Cosentyx® (secukinumab) – New Indications

- On January 15, 2016, Novartis announced the FDA approval of Cosentyx (secukinumab) for the treatment of two new indications, adult patients with active psoriatic arthritis (PsA) and active ankylosing spondylitis (AS).
    - Cosentyx is also FDA approved for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.
- In the U.S., it is estimated that up to 0.5% and 1% of the population have AS and PsA, respectively. These conditions may lead to irreversible damage to the spine and joints, causing life-long pain and disability.
- Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A cytokine, a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Secukinumab inhibits the release of pro-inflammatory cytokines and chemokines.
- Cosentyx's new indications are based on the efficacy and safety of four placebo-controlled clinical trials of over 1,500 adult patients with AS or PsA. The primary endpoint was at least a 20% improvement in the Assessment of Spondyloarthritis International Society criteria (ASAS 20) at 16 weeks, and a 20% reduction in the American College of Rheumatology (ACR 20) response criteria at 24 weeks.
    - In all four trials, significantly more Cosentyx-treated patients met the primary endpoints vs. placebo.
- The recommended dose of Cosentyx for PsA in patients with coexistent plaque psoriasis is the same recommended dose for the treatment of plaque psoriasis: 300 mg by subcutaneous injection at weeks 0, 1, 2, 3 and 4 followed by 300 mg every 4 weeks. For some patients, a dose of 150 mg may be acceptable.
- For other PsA patients and for the treatment of AS, Cosentyx may be administered with or without a loading dose:
    - With a loading dose: 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter
    - Without a loading dose: 150 mg every 4 weeks
    - If a patient continues to have active PsA, a dose of 300 mg may be considered