New Drug Manufacturer Report

Section		Data element	Field type	Drug #1
1.	**Drug identification**	National drug code (11-digit NDC)	Numeric	71332-0005-01
		Drug name	Text	Rezlidhia 150mg 30 Tablets
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	Rezlidhia (Olutasidenib) 150 mg capsules is an FDA approved treatment for adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test. Rigel's approach for a new product launch is to develop marketing materials for our sales teams to educate healthcare professionals on the appropriate utilization of REZLIDHIA consistent with the US FDA approved indication. Rigel utilizes printed materials, websites, and other digital media to communicate this information to relevant healthcare professionals. We provide patient assistance programs, including a copay assistance program which can be found at www.rezlidhia.com, and our Rigel OneCare program which aids in patient support services, benefit verifications, prior authorizations, temporary and long term free drug supply, and adherence support. Additional company and product information is included on Rigel's website at www.rigel.com. Rigel gives careful consideration to a number of interdependent factors when setting the price of the Company's pharmaceutical products, some of which include the clinical and economic value that a particular therapy provides to the patients and the nation's healthcare system overall (e.g. objective and subjective measures of individual health outcomes and overall costs of therapy in both inpatient and outpatient settings, for public and private facilities and payors). Fundamentally, Rigel gives serious consideration to a number of factors impacting the final price determined for each of its products, including Rezlidhia, including but not limited to; (1) clinical and economic value of a particular therapy, (2) the therapeutic category, its market dynamics, and competitor pricing, (3) discounts provided to customers in both the commercial and government channels, (4) patient support provided by Rigel to ensure patient access to life-saving and life-changing medications, (5) ongoing capital investments, and (6) overall research and development or product acquisition costs. This consideration into pricing is based on an overall assessment of the particular circumstances of these and other interdependencies and the judgement and expertise of Rigel's leadersip team, and does not follow a fixed algorithm. Related to the product pricing is the discounted pricing available in certain circumstances, generally a fixed percent off the wholesale acquisition cost, which is set by contract or regulation, and is based on assessment of market dynamics, product access, and overall commercial economics.
		Estimated volume of patients per year who may be prescribed the drug	Numeric	20380
		Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text	No
		Date and price of acquisition if the drug was not developed by the manufacturer	Text	Acquisition Date- 7/27/2022 Under the terms of the agreement, Forma will receive an upfront payment of $2.0 million, and is eligible to receive an additional $17.5 million upon the achievement of certain near-term regulatory, approval, and first commercial sale milestones. In addition, Forma is eligible to receive a total of up to an additional $215.5 million in connection with the achievement of certain development and commercial milestones. Forma is also eligible to receive tiered royalties in the low-teens to mid-thirties. Moving forward, Rigel will be responsible for the potential launch and commercialization of olutasidenib in the U.S., and intends to work with potential partners to further develop and commercialize olutasidenib outside the U.S.