Yusimry™ (adalimumab-aqvh) – New biosimilar approval

- On December 20, 2021, Coherus announced the FDA approval of Yusimry (adalimumab-aqvh), a biosimilar to AbbVie's Humira® (adalimumab).
  - Yusimry is the seventh FDA-approved biosimilar to Humira.
  - Amgen's Amjevita™ (adalimumab-atto) was the first biosimilar to Humira and was approved on September 23, 2016.
  - Additional biosimilars to Humira include Boehringer Ingelheim's Cyltezo® (adalimumab-adbm), approved on August 25, 2017; Sandoz's Hyrimoz™ (adalimumab-adaz), approved on October 31, 2018; Samsung Bioepis/Merck's Hadlima™ (adalimumab-bwwd), approved on July 23, 2019; Pfizer's Abrilada™ (adalimumab-afzb), approved on November 18, 2019; and Mylan's Hulio® (adalimumab-fkjp), approved on July 6, 2020.
  - In addition, Cyltezo was granted *interchangeable* status on October 15, 2021.
  - Licensing agreements have been signed with AbbVie allowing launch of Amjevita on January 31, 2023, Cyltezo on July 1, 2023, Hyrimoz on September 30, 2023, Hadlima after June 30, 2023, Abrilada on July 1, 2023, and Hulio on July 31, 2023.

- Yusimry, Hulio, Abrilada, Amjevita, Cyltezo, Hyrimoz, Hadlima, 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), and plaque psoriasis (PsO).

- In addition, Humira is also approved for hidradenitis suppurativa and uveitis.

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

- Warnings and precautions of Yusimry include hypersensitivity reactions, hepatitis B virus reactivation, neurologic reactions, hematological reactions, increased risk of infection when used with Kineret® (anakinra), heart failure, autoimmunity, immunizations, and increased risk of infection when used with Orencia® (abatacept).

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

- The recommended dose of Yusimry 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 Day 8 and maintenance: 40 mg every other week

Continued . . .

*Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week or 80 mg every other week.
§Yusimry should only be continued in UC if patients have shown clinical remission by 8 weeks (day 57).

- Yusimry is intended for use under the guidance and supervision of a physician. A patient may self-inject Yusimry or a caregiver may inject Yusimry prefilled syringe if a physician determines that it is appropriate, and with medical follow-up, as necessary, after proper training in SC injection technique.
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- Consult the Humira drug label for dosing recommendations for its additional indications.

- Per a licensing agreement signed with AbbVie, Coherus may launch Yusimry on July 1, 2023. Yusimry will be available as a 40 mg/0.8 mL prefilled syringe.