Novartis Cosentyx® builds on its axSpA leadership with US label update for dosing flexibility in ankylosing spondylitis

- New Cosentyx® (secukinumab) US label to include 300 mg up-titration option is based on Phase III MEASURE 3 study results in ankylosing spondylitis (AS)

- Label update provides clinicians with greater choice for their patients, based on clinical response to treatment

- Novartis has submitted to FDA and EMA for approval in non-radiographic axial spondyloarthritis (nr-axSpA); potentially providing patients with a treatment that addresses the axSpA disease spectrum

- Cosentyx is backed by 5-year sustained efficacy and safety data across AS, psoriatic arthritis and psoriasis, with over 300,000 patients treated worldwide

 Basel, January 31, 2020 — Novartis, a leader in rheumatology and immuno-dermatology, announced today that the US Food and Drug Administration (FDA) has approved a label update for Cosentyx® (secukinumab) to include the option for up-titration to a 300 mg dose for adults with active ankylosing spondylitis (AS).

“This approval gives clinicians added flexibility to ensure patients are able to achieve the best response to treatment and experience full relief from the signs and symptoms of AS,” said Todd Fox, Global Head of Medical Affairs Immunology, Hepatology and Dermatology at Novartis. “It’s further encouraging news in our efforts to reimagine medicine across the axSpA disease spectrum.”

The FDA based the approval on data from MEASURE 3, a three-year study that assessed the efficacy and safety of two doses of Cosentyx, 300 mg and 150 mg, in patients with AS. Both doses met the primary efficacy endpoint of improving the signs and symptoms of AS. Long term data show that the response rate was greater in the 300 mg dose group, particularly among patients with previous anti-TNF exposure, compared with the recommended 150 mg dose. The safety profile was consistent with previous studies.

About axSpA
Axial spondyloarthritis (axSpA) is a spectrum of long-term inflammatory disease characterized by chronic inflammatory back pain. The axSpA spectrum includes amongst other indications ankylosing spondylitis (AS), in which joint damage is generally visible on X-ray, and non-radiographic axial spondyloarthritis (nr-axSpA), in which joint damage is not visible on X-ray. Both parts of the disease spectrum have a comparable symptom burden, including nocturnal waking caused by pain, morning stiffness, fatigue and functional disability. If left
untreated, axSpA could impair activity, lead to lost work time and have a significant impact on quality of life\textsuperscript{10}.

**About Cosentyx (secukinumab)**

Cosentyx is the first and only fully-human biologic that directly inhibits interleukin-17A (IL-17A), a cornerstone cytokine involved in the inflammation and development of ankylosing spondylitis (AS), psoriasis (PsO) and psoriatic arthritis (PsA)\textsuperscript{11-14}.

Cosentyx is backed by robust clinical evidence, including 5-year data across PsO, PsA and AS, as well as data from real world evidence\textsuperscript{4-6}. These data strengthen the unique position of Cosentyx as a rapid and long-lasting comprehensive treatment across axSpA, PsA and psoriatic disease, with more than 300,000 patients treated worldwide with Cosentyx since its launch\textsuperscript{7}.

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This media update 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,” “may,” “could,” “would,” “expect,” “anticipate,” “seek,” “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 media update, 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 media update 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 and requirements for increased pricing transparency; 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, data integrity 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 media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update 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 more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at [www.novartis.com](http://www.novartis.com)
References
4. Baraliakos X, et al. Long-term evaluation of secukinumab in ankylosing spondylitis: 5-year efficacy and safety results from a Phase 3 trial. Presented as a late-breaking abstract at the American College of Rheumatology Annual Meeting; October 19–24, 2018; Chicago, IL.

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**Novartis Media Relations**
E-mail: media.relations@novartis.com

Antonio Ligi  
Novartis Global External Communications  
+41 61 324 1974 (direct)  
antonio.ligi@novartis.com

Friedrich von Heyl  
Novartis Pharma Communications  
+41 79 749 0286 (mobile)  
friedrich.vonheyl@novartis.com

Eric Althoff  
Novartis US External Communications  
+1 646 438 4335  
eric.althoff@novartis.com

**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>Sloan Simpson</td>
</tr>
<tr>
<td>+41 61 324 7944</td>
<td>+1 862 778 5052</td>
</tr>
<tr>
<td>Pierre-Michel Bringer</td>
<td>Cory Twining</td>
</tr>
<tr>
<td>+41 61 324 1065</td>
<td>+1 862 778 3258</td>
</tr>
<tr>
<td>Thomas Hungerbuehler</td>
<td></td>
</tr>
<tr>
<td>+41 61 324 8425</td>
<td></td>
</tr>
</tbody>
</table>
Isabella Zinck +41 61 324 7188