FDA approves Novartis Cosentyx® as first intravenous (IV) formulation interleukin-17A antagonist for rheumatic diseases

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- First new intravenous (IV) treatment option in six years for adults with psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[1-6]
- Cosentyx® (secukinumab) administered via IV infusion offers healthcare providers choice and flexibility to tailor treatment to their patients' unique needs
- With both IV and subcutaneous formulations, Cosentyx can now help a broader range of PsA, AS and nr-axSpA patients manage their condition

EAST HANOVER, N.J., Oct. 6, 2023 -- Novartis, a global leader in immuno-dermatology and rheumatology, announced today that the US Food and Drug Administration (FDA) has approved an intravenous (IV) formulation of Cosentyx® (secukinumab) for the treatment of adults with psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA). Cosentyx is the only treatment approved in an IV formulation that specifically targets and blocks interleukin-17A (IL-17A), and the only non-tumor necrosis factor alpha (TNF-α) IV option available in all these indications. The IV formulation of Cosentyx offers patients a monthly 30-minute, weight-based dosing option, requiring no pre-medication and no lab monitoring.[1] The new IV administration option will be available in Q4 of 2023.

"A significant portion of the millions of PsA, AS and nr-axSpA patients in the US require treatment through IV infusions for a variety of reasons, including not being comfortable with self-injections or simply preferring to have treatments administered in their healthcare provider's office," said Philip J. Mease, M.D., Clinical Professor at the University of Washington School of Medicine and Director of Rheumatology Research at the Swedish Medical Center in Seattle, WA. "The approval of Cosentyx as an IV formulation is an important milestone for patients because it expands the treatment options available to them with a different mechanism of action than existing biologic IV therapies, along with the comfort and familiarity of an established treatment."

"At Novartis, we are committed to ensuring healthcare providers and patients have treatment options available to meet their unique needs. With this approval of Cosentyx as an IV formulation, along with the subcutaneous formulation, we can broaden the use of Cosentyx to help more patients manage their condition with a medicine backed by more than a decade of clinical research and eight years of real-world experience," said Christy Siegel, Vice President and Head of Immunology, Novartis US.

About Cosentyx® (secukinumab)
Cosentyx is a fully human biologic that specifically targets and blocks interleukin-17A (IL-17A), an important cytokine involved in the inflammation of psoriatic arthritis (PsA), moderate to severe plaque psoriasis, ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).[7,8] Cosentyx is a proven medicine and has been studied clinically for more than 14 years. The medicine is backed by robust evidence, including 8 years of real-world data in adults and 5 years of long-term safety and efficacy in adults with moderate to severe plaque psoriasis, PsA and AS.[1,9-15] These data strengthen the position of Cosentyx as a

treatment across AS, nr-axSpA, PsA, moderate to severe plaque psoriasis (adult and pediatric) and two subtypes of juvenile idiopathic arthritis (JIA), enthesitis-related arthritis and juvenile psoriatic arthritis.[1] More than 1 million patients have been treated with Cosentyx worldwide since its launch in 2015.[16] Cosentyx is approved in more than 100 countries, most recently gaining approval for JIA and hidradenitis suppurativa in Europe.[17-20]

INDICATIONS
COSENTYX® (secukinumab) is a prescription medicine used to treat:

- people 6 years of age and older with moderate to severe plaque psoriasis (PsO) that involves large areas or many areas of the body, and who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light alone or with systemic therapy)
- people 2 years of age and older with active psoriatic arthritis (PsA)
- adults with active ankylosing spondylitis (AS)
- adults with active non-radiographic axial spondyloarthritis (nr-axSpA) and objective signs of inflammation
- people 4 years of age and older with active enthesitis-related arthritis (ERA)

IMPORTANT SAFETY INFORMATION
Do not use COSENTYX if you have had a severe allergic reaction to secukinumab or any of the other ingredients in COSENTYX. See the Medication Guide for a complete list of ingredients.

What is the most important information I should know about COSENTYX?
COSENTYX is a medicine that affects your immune system. COSENTYX may increase your risk of having serious side effects such as:

Infections
COSENTYX may lower the ability of your immune system to fight infections and may increase your risk of infections. Some people have died from these infections.

- Your doctor should check you for tuberculosis (TB) before starting treatment with COSENTYX.
- If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with COSENTYX and during treatment with COSENTYX.
- Your doctor should watch you closely watch for signs and symptoms of TB during treatment with COSENTYX. Do not take COSENTYX if you have an active TB infection.

Before starting COSENTYX, tell your doctor if you:

- are being treated for an infection
- have an infection that does not go away or that keeps coming back
- have TB or have been in close contact with someone with TB
- think you have an infection or have symptoms of an infection such as: fevers, sweats, or chills; muscle aches; cough; shortness of breath; blood in your phlegm; weight loss; warm, red, or painful skin or sores on your body; diarrhea or stomach pain; burning when you urinate or urinate more often than normal

After starting COSENTYX, call your doctor right away if you have any signs of infection listed above. Do not use COSENTYX if you have any signs of infection unless you are instructed to by your doctor.

What are the possible side effects of COSENTYX?
COSENTYX may cause serious side effects, including:

Inflammatory bowel disease

New cases of inflammatory bowel disease or "flare-ups" can happen with COSENTYX and can sometimes be serious. If you have inflammatory bowel disease (ulcerative colitis or Crohn's disease), tell your doctor if you have worsening disease symptoms during treatment with COSENTYX or develop new symptoms of stomach pain or diarrhea.

Serious allergic reactions
Serious allergic reactions can occur. Get emergency medical help right away if you get any of the following symptoms: feeling faint; swelling of your face, eyelids, lips, mouth, tongue, or throat; trouble breathing or throat tightness; chest tightness; skin rash or hives (red, itchy bumps).
If you have a severe allergic reaction, do not give another injection of COSENTYX.

Severe skin reactions that look like eczema can happen during treatment with COSENTYX from days to months after your first dose and can sometimes lead to hospitalization. Your healthcare provider may temporarily stop treatment with COSENTYX if you develop severe skin reactions. Tell your healthcare provider if you have any of the following signs or symptoms: redness or rash, itching, small bumps or patches, your skin is dry or feels like leather, blisters on the hands or feet that ooze or become crusty and skin peeling.

The most common side effects of COSENTYX include: cold symptoms, diarrhea, and upper respiratory infections.

These are not all of the possible side effects of COSENTYX. Call your doctor for medical advice about side effects.

Before using COSENTYX, tell your doctor if you:

- have any of the conditions or symptoms listed above for infections.
- have inflammatory bowel disease (Crohn's disease or ulcerative colitis).
- are allergic to latex. The needle cap on the COSENTYX Sensoready® pen, and 150 mg/mL and 75 mg/0.5 mL prefilled syringes contains latex.
- have recently received or are scheduled to receive an immunization (vaccine). People who take COSENTYX should not receive live vaccines. Children should be brought up to date with all vaccines before starting COSENTYX.
- have any other medical conditions and all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- are pregnant or plan to become pregnant. It is not known if COSENTYX can harm your unborn baby. You and your doctor should decide if you will use COSENTYX.
- are breastfeeding or plan to breastfeed. It is not known if COSENTYX passes into your breast milk.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for Cosentyx full Prescribing Information.

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," "may," "could," "would," "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 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, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases; 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 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 a focused innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide.

Reimagine medicine with us: Visit us at https://www.novartis.com and connect with us on LinkedIn, Facebook, X/Twitter and Instagram.

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