Cosentyx® (secukinumab) – New indication

- On October 31, 2023, Novartis announced the FDA approval of Cosentyx (secukinumab), for the treatment of adult patients with moderate to severe hidradenitis suppurativa (HS).

- Cosentyx is also approved for the treatment of plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and enthesitis-related arthritis.

- HS is a chronic skin disease that causes recurring boil-like lumps that may burst into open wounds and cause irreversible scarring.

- The approval of Cosentyx for the new indication was based on two randomized, double-blind, placebo-controlled studies in 1,084 adult patients with moderate to severe HS. In both studies, patients were randomized to placebo or Cosentyx at weeks 0, 1, 2, 3 and 4, followed by 300 mg every 2 weeks or every 4 weeks. The primary endpoint in both studies was the proportion of patients who achieved a Hidradenitis Suppurativa Clinical Response (HiSCR50) defined as at least a 50% decrease in abscesses and inflammatory nodules count with no increase in the number of abscesses and/or in the number of draining fistulae relative to baseline at week 16.

    - In both studies, a statistically significantly higher proportion of patients treated with Cosentyx every 2 weeks (after the first four weeks) achieved a HiSCR50 response at week 16 compared to patients treated with placebo (see table).
    - In both studies, a higher proportion of patients treated with Cosentyx every 4 weeks (after the first four weeks) achieved HiSCR50 at week 16 compared to patients treated with placebo (see table), where statistical significance was reached in Trial 2.

	Trial 1			Trial 2		
	Placebo	Cosentyx every 4 weeks	Cosentyx every 2 weeks	Placebo	Cosentyx every 4 weeks	Cosentyx every 2 weeks
HiSCR50	29.4%	41.3%	44.5%*	26.1%	42.5%*	38.3%*

*Statistically significant vs. placebo based on the pre-defined hierarchy

- The recommended dose of Cosentyx in adult patients with moderate to severe HS is 300 mg by subcutaneous injection at weeks 0, 1, 2, 3 and 4 and every 4 weeks thereafter. If a patient does not adequately respond, increasing the dosage to 300 mg every 2 weeks should be considered. Each 300 mg dosage is given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.

    - Refer to the Cosentyx drug label for dosing for all its other indications.