Cosentyx™ (secukinumab) ▼, an innovative new psoriasis treatment receives a final positive NICE recommendation

- Cosentyx™ (secukinumab) ▼ recommended by NICE as an option for the treatment of eligible adults with severe plaque psoriasis

- NICE moves quickly issuing a positive recommendation in Final Appraisal Determination (FAD) without the requirement of an Appraisal Consultation Document (ACD) step – a first for a psoriasis treatment

- Eligible patients struggling with the devastating impact of poorly controlled psoriasis have the potential for significantly faster access to secukinumab, recognised by NICE as an innovative step change in the treatment of psoriasis

Frimley, 29 May 2015 – The National Institute for Health and Care Excellence (NICE) has today issued a Final Appraisal Determination (FAD) recommending secukinumab for use on the NHS as an option for the treatment of adults with severe plaque psoriasis when they have failed to respond to, are contraindicated to or cannot take standard systemic* therapies. Secukinumab is the first in a new generation of psoriasis treatments and is the only biologic treatment for psoriasis appraised by NICE to be issued with a FAD recommendation without the requirement of an ACD step.

It is estimated that 1.8 million people in the UK live with psoriasis and 20% are thought to have the moderate to severe form. In the recommendation issued today, NICE recognises secukinumab as being an innovative step change in the treatment of this debilitating skin condition because it is able to clear the skin in some patients. Approximately two thirds of patients with moderate to severe psoriasis are failing to achieve, or maintain effective control of their symptoms with current treatments. The news that secukinumab could soon be available on the NHS may offer hope to those patients within this group who are eligible to receive this new treatment.

Commenting on today’s positive recommendation, Professor Chris Griffiths, Foundation Professor of Dermatology University of Manchester said, “Psoriasis is a common, life-long debilitating condition which has a significant impact on every aspect of the lives of those afflicted with it. Our participation in the secukinumab clinical trial programme has shown us first-hand its impact on patients by delivering high levels of skin clearance. As NICE has recognised in its Final Appraisal Determination, secukinumab is an innovative medicine and represents a step change in the treatment of psoriasis.”

*Systemic: treatments or medication that travel through the blood stream, allowing them to be carried where they are needed to work

▼ New medicines and vaccines are subject to additional monitoring by the European Medicines Agency. They must display an inverted black triangle in their package leaflets and summary of product characteristics, to encourage reporting of any suspected adverse reactions, it does not mean the medicine is unsafe.
management of psoriasis. I am delighted that NICE has moved quickly to make secukinumab available within the NHS and that people with psoriasis will now have a real opportunity to achieve clear skin."

Commenting on the potential impact of the decision for patients, Helen McAteer, Chief Executive of the Psoriasis Association said, “Psoriasis is so much more than just a skin condition; it can be life consuming, affecting psychological wellbeing as well as physical health. Today’s news offers promise for many people with psoriasis who are striving for clear skin. I hope that this guidance will be implemented swiftly in order that patients can appropriately access this new treatment as soon as possible.”

Psoriasis is a chronic inflammatory disease. A goal of treatment is to achieve a 75 per cent improvement in each individual patients’ symptoms, however approximately two in three people in the UK with moderate to severe plaque psoriasis either fail to achieve, or fail to maintain this with currently available treatments. Poorly controlled moderate to severe psoriasis patients can cost the NHS up to £6 million per year.

Across a clinical trial programme in moderate to severe plaque psoriasis, secukinumab has consistently demonstrated high levels of skin clearance showing superiority to NICE-recommended biologic treatments, Stelara (ustekinumab) and Enbrel® (etanercept), with a comparable safety profile to both. The most frequently reported adverse drug reactions in the clinical trial programme (ADRs) were upper respiratory tract infections (most frequently nasopharyngitis, rhinitis). Most of the reactions were mild or moderate in severity.

In the ERASURE study: Eight in ten secukinumab patients achieved a 75 per cent improvement of psoriasis by week 12 and almost seven in ten secukinumab patients achieved a 90 per cent improvement of psoriasis by week 16.

In the FIXTURE study: A third more secukinumab patients achieved a 75 per cent improvement of psoriasis by week 12 compared to a NICE-recommended treatment, etanercept (77.11 vs 44%). Secukinumab patients achieved 50 per cent average improvement of their psoriasis at three weeks – more than twice as fast as etanercept.

In the CLEAR study: Almost eight in ten secukinumab patients achieved 90 per cent improvement in their psoriasis at Week 16, significantly more than those on ustekinumab.

In the FIXTURE and ERASURE studies the majority of secukinumab patients maintained improvement up to Week 52 (with continued treatment).

Novartis looks forward to the publication of NICE’s final Technology Appraisal Guidance for secukinumab in the coming months and is committed to working with NICE and the NHS to support its swift implementation.

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About Psoriasis
NICE recognises psoriasis as ‘more than just a skin condition’, affecting psychological and social wellbeing and being associated with significant co-morbidities including arthritis, diabetes and hypertension. A study showed that fifty nine per cent of people with psoriasis lost 26 working days a year due to their disease. An audit of English dermatology centres showed that up to 40 per cent of patients continued to receive biologic treatments despite not achieving an adequate response according to NICE criteria. Keeping people on treatment that is not providing an adequate response imposes a considerable economic burden to the NHS.

About Cosentyx ™ (secukinumab) and interleukin-17A (IL-17A)
Secukinumab is licensed and available in the UK for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic treatment (medicines that affect the entire body). People seeking further information about secukinumab should contact the Novartis UK medical information team at: medinfo.uk@novartis.com or on: +44 1276 698370.

Secukinumab is a fully human monoclonal antibody (a special type of infection-fighting immune molecule) being investigated for diseases that affect the immune system. Secukinumab inhibits a protein called interleukin-17A (IL-17A), which appears to play a central role in the development of psoriasis. IL-17A is found in higher concentrations in skin affected by psoriasis and has been a target for investigational therapies. Secukinumab has shown superiority to both Stelara (ustekinumab) and Enbrel® (etanercept), NICE-recommended biologic treatments. Secukinumab is licensed for use at a dose of 300 mg.

Studies in palmo-plantar psoriasis, nail psoriasis, scalp psoriasis and palmo-plantar pustular psoriasis are ongoing. Additionally, secukinumab is being studied in Phase III trials for psoriatic arthritis and ankylosing spondylitis.

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 and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortisation charges). As of 31 December 2014 Novartis Group companies employ approximately 133,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.co.uk.

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The foregoing release contains forward-looking statements that can be identified by words such as “committed,” “plans,” “investigated,” or similar terms, or by express or implied discussions regarding potential new indications or labelling 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 labelling 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.

References
15. NICE. Psoriasis is “more than just a skin condition.”(2014). at <https://www.nice.org.uk/news/article/psoriasis-is-more-than-just-a-skin-condition>