Novartis first-in-class Cosentyx® approved in China for psoriasis patients

- China Health Authority NMPA approved Cosentyx® (secukinumab) for moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
- Cosentyx is the first biologic approved in China that specifically inhibits interleukin-17A (IL-17A), a cornerstone cytokine involved in the inflammation of psoriasis (PsO), psoriatic arthritis (PsA) and ankylosing spondylitis (AS)\(^1\)\(^2\)
- A Phase III study in patients in China with psoriasis confirmed a sustained safety profile and rapid onset of relief with Cosentyx as early as week 3. Data showed close to 9/10 patients who received Cosentyx® (300mg on an every 4 week dosing regimen after loading) achieved clear or almost clear skin after 16 weeks\(^3\)

Basel, April 02, 2019 – Novartis, a global leader in immuno-dermatology and rheumatology, announced today that the China Health Authority NMPA approved Cosentyx® (secukinumab), the first-in-class interleukin-17A (IL-17A) inhibitor for moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

“Reimagining the management of psoriatic disease to provide patients with the ability to live their life free from the burden of psoriasis is a key focus for us,” said Paul Hudson, CEO Novartis Pharmaceuticals. “With Cosentyx, we are offering a new treatment to doctors and psoriasis patients in China which can act within 3 weeks, has demonstrated sustained safety in more than 200,000 patients worldwide and can deliver what doctors and patients are looking for.”

“We are delighted to bring Cosentyx to doctors and patients in China. The approval of Cosentyx has marked a new era of psoriasis treatment, redefining the treatment goal by making clear or almost clear skin achievable. The introduction of Cosentyx should bring outstanding clinical benefit to many patients with psoriasis in China and improve their quality of life,” said Ingrid Zhang, President, Novartis Pharmaceuticals China.

Cosentyx is the first and only fully-human treatment for psoriasis, that specifically inhibits IL-17A. Cosentyx is characterized by sustained safety, fast and long-lasting control, and placebo-like injection site reaction\(^1\)\(^2\)\(^4\)\(^5\)\(^6\)\(^8\). A recently published Phase III study in patients in China showed that 80.9% of the patients treated with Cosentyx 300mg on an every 4 week dosing regimen (q4w) after loading achieved clear or almost clear skin during the first 12 weeks of treatment, and close to 9/10 patients after 16 weeks (87.0%)\(^3\).

“The average onset age of psoriasis in China is around 30, and many of the moderate-to-severe patients are in their prime. This population plays an irreplaceable role in their family, workplace and society. Thus, treatment with high efficacy, a good safety profile and long-lasting disease control is what we are looking for to help patients get back to normal life and work,” said Prof. Jianzhong Zhang, former President of Chinese Society of Dermatology,
Chinese Medical Association. “Positive China data presented recently makes us hopeful for the clinical use of secukinumab in China. I hope to see Chinese patients benefit from this innovative treatment and be relieved from their illness burden.”

Currently in China there are more than 6 million people living with psoriasis including mild, moderate and severe forms of the disease. Psoriasis is a life-long debilitating disease that significantly impacts patients’ quality of life both physically and emotionally. Real-world data from the US has demonstrated that 2/3 of biologic-eligible patients have PsA or other persistent manifestations of psoriasis in nails, scalp and palmoplantar areas.

Cosentyx is backed by robust clinical evidence including 5-year Phase III extension studies in PsO, PsA and AS and dedicated studies in persistent manifestations of psoriasis, namely in nails, scalp and palmoplantar areas, addressing different parts of the psoriatic disease.

Today, more than 200,000 patients worldwide have been treated with Cosentyx since launch.

About the CAIN457A2318 trial
The Phase III CAIN457A2318 study is an ongoing 52 week, multicenter, randomized, double-blind, placebo-controlled, parallel-group study investigating the efficacy and safety of Cosentyx in 543 patients with moderate-to-severe plaque PsO, including 441 Chinese patients. The co-primary endpoints of the study were to demonstrate the superiority of Cosentyx compared to placebo with respect to PASI 75 response and Investigator’s Global Assessment (IGA) mod 2011 0/1 (clear or almost clear) response at Week 12. The key secondary endpoint was PASI 90 response at Week 12. Patients were randomized to receive on an every 4 week dosing regimen (q4w) after loading either Cosentyx 300mg, 150 mg or placebo.

The data showed 97.7% of patients treated with Cosentyx 300mg achieved PASI 75 and 80.9% PASI 90 by week 12, with 87.0% of patients reaching PASI 90 by week 16. In patients treated with Cosentyx 150mg, 87.8% achieved PASI 75 and 66.4% achieved PASI 90 at week 12. Cosentyx was well tolerated at both doses (150 mg and 300 mg on an q4w dosing regimen after loading). The overall safety profile was consistent with that of previous Phase III clinical trials with no new or unexpected safety signals identified.

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property protection; the particular prescribing preferences of physicians and patients; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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 more than 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 130 000 people of nearly 150 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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18. Novartis, data on file. February 2019

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