New Drug Manufacturer Report

Section		Data element	Drug
1.	**Drug identification**	National drug code (11-digit NDC)	83222-0200-01
		Drug name	Lenmeldy (atidarsagene autotemcel) Suspension for IV Infusion 10 to 20mL containing 1.8 to 11.8 x 10^6 CD34+ cell/mL, 1 Bag
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	Orchard Therapeutics is working collaboratively with commercial and government payers to offer outcomes and value-based agreements intended to ensure timely access by sharing risk between the payer and manufacturer. The primary objective of the LENMELDY market access plan is to create uniform access across all payer types that allows coverage consistent with label. LENMELDY has a WAC price of $4.25M USD. The WAC is consistent with the range that the Institute for Clinical and Economic Research ("ICER") identified in its Final Evidence Report, published on October 30, 2023, as the price at which the Product would be cost effective. Lenmeldy is being made available to eligible patients through a network of Qualified Treatment Centers (QTCs) in key regions throughout the United States to minimize the travel burden on patients and their families. Five treatment centers with specialized expertise in transplant and the treatment of neurometabolic diseases, like MLD, are being activated.
		Estimated volume of patients who may be prescribed the drug	15
		Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Priority Review
		Date and price of acquisition if the drug was not developed by the manufacturer	N/A