Simlandi® (adalimumab-ryvk) – New biosimilar approval

- On February 24, 2024, Alvotech and Teva announced the FDA approval of Simlandi (adalimumab-ryvk) citrate-free, high concentration (100 mg/mL) injection, interchangeable and biosimilar to AbbVie's Humira® (adalimumab).
    - Simlandi is the fourth FDA-approved biosimilar to Humira in the high-concentration strength. Others include Samsung Bioepis/Organon's Hadlima™ (adalimumab-bwwd), Sandoz's Hyrimoz® (adalimumab-adaz) and Celltrion's Yuflyma® (adalimumab-aaty).
    - Simlandi is the first high-concentration biosimilar to Humira to be granted interchangeable status. Boehringer Ingelheim's Cyltezo® (adalimumab-adbm) and Pfizer's Abrilada™ (adalimumab-afzb) low concentration formulations have also been granted interchangeable status.
    - Amgen's Amjevita™(adalimumab-atto) was the first biosimilar to Humira and launched in January 2023.
    - Additional biosimilars to Humira include Hyrimoz 50 mg/mL; Hadlima 50 mg/mL; Mylan's Hulio®(adalimumab-fkjp); Coherus' Yusimry™ (adalimumab-aqvh); and Fresenius Kabi's Idacio® (adalimumab-aacf).

- Simlandi, Yuflyma, Hyrimoz, Yusimry, Hulio, Amjevita, Cyltezo, Hadlima, Idacio, Abrilada 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), hidradenitis suppurativa (HS) and uveitis (UV).
    - In addition, Humira is also approved for UC in pediatric patients 5 years and older, HS in 12 years of age and older, and uveitis in 2 years of age and older.

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

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

- The recommended dose of Simlandi 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 or UV	Day 1: 80 mg Day 8 and maintenance: 40 mg every other week
Adult HS	Day 1: 160 mg Day 15: 80 mg

Continued . . .

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

- Simlandi is intended for use under the guidance and supervision of a physician. A patient may self-inject Simlandi or a caregiver may inject Simlandi 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.

- Teva plans to launch Simlandi very soon. Simlandi will be available as a single-dose auto-injector: 40 mg/0.4 mL