Novartis receives approval for Cosentyx® label update in Europe to include dosing flexibility in psoriatic arthritis

- New Cosentyx® (secukinumab) label to include dosing flexibility up to 300 mg, based on clinical response, and 24-week structural data with subcutaneous (sc) regimens.

- Cosentyx inhibits progression of joint damage in psoriatic arthritis (PsA) and shows rapid and sustained resolution of enthesitis, by inhibiting IL-17A.

- PsA is a chronic, progressive and irreversible disease leading to pain, fatigue, activity impairment and significant mobility loss due to structural damage.

**Basel, October 26, 2018** – Novartis, a leader in immuno-dermatology and rheumatology, announced today that the European Commission (EC) has approved a label update for Cosentyx® (secukinumab). Cosentyx is the first and only fully-human treatment that specifically inhibits interleukin-17A (IL-17A), in psoriatic arthritis (PsA). The new label update includes dosing flexibility of up to 300 mg based on clinical response that will provide clinicians with greater choice for their patients.

The label update also includes 24-week structural data with subcutaneous (sc) regimens demonstrating that Cosentyx inhibits progression of joint damage in PsA.

“Cosentyx has shown that it can slow the progression of joint damage inflicted by psoriatic arthritis, which can lead to significant mobility loss for patients,” said Paul Emery, Professor of Rheumatology, Arthritis Research UK and Director Leeds NIHR Biomedical Research Centre. “The label update allows dosing flexibility up to 300 mg, giving clinicians and patients greater choice in how to target this progressive and debilitating condition, based on individual response to treatment.”

This label update is significant as PsA can lead to significant mobility loss and irreversible joint damage if sub-optimally-treated. PsA is a chronic, progressive and irreversible disease leading to pain, fatigue, as well as activity impairment and significant mobility loss due to structural damage.

The label update is based on Cosentyx sustained efficacy and consistent safety following up-titration to 300 mg in PsA. Cosentyx specifically inhibits IL-17A – a cornerstone cytokine involved in the development of spondyloarthritis and psoriatic disease. The 24-week structural disease progression data are from FUTURE 5, the largest Phase III study for a biologic conducted in PsA to date (996 patients). In this study, almost 90% of patients treated with Cosentyx 300 mg had no radiographic disease progression at 24 weeks.

“Cosentyx is the only IL-17A inhibitor to demonstrate 5-year safety and efficacy in Phase III studies of PsA and AS. We are reimagining the well-being of patients living with all facets of psoriatic arthritis,” said Eric Hughes, Global Development Unit Head, Immunology.
Hepatology and Dermatology. “This label update further supports prescribing doctors and patients in their treatment choice.”

The label update is applicable to all European Union and European Economic Area countries and is effective immediately. To date, Cosentyx has been prescribed to more than 160,000 patients worldwide.9

About Cosentyx
Cosentyx is the first and only fully-human biologic that specifically inhibits interleukin-17A (IL-17A), a cornerstone cytokine involved in the inflammation and development of psoriasis, ankylosing spondylitis, and PsA.6-8 IL-17A is produced by various cells from both the innate immune system (which can be triggered by mechanical stress) and the adaptive immune system.3 To date, Cosentyx has been prescribed to more than 160,000 patients worldwide and is being evaluated in 100 studies, including a comprehensive head-to-head clinical trial program.10-16

Disclaimer
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, 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 the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; our ability to obtain or maintain proprietary intellectual 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 nearly 1 billion people globally and we are finding innovative ways to expand access to our latest treatments. About 125 000 people of more than 140 nationalities work at Novartis around the world. Find out more at http://www.novartis.com
Novartis is on Twitter. Sign up to follow @Novartis at [http://twitter.com/novartis](http://twitter.com/novartis)

For Novartis multimedia content, please visit [www.novartis.com/news/media-library](http://www.novartis.com/news/media-library)

For questions about the site or required registration, please contact [media.relations@novartis.com](mailto:media.relations@novartis.com)

References


**Novartis Investor Relations**  
Central investor relations line: +41 61 324 7944  
E-mail: investor.relations@novartis.com

<table>
<thead>
<tr>
<th>Central</th>
<th>North America</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samir Shah</td>
<td>Richard Pulik</td>
</tr>
<tr>
<td>+41 61 324 7944</td>
<td>+1 212 830 2448</td>
</tr>
<tr>
<td>Pierre-Michel Bringer</td>
<td>Cory Twining</td>
</tr>
<tr>
<td>+41 61 324 1065</td>
<td>+1 212 830 2417</td>
</tr>
<tr>
<td>Thomas Hungerbuehler</td>
<td></td>
</tr>
<tr>
<td>+41 61 324 8425</td>
<td></td>
</tr>
<tr>
<td>Isabella Zinck</td>
<td></td>
</tr>
<tr>
<td>+41 61 324 7188</td>
<td></td>
</tr>
</tbody>
</table>