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**Novartis is leading the way with a new generation targeted psoriasis treatment: CosentyxTM (secukinumab) the first IL-17A inhibitor with positive CHMP opinion**

* *Cosentyx*™ *(secukinumab) is* *recommended for approval as first-line systemic\* therapy for the treatment of moderate-to-severe plaque psoriasis in adult patients, and is a first-in-class therapy that blocks the protein IL-17A, which is found in high concentrations in psoriasis affected skin*1,2
* *Secukinumab has demonstrated greater efficacy in reducing plaque psoriasis than seen with an existing NICE-recommended treatment*1
* *NICE recognises psoriasis is 'more than just a skin condition', affecting psychological and social wellbeing, and being associated with complex co-morbidities, including arthritis, diabetes and hypertension*3–6

**Frimley, 21 November 2014** **–** Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending approval of Cosentyx™(secukinumab) as a first-line systemic\* treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic\* treatment.

This recommendation means secukinumab could be used as an alternative to other first-line systemic\* treatments, which do not deliver sustained high levels of skin clearance as seen with secukinumab and which can have significant side effects.1,7–12 Currently, all other biologic treatments for psoriasis, including anti-tumor necrosis factor therapies (anti-TNFs) and ustekinumab, are recommended for second-line use.13–15

Novartis is leading the way with secukinumab, a more targeted psoriasis treatment and the first inhibitor of interleukin-17A (IL-17A) to receive a positive CHMP opinion in Europe. Secukinumab works by stopping the action of IL-17A, a protein that is found in high concentrations in skin affected by the disease.1,2

Professor Chris Griffiths, Foundation Professor of Dermatology, University of Manchester and Consultant Dermatologist at Salford Royal NHS Foundation Trust, “Psoriasis is a life-long debilitating disease, which affects nearly two million people in the UK. Moderate to severe plaque psoriasis can have a very negative impact on the quality of life of those it afflicts and as such it is of great importance for these patients that secukinumab has received a positive opinion from the CHMP. Secukinumab offers the chance for patients with moderate to severe psoriasis to achieve a high level of skin clearance thereby allowing them to lead normal lives.”

Two thirds of UK patients with moderate to severe psoriasis fail to reach, or maintain, effective control of their symptoms with currently available therapies, demonstrating a real need for new treatments that clear skin faster and for longer.16 Sub-optimal outcomes in psoriasis management can have profound effects with patients becoming isolated and experiencing functional, psychological and social morbidity.17–20 The condition is associated with significant co-morbidities including arthritis, diabetes and hypertension.3–5For many people, psoriasis results in reduced levels of employment and income.17,21,22 Poorly controlled moderate to severe psoriasis patients can cost the NHS up to £6million per year.16,23,24

The European Commission now reviews the recommendations of the CHMP. The final decision on approval, usually granted in approximately two months of the CHMP opinion, will apply to the UK.

The CHMP opinion was based on the positive results of the Phase III clinical trial program in moderate to severe plaque psoriasis.1,25,26 In these trials, secukinumab consistently demonstrated rapid, very high skin clearance, including superiority to etanercept in the head-to-head FIXTURE study.1,25,26 Eight in ten patients achieved a 75 per cent improvement of their psoriasis at week 12.1 More than 70 per cent of secukinumab patients experienced at least 90 per cent improvement of their psoriasis, and many patients experienced totally clear skin (100 per cent improvement), during the first 16 weeks of treatment; the majority of these patients maintained improvement up to Week 52 (with continued treatment).1 In FIXTURE, at three weeks, secukinumab patients achieved a 50 per cent improvement in their psoriasis – more than twice as fast as etanercept.1 Secukinumab has been studied in almost 4,500 patients globally and has demonstrated an acceptable safety profile compared to etanercept.1

“We are delighted with the positive opinion issued by the CHMP. This recognition of the positive clinical benefits of secukinumab brings us closer to providing the first targeted anti-IL17A treatment for psoriasis to patients in the UK,” said Dimitrios Georgiopoulos, UK Medical Director, Novartis. “The UK has played a significant role in the research and development of this compound and Novartis’ commitment to anti-IL17A pathway continues with a number of ongoing trials studying secukinumab in further inflammatory conditions.”

**About psoriasis**

It is estimated that 1.8 million people in the UK live with psoriasis and 20 per cent are thought to have moderate to severe psoriasis.27,28 59 per cent of people with psoriasis lose 26 working days a year due to their psoriasis and of those not working, a third attribute this directly to their psoriasis.29 In addition to the impact on earning potential, psoriasis has been shown to be associated with depression, anxiety and tendency to suicide (350 cases per year) as well as reduced levels of employment and income.17,19,21,22 People living with psoriasis are at an increased risk of comorbidities, such as high blood pressure, with risk increasing with disease severity.3

**About Cosentyx™ (secukinumab) and interleukin-17A (IL-17A)**

Secukinumab is a fully human monoclonal antibody (a special type of infection-fighting immune cell) being investigated for diseases that affect the immune system.1 Secukinumab inhibits a protein called interleukin-17A (IL-17A) from its involvement in the development of psoriasis.1 IL-17A is found in high concentrations in skin affected by psoriasis and is a preferred target for investigational therapies.1,2 Secukinumab will be recommended for use at a dose of 300 mg.

Phase IIIb studies with secukinumab in psoriasis are also ongoing, including the head-to-head CLEAR study of secukinumab versus ustekinumab in moderate to severe plaque psoriasis and studies in palmo-plantar psoriasis, nail psoriasis, scalp psoriasis and palmo-plantar pustular psoriasis.

Secukinumab is also in Phase III development for psoriatic arthritis (PsA) and ankylosing spondylitis (AS); regulatory applications for secukinumab in these arthritic conditions are planned for 2015.

**About Novartis**

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortisation charges). Novartis Group companies employ approximately 133,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit <http://www.novartis.co.uk>.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by words such as “plans,” “investigated,” or similar terms, or by express or implied discussions regarding potential new indications or labeling for secukinumab, or regarding potential future revenues from secukinumab. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that secukinumab will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that secukinumab will receive regulatory approval or be commercially successful in the future. In particular, management’s expectations regarding secukinumab could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company’s ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, 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.

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