Manufacturer	NDC 11	Drug Name	Commercial Launch Date
Celltrion USA	72606002304	Yuflyma Subcutaneous Auto-injector Kit 80 MG/0.8ML	12/13/2023
Celltrion USA	72606002307	Yuflyma-CD/UC/HS Starter Subcutaneous Auto-injector Kit 80 MG/0.8ML	12/13/2023

Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally
Yuflyma is a biosimilar in the adalimumab class in this package configuration (auto-injector) and has been granted approval for eight indications: Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis and Hidradenitis Suppurativa. As part of the determination to launch Yuflyma, Celltrion conducted extensive market research utilizing data established in the US and abroad. Based on this information along with the market competitiveness as well as establishing a convenient delivery system which provides patients with one of only a few FDA-approved adalimumab biosimilars that has a high-concentration, citrate-free formulation. This formulation can reduce injection discomfort for patients with chronic conditions like rheumatoid arthritis, thereby improving adherence to treatment. Celltrion’s product is priced 5% below the referenced product and is priced the same as the other competitors within the class that has launched a biosimilar with this packaging configuration containing the same delivery system.
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The estimated volume of patients who may be prescribed the drug
398,619.00
398,619.00

Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval
N
N

Date and price of acquisition if the drug was not developed by the manufacturer
N/A
N/A