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## **Novartis receives two landmark European authorisations for Cosentyx® (secukinumab) to treat patients with ankylosing spondylitis and psoriatic arthritis**

- *Cosentyx (secukinumab) is the first and only IL-17A inhibitor from a new class of medicines shown to treat two of the most common inflammatory joint conditions in Europe<sup>1</sup>*
- *Secukinumab shows rapid and sustained clinical benefits in ankylosing spondylitis (AS) and psoriatic arthritis (PsA) with no progression of spinal damage in approximately 80% of AS patients and no progression of joint damage in 84% of PsA patients as measured by x-ray over two years<sup>2,3,4,5</sup>*
- *High unmet need for new medicines exists as a significant number of patients do not respond well to current treatments<sup>6</sup>*

**Frimley, 23 November, 2015** – Novartis announced today that the European Commission (EC) has granted authorisation for Cosentyx® (secukinumab) for the treatment of people living with ankylosing spondylitis (AS) and psoriatic arthritis (PsA). For AS, this is the first new treatment advance in 16 years since the development of the current standard of care, anti-tumor necrosis factor (anti-TNF) therapy<sup>7</sup>.

Secukinumab is the first in a new class of medicines called interleukin-17A (IL-17A) inhibitors to be made available in Europe for AS and PsA. These authorisations follow on from the earlier licensing of secukinumab for the treatment of patients with moderate-to-severe plaque psoriasis.

AS and PsA are common inflammatory joint conditions affecting approximately 270,000 people in the UK<sup>8,9</sup>. 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<sup>3,10</sup>. New treatments are needed for both conditions as many patients do not respond well to existing treatments, with up to 40% not responding sufficiently to anti-TNFs<sup>6,11</sup>.

Recent studies have shown that secukinumab provided a significant reduction in the signs and symptoms of AS or PsA as early as Week 1-3, which were sustained over two years<sup>2,3</sup>. Up to 80% of AS patients treated with secukinumab showed no progression of spinal damage as measured by x-ray over two years<sup>4</sup>. In PsA, 84% of patients showed no progression of joint damage on x-ray over two years<sup>5</sup>.

More than 9,600 patients have been treated with secukinumab in clinical trials across multiple indications, and over 12,500 patients have been treated in the post-marketing setting<sup>12</sup>. The safety profile of secukinumab was shown to be consistent with that seen in clinical trials across multiple indications<sup>2-5</sup>.

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<sup>13</sup>.

Secukinumab is now licensed to treat active AS in adults who have responded inadequately to conventional therapy, such as non-steroidal anti-inflammatory drugs, and for the treatment of active PsA in adult patients alone or in combination with methotrexate when the response to previous disease modifying anti-rheumatic drug therapy has been inadequate.

#### **About the European Commission approval**

The European Commission marketing authorisations for secukinumab are applicable to all European Union and European Economic Area countries.

For patients with AS and PsA, the approved dose is secukinumab 150 mg by subcutaneous injection (under the skin) with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. For patients with PsA who also have moderate-to-severe plaque psoriasis, or those who have responded inadequately to anti-TNF treatment, the recommended dose is secukinumab 300 mg for the initial maintenance dosing.

Pivotal Phase III studies in the secukinumab clinical trial programme, that provided key data for the submission, were MEASURE 1 and MEASURE 2 in AS, and FUTURE 1 and FUTURE 2 in PsA<sup>2,3,14,15</sup>. These are ongoing multi-centre, randomised, placebo-controlled studies that have been designed to evaluate the efficacy and safety of secukinumab in AS and PsA.

#### **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<sup>16</sup>. AS occurs in approximately 153,000 people in the UK and typically affects young men and women aged 25 or older<sup>8,17</sup>.

#### **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<sup>9</sup>. As many as one in four people with psoriasis may have undiagnosed PsA<sup>18</sup>.

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

Secukinumab is a human monoclonal antibody that selectively neutralises circulating IL-17A<sup>19</sup>. 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<sup>20,21</sup>. In Europe, secukinumab is approved for the treatment of moderate-to-severe plaque psoriasis in adult patients.

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#### **Media contacts**

##### **Novartis Media Relations**

Novartis Pharmaceuticals UK Ltd.

Tel : + 44 (0) 1276 698691

Email: [press.office@novartis.com](mailto:press.office@novartis.com)

**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 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 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

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