Cyltezo® (adalimumab-adbm) – First interchangeable biosimilar to Humira

- On October 18, 2021, the FDA announced the approval of Boehringer Ingelheim's Cyltezo (adalimumab-adbm), as the first interchangeable biosimilar to AbbVie's Humira® (adalimumab).
    - Cyltezo was originally approved as a biosimilar to Humira on August 25, 2017.
- Cyltezo and Humira share the following indications: rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis.
- Humira is also indicated for hidradenitis suppurativa and uveitis.
    - These indications are protected by orphan drug exclusivity until approximately 2022 and 2023, respectively.
- The approval for interchangeability was supported by VOLTAIRE-X, a 58-week, randomized switching study enrolling 238 patients with moderate-to-severe chronic plaque psoriasis. Patients received Humira and were then randomized to 'switching' or 'continuous' treatment.
    - Switching several times from Humira to Cyltezo produced similar clinical outcomes in terms of pharmacokinetics, efficacy, immunogenicity, and safety.
- Cyltezo is the first biosimilar product that has been granted interchangeability to Humira.
    - An interchangeable biosimilar product may be substituted for the reference product by the pharmacist without the intervention of the prescriber.
    - The substitution can occur at the pharmacy, a practice commonly called "pharmacy-level substitution"— much like how generic drugs are substituted for brand name drugs, subject to state pharmacy laws, which vary by state.
- Similar to Humira, Cyltezo carries a boxed warning for serious infections and malignancy.
- Boehringer Ingelheim has signed a patent settlement allowing commercial launch of Cyltezo on July 1, 2023. Cyltezo will be available as 40 mg/0.8 mL and 20 mg/0.4 mL in single-dose prefilled syringes