Avsola™ (infliximab-axxq) – New biosimilar approval

- On December 6, 2019, Amgen announced the FDA approval of Avsola (infliximab-axxq), a biosimilar to Janssen's Remicade® (infliximab).
    - Avsola is the fourth FDA-approved biosimilar to Remicade.
    - Celltrion/Pfizer's Inflectra® (infliximab-dyyb) was the first biosimilar to Remicade and was launched on November 11, 2016. The second biosimilar to Remicade was Merck's Renflexis® (infliximab-abda), launched on July 24, 2017. Pfizer's Ixifi™ (infliximab-qbtx) was approved on December 13, 2017, but will likely not be launched in the U.S.

- Avsola, Inflectra, Renflexis, Ixifi and Remicade share the following indications: Crohn's disease (CD), pediatric CD, ulcerative colitis (UC), pediatric UC (Ixifi is not approved for this indication), rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS) and plaque psoriasis (PsO).

- A biosimilar product is a biological agent that is considered highly similar to an already-approved biological drug, known as the reference product. Biological products are generally derived from a living organism and can come from many sources, including humans, animals, microorganisms or yeast.
    - A biosimilar product must show no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
    - In addition, a biosimilar product may only be approved for the indication(s) and condition(s) that have been FDA approved for the reference product, and must have the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product.

- Avsola has been approved as a biosimilar, ***not*** as an interchangeable product.

- The approval of Avsola is based on a review of analytical, non-clinical, pharmacokinetic and clinical data confirming that Avsola is highly similar to Remicade.

- Similar to Inflectra, Renflexis, Ixifi and Remicade, Avsola carries a boxed warning for serious infections and malignancy.

- Avsola is contraindicated in doses > 5 mg/kg in patients with moderate to severe heart failure, and should not be re-administered to patients with previous severe hypersensitivity reaction to infliximab products or known hypersensitivity to inactive components of Avsola or to any murine proteins.

- Warnings and precautions of Avsola include hepatitis B virus reactivation, hepatotoxicity, patients with heart failure, hematologic reactions, hypersensitivity, cardiovascular and cerebrovascular reactions during and after infusion, neurologic reactions, use with Kineret® (anakinra), use with Orencia® (abatacept), concurrent administration with other biological therapeutics, switching between biological disease-modifying antirheumatic drugs, autoimmunity, and live vaccines/therapeutic infectious agents.

- The most common adverse reactions (> 10%) with Avsola use were infections (eg, upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain.

- The recommended dose of Avsola administered by intravenous injection is as follows:

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Indication	Recommended Dose
Adult CD	5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. For some adult patients who initially respond, then lose their response, consideration may be given to treatment with 10 mg/kg.
Adult UC, pediatric CD, pediatric UC, PsA, and PsO	5 mg/kg at 0, 2 and 6 weeks, then 5 mg/kg every 8 weeks.
RA	In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks followed by 3 mg/kg every 8 weeks. For patients who have an incomplete response, consideration may be given to adjusting increasing the dose up to 10 mg/kg or as often as every 4 weeks.
AS	5 mg/kg at 0, 2 and 6 weeks, then 5 mg/kg every 6 weeks.

- Amgen's launch plans for Avsola are pending. Avsola will be available as a 100 mg single-use vial for intravenous infusion.