New Drug Manufacturer Report

Section		Data element	Field type	Drug #1	Drug #2	Drug #3
1.	**Drug identification**	National drug code (11-digit NDC)	Numeric	82576006030	82576008030	82576010030
		Drug name	Text	Rezdiffra (resmetirom) tablets, 60 mg, 30 CT bottle	Rezdiffra (resmetirom) tablets, 80 mg, 30 CT bottle	Rezdiffra (resmetirom) tablets, 100 mg, 30 CT bottle
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	Rezdiffra is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Madrigal is launching REZDIFFRA™ (resmetirom) for the treatment of adults with novel therapeutics for non-alcoholic steatohepatitis (NASH), also known as metabolic dysfunction associated steatohepatitis (MASH). The FDA granted accelerated approval of Madrigal's REZDIFFRA™ (resmetirom) since NASH is a growing global health burden in all regions of the world. As the first FDA-approved treatment that both reduces fibrosis and resolves NASH, Rezdiffra has the potential to both support better health outcomes and reduce spending across the health care system by reversing or halting disease progression before patients develop cirrhosis and its complications. Madrigal considered factors associated with development expenditures, manufacturing and commercialization of Rezdiffra, along with the potential of annual cost of care for a patient with NASH quadrupling when cirrhosis develops (Quian C, et al. Poster presented at AMCP Nexus 2023) are determining factors for establishment of commercial pricing. The potential benefits of reduction of risk of progression to cirrhosis alleviates some of the financial burden that otherwise would be borne by the patient and/or healthcare systems. Madrigal considered additional industry statements when setting pricing based on data provided from an independent non-profit research institute assuming that short-term effects on liver fibrosis translate into longer-term reductions in cirrhosis. (Quian C, et al. Poster presented at AMCP Nexus 2023.) Key marketing tactics will include peer to peer education that provides training for healthcare professionals (HCP's); a professional sales team that will supply disease and product print brochures to educate and be of use in specialist offices with relevant HCP's and consumers; product specific websites, consumer relationship management email content, digital banners and content to drive awareness across different channels such as Medscape, Healio and Doximity. A direct to consumer video content for deployment via targeted digital TV. Patient assistance can be found at https://link.edgepilot.com/s/48c1455d/409AeCeZR02fMr6yosNFuw?u=http://www.rezdiffra.com/ and for HCP's https://link.edgepilot.com/s/0ff414bf/vogxDFo1PU2Qw2WGGq4MXw?u=http://www.rezdiffrahcp.com/ provides an overview of materials available for REZDIFFRA™ (resmetirom).	Rezdiffra is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. 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		Estimated volume of patients who may be prescribed the drug	Numeric	315000	315000	315000
		Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text	Madrigal is launching REZDIFFRA™ (resmetirom) for the treatment of adults with novel therapeutics for non-alcoholic steatohepatitis (NASH), also known as metabolic dysfunction associated steatohepatitis (MASH). The FDA granted accelerated approval of Madrigal's REZDIFFRA™ (resmetirom) since NASH is a growing global health burden in all regions of the world.	Madrigal is launching REZDIFFRA™ (resmetirom) for the treatment of adults with novel therapeutics for non-alcoholic steatohepatitis (NASH), also known as metabolic dysfunction associated steatohepatitis (MASH). The FDA granted accelerated approval of Madrigal's REZDIFFRA™ (resmetirom) since NASH is a growing global health burden in all regions of the world.	Madrigal is launching REZDIFFRA™ (resmetirom) for the treatment of adults with novel therapeutics for non-alcoholic steatohepatitis (NASH), also known as metabolic dysfunction associated steatohepatitis (MASH). The FDA granted accelerated approval of Madrigal's REZDIFFRA™ (resmetirom) since NASH is a growing global health burden in all regions of the world.
		Date and price of acquisition if the drug was not developed by the manufacturer	Text	12/18/2008 & 8,750,000	12/18/2008 & 8,750,000	12/18/2008 & 8,750,000