Novartis real-world evidence confirms efficacy and safety benefits of Cosentyx® in daily life for psoriasis patients

- *Real-world evidence confirms Cosentyx® efficacy and safety consistent with previously reported clinical studies*¹⁻⁴

- *Novartis presents a large program of real-world evidence at the 27th European Academy of Dermatology and Venereology (EADV) Congress, adding to the robust body of clinical data supporting the use of Cosentyx in moderate-to-severe psoriasis*¹⁻⁴

- *Cosentyx 5-year data in psoriasis from a Phase III study were presented in 2017⁵, proving long term efficacy and sustained safety of Cosentyx and the importance of IL-17A inhibition – the cornerstone cytokine in the treatment of psoriasis*⁶⁻⁸

**Basel, September 13, 2018** – Novartis, a leader in immuno-dermatology, announced today new data from multiple real-world sources in moderate-to-severe plaque psoriasis, which confirm Cosentyx® (secukinumab) efficacy and safety in clinical practice is comparable to previously reported clinical studies¹⁻⁴. Real-world evidence also confirmed the additional benefits of Cosentyx with PROSPECT, the largest prospective real-world analysis on Cosentyx to date, demonstrating a pronounced improvement in quality of life in a real-world setting (59% of patients at 24 weeks experience no or little impact of their skin disease on their quality of life)¹. Cosentyx is the first and only fully-human treatment that specifically inhibits IL-17A. A large program of real-world evidence was presented for the first time at the 27th European Academy of Dermatology and Venereology (EADV) Congress in Paris, France.

Additional real-world data presented at EADV showed that 87% of bio-naïve psoriasis patients remain on Cosentyx at 12 months, further supporting the use of Cosentyx in real-world settings².

“Novartis commitment to well-designed Phase-IV studies and other real world evidence is providing dermatologists around the world with an opportunity to see how psoriasis treatments respond in everyday clinical practice,” said Dr. Kim Papp, Dermatologist and Principal Investigator of the PURE Study, Waterloo, Ontario, Canada. “As a clinician and researcher, I find it exciting and rewarding to contribute to this growing volume of real world evidence on Cosentyx.”

“For both psoriasis patients and doctors, these data confirm that Cosentyx clinical data profile translates into real-world benefits,” said Dr. Richard G.B. Langley MD, RPC(C), Professor of Dermatology and Director of Research, Dalhousie University, Halifax, Nova Scotia, Canada. “In the everyday management of psoriasis, this provides added reassurance that with Cosentyx, patients achieve and maintain high levels of skin clearance and improved quality of life.”

At EADV 2017, Novartis presented 5-year data from the Phase III SCULPTURE study reinforcing Cosentyx long term skin clearance and safety⁵. Cosentyx is the first and only fully
human IL-17A inhibitor to show sustained skin clearance rates at 5 years in Phase III in psoriasis. Landmark data show that PASI 90 and PASI 100 response rates were nearly 100% maintained with Cosentyx from Year 1 to Year 5 in patients with moderate-to-severe plaque psoriasis.

“This large program of real-world evidence adds to the robust body of clinical data supporting the use of Cosentyx for psoriasis,” said Eric Hughes, Global Development Unit Head, Immunology, Hepatology and Dermatology. “As a leader in immuno-dermatology, we are reimagining the lives of psoriasis patients by providing doctors with the best evidence possible, including in real-world settings.”

These data add to the growing body of evidence showing the unique position of Cosentyx as the first and only fully-human IL-17A inhibitor. To date, Cosentyx has been prescribed to more than 160,000 patients worldwide. The clinical Phase III program has demonstrated long-term efficacy and a proven safety profile of Cosentyx to treat moderate-to-severe psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS). In May, Novartis announced its plan to initiate the ARROW trial to assess the mechanistic superiority of direct IL-17A inhibition (Cosentyx) over IL-23 inhibition (Tremfya®) as the 100th study with Cosentyx.

About XPOSE, PROSPECT, CORRONA, and PURE

These findings are from analysis of real-world data from 2 non-interventional studies and 2 registries across multiple countries: Data from the Canadian patient support program XPOSE (3,020 patients with moderate-to-severe psoriasis) were analysed for the patients where efficacy data was reported by a physician (192 patients); PROSPECT is the largest real-world study of Cosentyx in psoriasis, involving 2,002 patients in Germany (905 patients followed up for 24 weeks to date); CORRONA® is an independently run registry of patients with psoriasis from the United States (306 patients initiated Cosentyx at enrollment, with effectiveness data available to date for 118 patients for 6 months, and 56 patients for 12 months); and PURE a prospective, international, observational, two cohort registry of adult patients with moderate-to-severe chronic plaque psoriasis in Latin America and Canada (397 patients, with efficacy data available to date for 124 patients for 12 months, and 59 patients for 18 months).

Real-world evidence (RWE) is clinical evidence based upon data taken from a variety of sources in daily life, outside of the clinical trial setting. RWE helps to bridge the gap in knowledge that exists between clinical trials and clinical practice, making it an important complement to long-term data from clinical trials.

About Cosentyx

Cosentyx is the first and only fully-human biologic that specifically inhibits interleukin-17A (IL-17A), a cornerstone cytokine involved in the inflammation and development of psoriasis, AS, and PsA. IL-17A is produced by both IL-23 dependent and IL-23 independent pathways, by various cells from both the innate immune system (which can be triggered by mechanical stress) and the adaptive immune system. By acting directly on IL-17A, Cosentyx inhibits this cornerstone cytokine irrespective of where the IL-17A comes from. Cosentyx has been used by more than 160,000 patients worldwide across all indications and is used in many countries as first-line therapy in biologic-naive patients.

Cosentyx has a broad head-to-head study program that includes FIXTURE, CLEAR, CLARITY, SURPASS and EXCEED clinical superiority trials. In May 2018, Novartis announced its plan to initiate the ARROW trial to assess the mechanistic superiority of direct IL-17A inhibition (Cosentyx) over IL-23 inhibition (Tremfya®) in treating recalcitrant plaques resistant to ustekinumab. This study is the 100th trial with Cosentyx in the last 10 years, adding to the wealth of data. The clinical Phase III program of Cosentyx has demonstrated...
long term efficacy and a proven safety profile of Cosentyx to treat moderate-to-severe psoriasis\textsuperscript{5}, PsA\textsuperscript{11} and AS\textsuperscript{12}.

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About Novartis
Novartis is reimagining medicine to improve and extend people’s lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world’s top companies investing in research and development. Novartis products reach nearly 1 billion people globally and we are finding innovative ways to expand access to our latest treatments. About 125 000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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14. Clinicaltrials.gov. Active trials include all those that are listed as recruiting, active but not recruiting, enrolling by invitation and not yet recruiting and completed. This list excludes all trials listed as suspended, terminated and withdrawn.


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