Novartis receives positive CHMP opinion for the first IL-17A inhibitor Cosentyx™ (secukinumab) to treat ankylosing spondylitis and psoriatic arthritis

- **Cosentyx (secukinumab) is recommended for approval in Europe for the treatment of ankylosing spondylitis (AS) and psoriatic arthritis (PsA) patients**

- **In clinical trials secukinumab demonstrated efficacy in patients with and without prior treatment using anti-tumor-necrosis-factor (anti-TNF) therapy**\(^1,5\)

- **Unmet need exists for new medicines as significant numbers of AS and PsA patients fail to respond to current treatments**\(^3\)

Frimley, October 23, 2015 – Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of secukinumab in Europe to treat ankylosing spondylitis (AS) and psoriatic arthritis (PsA) patients. Following two separate regulatory submissions, approval of secukinumab is now recommended for the treatment of active AS in adults who have responded inadequately to conventional therapy, such as non-steroidal anti-inflammatory drugs (NSAIDs), and for the treatment of active PsA in adult patients alone or in combination with methotrexate (MTX) when the response to previous disease modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

Secukinumab is the first of a new class of medicines called interleukin-17A (IL-17A) inhibitors to be recommended for AS and PsA - conditions that affect around 270,000 people in the UK\(^4,5\). Both are life-long, painful and debilitating inflammatory diseases that affect the joints and/or spine. If not treated effectively, both conditions can lead to irreversible joint and/or spinal damage caused by years of inflammation\(^2,6\).

New treatment options with an alternative way of working are needed for both conditions as many patients do not achieve an adequate response from standard treatments, such as DMARDs, NSAIDs or anti-TNF therapies. For example, up to 40% of patients with AS and PsA do not respond to the current biologic standard of care - anti-TNF\(^-\)\(^3,7\).

Secukinumab Phase III studies have consistently demonstrated significant improvements in the signs and symptoms of AS and PsA. Clinical improvements were seen as early as Week 3 through to Week 52, with benefits reported across the spectrum of patients who have either never taken or who have had prior treatment with anti-TNF therapies\(^1,2,8\).

The safety profile of secukinumab was shown to be consistent to that reported in clinical trials across multiple indications involving more than 9,600 patients\(^9\). The most frequently reported adverse drug reactions (ADRs) were upper respiratory tract infections (most
frequently nasopharyngitis, rhinitis). Most of the reactions were mild or moderate in severity.\textsuperscript{10}

The European Commission reviews the recommendations of the CHMP who then provide their final decision on approval, usually two months or earlier, following CHMP opinion. This is applicable to all European Union and European Economic Area countries. Secukinumab received EU approval for the treatment of moderate-to-severe plaque psoriasis in 2015.

**About the CHMP recommendation**

Pivotal Phase III studies in the secukinumab clinical trial programme, that provided key data for the CHMP submission, were MEASURE 1 and MEASURE 2 in AS, and FUTURE 1 and FUTURE 2 in PsA. These are all ongoing multi-centre, randomised, placebo-controlled studies that have been designed to evaluate the efficacy and safety of secukinumab in AS and PsA\textsuperscript{1,2,8,11}

**About ankylosing spondylitis (AS)**

AS is a painful, progressively debilitating condition caused by inflammation of the spine. Up to 70\% of patients with severe AS develop spinal fusion (where the bones grow together) over 10 to 15 years, which significantly reduces mobility and quality of life\textsuperscript{12}. AS occurs in approximately 153,000 people in the UK and typically affects young men and women aged 25 or older\textsuperscript{4,13}.

**About psoriatic arthritis (PsA)**

PsA, closely associated with psoriasis, is part of a family of long-term diseases impacting joints. PsA occurs in approximately 117,000 people in the UK\textsuperscript{5}. As many as one in four people with psoriasis may have undiagnosed PsA\textsuperscript{14}.

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

Secukinumab is a human monoclonal antibody that selectively neutralises circulating IL-17A\textsuperscript{15}. Secukinumab is the first IL-17A inhibitor with positive Phase III results for the treatment of PsA and AS. Research shows that IL-17A plays an important role in driving the body’s immune response in psoriasis and spondyloarthritis conditions, including PsA and AS\textsuperscript{16,17}. In Europe, secukinumab is approved for the treatment of moderate-to-severe plaque psoriasis in adult patients.

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**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). Novartis Group companies employ approximately 120,000 full-time-equivalent associates. Novartis products are
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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 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.
References


9. Novartis data on file


