

## Novartis' Cosentyx to achieve blockbuster sales following latest FDA approval

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The FDA's recent approval of Novartis' Cosentyx for the treatment of adults with active ankylosing spondylitis (AS) and psoriatic arthritis (PsA), will propel the drug to blockbuster status, as it now has three approved indications in the US and Europe, according to an analyst with research and consulting firm GlobalData.

Ms Alexandra Annis, GlobalData's Analyst covering Immunology, states that the latest approval will bring exciting new treatment options to US patients dissatisfied with current therapies.

Ms Annis explains: "Up to 40% of AS and PsA patients are intolerant of, or are not well-controlled by, anti-tumor necrosis factor therapy (anti-TNF), which was the only biologic for AS before Cosentyx's approval.

"Traditionally, swathes of AS and PsA sufferers have been left with unmet needs. Cosentyx marks a substantial turning-point for these disease areas by offering a novel and efficacious alternative to existing therapies."

Proof of the drug's effectiveness has been shown by four placebo-controlled Phase III studies. During these trials, the safety and efficacy of Cosentyx was tested in over 1,500 adult patients with active AS or PsA who were intolerant or had an inadequate response to anti-TNFs, or who were naÃ-ve to biologic therapy.

Both AS and PsA patients who took Cosentyx saw statistically significant improvements versus those who took placebos.

Ms Annis continues: "Following the European approval of Cosentyx back in November 2015, the drug will be the first-in-class interleukin-17A (IL-17A) inhibitor to enter the AS and PsA treatment paradigm in the US, giving it a major competitive edge in this market.

"However, while Cosentyx has the first-to-market advantage within its class, Eli Lilly's ixekizumab, an anti-IL-17 agent, is threatening to compete in the PsA and psoriasis markets, as it is currently under regulatory review for both indications."

The analyst adds that Kyowa Hakko Kirin filed an application for marketing approval to the Japanese Ministry of Health, Labour and Welfare for Valeant/AstraZeneca's brodalumab, an IL-17 inhibitor, for the treatment of PsA as well as plaque psoriasis, pustular psoriasis, and psoriatic erythroderma.

"With the competition heating up, Cosentyx may not retain its status as the most exciting new treatment in the AS and PsA markets for long," Ms Annis concludes.