Yuflyma® (adalimumab-aaty) – New biosimilar approval

- On May 23, 2023, the FDA approved Celltrion's Yuflyma (adalimumab-aaty) citrate-free, high concentration (100 mg/mL) injection, biosimilar to AbbVie's Humira® (adalimumab).
    - Yuflyma is the third FDA-approved biosimilar to Humira in the high-concentration strength. The first was Samsung Bioepis/Organon's Hadlima™ (adalimumab-bwwd), approved in August 2022, and the second was Sandoz's Hyrimoz (adalimumab-adaz) approved in March 2023.
    - Amgen's Amjevita™(adalimumab-atto) was the first biosimilar to Humira and launched in January 2023.
    - Additional biosimilars to Humira include Boehringer Ingelheim's Cyltezo® (adalimumab-adbm); Sandoz's Hyrimoz® (adalimumab-adaz) 50 mg/mL; Samsung Bioepis/Organon's Hadlima (adalimumab-bwwd) 50 mg/mL; Pfizer's Abrilada™(adalimumab-afzb); Mylan's Hulio®(adalimumab-fkjp); Coherus' Yusimry™ (adalimumab-aqvh); and Fresenius Kabi's Idacio® (adalimumab-aacf).
    - In addition, Cyltezo was granted interchangeable status on October 15, 2021. One-year of interchangeability status is granted from time of first commercial marketing.
    - Licensing agreements have been signed with AbbVie allowing launch of Yuflyma on July 1, 2023, Cyltezo on July 1, 2023, Hyrimoz on July 1, 2023, Hadlima on July 1, 2023, Abrilada on July 1, 2023, Hulio in July 2023, Yusimry on July 1, 2023, and Idacio in July 2023.

- Yuflyma, Hyrimoz, Yusimry, Hulio, Amjevita, Cyltezo, and Humira share the following indications: rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), ulcerative colitis (UC), plaque psoriasis (PsO) and hidradenitis suppurativa (HS).
    - Hadlima, Idacio and Abrilada share these same indications except for HS.

- In addition, Humira is also approved for UC in pediatric patients 5 years and older and uveitis.

- Similar to Amjevita, Cyltezo, Hadlima, Abrilada, Hulio, Yusimry, Idacio, Hyrimoz and Humira, Yuflyma carries a boxed warning for serious infections and malignancy.

- The most common adverse reactions (> 10%) with Yuflyma use were infections (eg, upper respiratory, sinusitis), injection site reactions, headache and rash.

- The recommended dose of Yuflyma administered by subcutaneous (SC) injection is as follows:

Indication	Recommended Dose
Adult RA*, PsA, AS	40 mg every other week
JIA (≥ 2 years of age) ≥ 30 kg	40 mg every other week
Adult CD and UC	Day 1: 160 mg Day 15: 80 mg Day 29 and maintenance: 40 mg every other week§
Pediatric CD (≥ 6 years of age) ≥ 40 kg	Day 1: 160 mg Day 15: 80 mg Day 29 and maintenance: 40 mg every other week
Adult PsO	Day 1: 80 mg

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	Day 8 and maintenance: 40 mg every other week
Adult HS	Day 1: 160 mg Day 15: 80 mg Day 29 and maintenance: 40 mg weekly or 80 mg every other week

*Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week or 80 mg every other week

[§]Yuflyma should only be continued in UC if patients have shown clinical remission by 8 weeks (day 57).

- Yuflyma is intended for use under the guidance and supervision of a physician. A patient may self-inject Yuflyma or a caregiver may inject Yuflyma prefilled syringe or autoinjector if a physician determines that it is appropriate, and with medical follow-up, as necessary, after proper training in SC injection technique.

- Consult the Humira drug label for dosing recommendations for its additional indications.

- Per a licensing agreement signed with AbbVie, Celltrion may launch Yuflyma on July 1, 2023. Yuflyma will be available as a single-dose prefilled syringe: 40 mg/0.4 mL; single-dose prefilled syringe with safety guard: 40 mg/0.4 mL; and single-dose auto-injector: 40 mg/0.4 mL.

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