

Manufacturer	NDC 11	Drug Name	Commercial Launch Date
Celltrion USA	72606-0022-06	ADALIMUMAB-AATY 40 mg/0.4 ml	5/1/2024
Celltrion USA	72606-0022-10	ADALIMUMAB-AATY AUTOINJECTOR 40 mg/0.4 ml	5/2/2024
Celltrion USA	72606-0041-01	ADALIMUMAB-AATY PFS 20 mg/0.2 ml	5/3/2024

Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally

Adalimumab-aaty is a low WAC biosimilar product 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 the unbranded generic of Adalimumab-aaty, 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 generics 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.

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The estimated volume of patients who may be prescribed the drug

398,619

398,619

398,619

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

N

N

N

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

N/A

N/A

N/A