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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis Cosentyx® shows encouraging results versus Humira®* from first-of-its-kind head-to-head trial in psoriatic arthritis

- *Cosentyx narrowly missed statistical significance for superiority in ACR 20, the primary endpoint of the EXCEED trial, while showing numerically higher results versus Humira®*[1]*
- *Statistically significant advantages of Cosentyx versus Humira®* in psoriatic arthritis (PsA)-specific endpoints were observed in a pre-specified sensitivity analysis*[1]
- *EXCEED underscores Novartis commitment in rheumatology as first double-blinded monotherapy head-to-head trial with a primary endpoint specific to joints in PsA*[1]

Basel, November 1, 2019 – Novartis, a leader in rheumatology and immuno-dermatology, today announced results from the EXCEED head-to-head trial comparing Cosentyx® (secukinumab) to Humira®* (adalimumab) in patients with active psoriatic arthritis (PsA)[1]. While Cosentyx narrowly missed statistical significance for superiority in ACR 20, the primary endpoint of the EXCEED trial, it showed numerically higher results versus Humira®*[1]. Statistically significant advantages of Cosentyx versus Humira®* in PsA-specific endpoints were observed in a pre-specified sensitivity analysis. The trial demonstrated a consistent and favorable safety profile for Cosentyx in line with previous clinical trials[1,2-7]. No new safety signals were detected[1].

“These data will be welcomed by patients and clinicians to guide clinical decision making and highlight secukinumab as a viable option as a first-line biologic for the treatment of psoriatic arthritis,” said Iain McInnes, Professor of Rheumatology, University of Glasgow and an investigator in the secukinumab clinical trial program.

“EXCEED is the first ever monotherapy head-to-head trial with a primary endpoint in psoriatic arthritis specific to joints.” said Eric Hughes, Global Development Unit Head, Immunology, Hepatology & Dermatology. “Novartis continues to reimagine care for patients and advance science in rheumatology. We will assess the EXCEED data in their totality and we view the results as confirming our vision of Cosentyx becoming standard of care in psoriatic arthritis.”

Detailed data is planned to be presented at a future scientific congress.

Cosentyx is the only biologic with proven efficacy in all key manifestations of psoriatic arthritis[8] and is backed by 5-year sustained efficacy and consistent safety data across psoriatic arthritis, ankylosing spondylitis and psoriasis[2-7]. To date, over 250,000 patients have been treated worldwide[9].

About Psoriatic Arthritis

* Humira is a registered trademark of AbbVie Inc.

Psoriatic arthritis (PsA) is a complex disease with multiple manifestations driving patient symptoms[10,11]. It is estimated to affect up to 50 million people worldwide[12,13].

PsA is part of a family of life-long inflammatory diseases (spondyloarthritis) that target the joints and is closely associated with psoriasis[13]. Approximately 40% of patients with psoriasis have PsA[13] and as many as one in four people with psoriasis may have undiagnosed PsA[14]. Symptoms of PsA include joint pain and stiffness, skin and nail psoriasis, swollen toes and fingers, persistent painful swelling of the tendons, and irreversible joint damage[13].

About EXCEED
EXCEED is the first double-blinded head-to-head clinical trial evaluating Cosentyx (secukinumab) 300 mg versus Humira®* (adalimumab) 40 mg. EXCEED is a 52-week, multi-center, randomized, double-blind, active control, Phase IIIb trial evaluating the efficacy of Cosentyx compared with Humira®* in patients with active PsA who are naïve to biologic therapy. The trial involves over 800 biologic-naïve patients with PsA[1].

The primary endpoint assessed statistical superiority of Cosentyx monotherapy against Humira®* monotherapy for ACR20 response rates at Week 52. The ACR20 is a composite measure defined as both improvement of 20% in the number of tender and number of swollen joints, and a 20% improvement in three of the following five criteria: patient global assessment, physician global assessment, Health Assessment Questionnaire (HAQ), visual analog pain scale, and erythrocyte sedimentation rate or C-reactive protein (CRP). Key secondary endpoints, tested for superiority at Week 52, are PASI90, ACR50, physical function (HAQ-DI (disability index) score relative to baseline), and resolution of enthesitis. PASI stands for Psoriasis Area and Severity Index[1].

Cosentyx 300 mg was administered at baseline, weeks 1-4, and then every 4 weeks until Week 48. Humira®* 40 mg was administered at baseline, and then every 2 weeks until Week 50.

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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 “encouraging,” “vision,” “to date,” “potential,” “can,” “will,” “expectations,” “commitment,” “planned,” “to be presented,” or similar terms, or by express or implied discussions regarding potential new indications or labeling for Cosentyx, or regarding potential future revenues from Cosentyx. 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 Cosentyx 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 Cosentyx will be commercially successful in the future. In particular, our expectations regarding Cosentyx 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 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

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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 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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