Hadlima™ (adalimumab-bwwd) – New biosimilar strength approval

- On August 17, 2022, Samsung Bioepis and Organon announced the FDA approval of Hadlima (adalimumab-bwwd) citrate-free, high concentration (100 mg/mL) injection, biosimilar to AbbVie's Humira® (adalimumab).
    - Hadlima is the first FDA-approved biosimilar to Humira in the high-concentration strength and the eighth biosimilar to Humira approved.
    - 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/Organon's Hadlima(adalimumab-bwwd) 50 mg/mL, approved on July 23, 2019; Pfizer's Abrilada™(adalimumab-afzb), approved on November 18, 2019; Mylan's Hulio®(adalimumab-fkjp), approved on July 6, 2020; and Coherus' Yusimry™ (adalimumab-aqvh) on December 20, 2021.
    - 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 Amjevita on January 31, 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, and Yusimry on July 1, 2023.

- Hadlima, Yusimry, Hulio, Abrilada, Amjevita, Cyltezo, Hyrimoz, 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 UC in pediatric patients 5 years and older, hidradenitis suppurativa and uveitis.

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

- Warnings and precautions of Hadlima 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 Hadlima use were infections (eg, upper respiratory, sinusitis), injection site reactions, headache and rash.

- The recommended dose of Hadlima 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) 10 kg (22 lbs) to less than 15 kg (33 lbs) 15 kg (33 lbs) to less than 30 kg (66 lbs) ≥ 30 kg	 10 mg every other week 20 mg every other week 40 mg every other week
Adult CD and UC	Day 1: 160 mg

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	Day 15: 80 mg Day 29 and maintenance: 40 mg every other week§
Pediatric CD (≥ 6 years of age) 17 kg (37 lbs) to less than 40 kg (88 lbs) ≥ 40 kg	Day 1: 80 mg; Day 15: 40 mg; Day 29 and maintenance: 20 mg every other week 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

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

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

- Hadlima is intended for use under the guidance and supervision of a physician. A patient may self-inject Hadlima or a caregiver may inject Hadlima prefilled syringe 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, Samsung Bioepis/Organon may launch Hadlima (all strengths) on July 1, 2023. Hadlima will be available as single-dose prefilled autoinjectors (Hadlima PushTouch): 40 mg/ 0.8 mL and 40 mg/0.4 mL and single-dose prefilled glass syringes: 40 mg/0.8 mL and 40 mg/0.4 mL.