Novartis ILARIS® (canakinumab) receives FDA approval for new indication to treat Adult-Onset Still's Disease (AOSD)

Jun 16, 2020

- *FDA granted an indication for active Still's disease including both systemic juvenile idiopathic arthritis (SJIA) and AOSD, a serious and rare inflammatory disorder with high unmet medical need*[1,2]
- *ILARIS (canakinumab) is the first FDA-approved treatment for AOSD*
- *AOSD has an estimated prevalence of less than 1 case per 100,000 people*[3]

East Hanover, June 16, 2020 - Novartis ILARIS (canakinumab) received US Food and Drug Administration (FDA) approval for a new indication to treat Adult-Onset Still's Disease (AOSD)[1]. The FDA granted an indication for active Still's disease including both systemic juvenile idiopathic arthritis (SJIA) and AOSD in patients aged 2 years and older[1].

"At Novartis, we are committed to bringing medicines that address high unmet needs to patients, including to those who are living with rare diseases," said Victor Bultó, President, Novartis Pharmaceuticals Corporation. "We are very proud that ILARIS is the first treatment approved by the FDA for patients with AOSD, a serious and rare inflammatory disorder."

The efficacy of ILARIS in adults with AOSD is based on the pharmacokinetic exposure and extrapolation of the established efficacy of ILARIS in SJIA patients[1]. Efficacy of ILARIS was also assessed in a randomized, double-blind, placebo-controlled study that enrolled 36 patients (22 to 70 years old) diagnosed with AOSD[4]. The efficacy and safety data in AOSD were generally consistent with the results of a pooled analysis of SJIA patients[1].

INDICATION

ILARIS® (canakinumab) is indicated for the treatment of active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

ILARIS is contraindicated in patients with confirmed hypersensitivity to the active substance or to any of the excipients.

WARNINGS AND PRECAUTIONS

Serious Infections

ILARIS has been associated with an increased risk of serious infections. Physicians should exercise caution when administering ILARIS to patients with infections, a history of recurring infections or underlying conditions,

which may predispose them to infections.

ILARIS should not be administered to patients during an active infection requiring medical intervention. Administration of ILARIS should be discontinued if a patient develops a serious infection.

Infections, predominantly of the upper respiratory tract, in some instances serious, have been reported with ILARIS. Generally, the observed infections responded to standard therapy. Isolated cases of unusual or opportunistic infections (eg, aspergillosis, atypical mycobacterial infections, cytomegalovirus, herpes zoster) were reported during ILARIS treatment. A causal relationship of ILARIS to these events cannot be excluded. In clinical trials, ILARIS has not been administered concomitantly with Tumor Necrosis Factor (TNF) inhibitors. An increased incidence of serious infections has been associated with administration of another interleukin-1 (IL-1) blocker in combination with TNF inhibitors. Coadministration of ILARIS with TNF inhibitors is not recommended because this may increase the risk of serious infections.

Drugs that affect the immune system by blocking TNF have been associated with an increased risk of new tuberculosis (TB) and reactivation of latent TB. It is possible that use of IL-1 inhibitors, such as ILARIS, increases the risk of reactivation of TB or of opportunistic infections.

Prior to initiating immunomodulatory therapies, including ILARIS, patients should be evaluated for active and latent TB infection. Appropriate screening tests should be performed in all patients. ILARIS has not been studied in patients with a positive TB screen, and the safety of ILARIS in individuals with latent TB infection is unknown. Patients testing positive in TB screening should be treated by standard medical practice prior to therapy with ILARIS. All patients should beinstructed to seek medical advice if signs, symptoms, or high risk exposure suggestive of TB (eg, persistent cough, weight loss, subfebrile temperature) appear during or after ILARIS therapy.

Immunosuppression

The impact of treatment with anti-IL-1 therapy on the development of malignancies is not known. However, treatment with immunosuppressants, including ILARIS, may result in an increase in the risk of malignancies.

Hypersensitivity

Hypersensitivity reactions have been reported with ILARIS therapy. During clinical trials, no anaphylactic reactions attributable to treatment with canakinumab have been reported. It should be recognized that symptoms of the underlying disease being treated may be similar to symptoms of hypersensitivity. If a severe hypersensitivity reaction occurs, administration of ILARIS should be discontinued and appropriate therapy initiated.

Immunizations

Live vaccines should not be given concurrently with ILARIS. Prior to initiation of therapy with ILARIS, patients should receive all recommended vaccinations. In addition, because ILARIS may interfere with normal immune response to new antigens, vaccinations may not be effective in patients receiving ILARIS.

Canakinumab, like other monoclonal antibodies, is actively transported across the placenta mainly during the third trimester of pregnancy and may cause immunosuppression in the *in utero* exposed infant. The risks and benefits should be considered prior to administering live vaccines to infants who were exposed to ILARIS *in utero* for at least 4 to 12 months following the mother’s last dose of ILARIS.

Macrophage Activation Syndrome

Macrophage Activation Syndrome (MAS) is a known, life-threatening disorder that may develop in patients with rheumatic conditions, in particular Still's disease, and should be aggressively treated. Physicians should be attentive to symptoms of infection or worsening of Still's disease, as these are known triggers for MAS. Eleven cases of MAS were observed in 201 SJIA patients treated with canakinumab in clinical trials. Based on the clinical trial experience, ILARIS does not appear to increase the incidence of MAS in Still's disease patients, but no definitive conclusion can be made.

ADVERSE REACTIONS

The most common adverse drug reactions greater than 10% associated with ILARIS treatment in SJIA patients were infections (nasopharyngitis and upper respiratory tract infections), abdominal pain, and injection site reactions.

Please see full Prescribing Information, including Medication Guide, for ILARIS.

About Novartis

Located in East Hanover, NJ Novartis Pharmaceuticals Corporation – an affiliate of 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 employs about 15,000 people in the United States. For more information, please visit http://www.novartis.us.

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References

1. ILARIS [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2020.
2. National Organization for Rare Disorders (NORD). Adult onset Still's disease. Updated 2015. Accessed May 5, 2020. https://rarediseases.org/rare-diseases/adult-onset-stills-disease/
3. Efthimiou P. *Auto-Inflammatory Syndromes*. Springer Nature Switzerland AG; 2019.
4. Kedor C, et al. Canakinumab for treatment of Adult-Onset Still’s Disease to achieve reduction of arthritic manifestation (CONSIDER): phase II, randomised, double-blind, placebo-controlled, multicentre, investigator-initiated trial. *Ann Rheum Dis*. 2020;0:1-8.

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