distribution requirements of an ultra-cold chain process, commercial scalability, quality control issues for each patient-specific product, and support requirements of establishing process competence in our network of accredited treatment centers were all factored into the pricing determination. To ensure the market price sustainability, qualitative market research on price justification was employed across a broad spectrum of treatment centers and payer economic stakeholders.
		Estimated volume of patients who may be prescribed the drug	Numeric	6200
		Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text	Yes
		Date and price of acquisition if the drug was not developed by the manufacturer	Text	N/A