Novartis Cosentyx® shows superior improvements in psoriasis patients’ quality of life versus Janssen’s IL-23 Stelara®*

- New CLARITY data show over two-thirds of Cosentyx (secukinumab) treated patients with moderate to severe psoriasis reported no impact of skin disease on their quality of life (QoL) up to Week 16 compared to Stelara®* (68.4% versus 55.9%, respectively)¹

- Results from CLARITY study presented in 2018 showed Cosentyx was significantly more effective than Stelara®* in delivering clear and almost clear skin at 12 and 16 weeks. CLARITY study met all primary and secondary endpoints²

- In addition, new PROSE study data presented as a late-breaker supporting benefit of Cosentyx to improve patient QoL³

- Results strengthen unique position of Cosentyx reimagining care as a rapid and long-lasting complete treatment of psoriatic disease, with 200,000+ patients⁴

Basel, March 5, 2019 – Novartis, a global leader in immuno-dermatology and rheumatology, announced today additional results from the head-to-head CLARITY study demonstrating the superiority of Cosentyx® (secukinumab) compared to Stelara®* (ustekinumab) in delivering specific quality of life (QoL) aspects in adults with moderate-to-severe plaque psoriasis at 16 weeks. New CLARITY data show over two-thirds of Cosentyx treated patients with moderate to severe psoriasis reported no impact of skin disease on their QoL up to Week 16 compared to Stelara®* (ustekinumab) treated patients (68.4% versus 55.9%, respectively)¹. These data were presented at the 2019 American Academy of Dermatology (AAD) Annual Meeting in Washington, D.C.

The proportion of patients achieving Dermatology Life Quality Index (DLQI) 0 or 1 response showed a superior improvement with Cosentyx over Stelara®: DLQI 0 or 1 response was higher when patients were treated with Cosentyx vs. Stelara®* at Week 12 (64.0% vs. 51.7%) and at Week 16 (68.4% vs. 55.9%) (both p<0.0001)¹. The new study results add to findings from CLARITY published in 2018, which showed Cosentyx was significantly more effective than Stelara®* in delivering clear and almost clear skin at 12 and 16 weeks². Cosentyx continues to have a favorable and consistent safety profile¹. Previously presented data from the CLEAR study also demonstrated the superiority of Cosentyx to Stelara®* in achieving sustained skin clearance (PASI 90 response rates) at 52 weeks⁵.

Psoriasis is not simply a cosmetic problem, but a persistent, chronic (long-lasting), and sometimes distressing disease, which can affect even the smallest aspects of people’s lives on a daily basis. “We are proud to present strong improvement in quality of life data, reinforcing our confidence in Cosentyx as a complete treatment for psoriasis patients,” said Sam Khalil, Worldwide Head of Medical Affairs Immunology, Hepatology and Dermatology.

“Over two-thirds of psoriasis patients experience persistent manifestations beyond skin plaques including nail, scalp, palmoplantar psoriasis as well as joints involvement. Our goal is
to provide a treatment that targets all these manifestations and improves the quality of life of patients suffering from psoriatic diseases, with a proven long-term safety and efficacy."

In addition to CLARITY, new data from the PROSE study was presented as a late-breaker at AAD analyzing the impact of skin disease on patient QoL.

These QoL results add to findings from the SCULPTURE study published in 2018, showing that two-thirds of moderate to severe plaque psoriasis patients treated with Cosentyx® reported no impact of skin disease on their quality of life through 5 years, as described by the DLQI 0/1 response (72.7% at Year 1 and 65.5% at Year 5) – a questionnaire used to evaluate the impact of skin disease on a patient's quality of life.

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 (PsO), psoriatic arthritis (PsA) and ankylosing spondylitis (AS).

Cosentyx is backed by robust clinical evidence and more than 100 studies to date including dedicated studies in persistent manifestations of psoriasis, namely nails, scalp, palms and soles, as well as PsA and AS. Cosentyx has shown long-lasting efficacy and a favorable safety profile while addressing psoriatic disease, therefore offering a complete treatment.

Today, more than 200,000 patients worldwide have been treated with Cosentyx since launch.

About the CLARITY study
CLARITY (NCT02826603) is a 52-week, multicenter, randomized, double-blind study to demonstrate the superiority of Cosentyx 300 mg versus Stelara® in moderate-to-severe plaque psoriasis patients. Patients were randomized 1:1 to receive subcutaneous Cosentyx 300 mg (n = 550) at Baseline, Weeks 1, 2 and 3, then every 4 weeks from Week 4 to 48, or Stelara® (n = 552) 45 mg or 90 mg subcutaneously (depending upon body weight at randomization), according to approved label.

Co-primary endpoints were 90% or more improvement from Baseline Psoriasis Area and Severity Index (PASI) 90 and Investigator's Global Assessment (IGA) mod 2011 0/1 (clear or almost clear) response rates at Week 12. Key secondary endpoints included demonstrating superiority of Cosentyx versus Stelara® with respect to PASI 75 at Week 4; PASI 75 and 100 at Week 12; PASI 75, 90, 100 and IGA mod 2011 0/1 at Week 16. Missing values were handled by multiple imputation.

The study results showed 66.5% and 72.3% of patients treated with Cosentyx (p < 0.0001) achieved both co-primary endpoints PASI 90 and IGA mod 2011 0/1, respectively, compared to 47.9% and 55.4% patients, respectively, treated with Stelara® at Week 12 (p < 0.0001). Patients receiving Cosentyx had significantly greater PASI 100 responses (key secondary endpoint) compared to those receiving Stelara® (38.1% vs. 20.1%, respectively at Week 12; p < 0.0001).

All key secondary endpoints in the CLARITY study were met. At Week 4, PASI 75 response rates were significantly superior with Cosentyx compared to Stelara® (40.2% vs. 16.3%; p < 0.0001). At Week 16, Cosentyx demonstrated significantly superior response rates compared to Stelara® for PASI 75 (91.7% vs. 79.8%; p < 0.0001), PASI 90 (76.6% vs. 54.2%; p < 0.0001), PASI 100 (45.3% vs. 26.7%; p < 0.0001), and IGA mod 2011 0/1 (78.6% vs. 59.1%; p < 0.0001).
The proportion of patients achieving DLQI 0 or 1 response was higher when patients were treated with secukinumab vs. ustekinumab at Week 12 (64.0% vs. 51.7%) and at Week 16 (68.4% vs. 55.9%) (both p<0.0001).1

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 more than 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 130 000 people of nearly 150 nationalities work at Novartis around the world. Find out more at www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis
For Novartis multimedia content, please visit www.novartis.com/news/media-library
For questions about the site or required registration, please contact media.relations@novartis.com

* Stelara® is a registered trademark of Janssen Biotech, Inc.

References
2. Bagel J et al. Secukinumab is Superior to Ustekinumab in Clearing Skin of Patients with Moderate to Severe Plaque Psoriasis (16-week CLARITY Results). Dermatol Ther (Heidelb). 2018 Dec;8(4):571-579
3. Augustin et al. Baseline characteristics according to previous exposure to systemic treatment in patients with moderate to severe psoriasis: Results from the PROSE study. Presented as a late-blower at the 2019 American Academy of Dermatology (AAD) Annual Meeting; March 1-5, 2019, Washington, D.C.
5. Blauvelt A et al. Secukinumab is superior to ustekinumab in clearing skin of subjects with moderate-to-severe plaque psoriasis up to 1 year: Results from the CLEAR study. J Am Acad Dermatol. 2017;76(1).
8. Reich, K et al. Secukinumab Shows Sustained Efficacy in Difficult-to-Treat Palmoplantar, Nail, and Scalp Psoriasis: Long-term Results From 3 Phase III Placebo-Controlled Randomized Trials. Presented as a Late Breaking Poster #6 at the 3rd Inflammatory Skin Disease Summit (ISDS), Vienna. December 2018.

# # #

Novartis Media Relations
Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Friedrich von Heyl
Novartis Global Pharma Communications
+41 61 324 8984 (direct)
+41 79 749 0286 (mobile)
friedrich.vonheyl@novartis.com

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

Central
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America
Richard Pulik +1 212 830 2448
Cory Twining +1 212 830 2417