Ilaris® (canakinumab) – Expanded indication

- On June 16, 2020, the FDA announced the approval of Novartis' Ilaris (canakinumab), for the treatment of active Still's disease, including Adult-Onset Still's Disease (AOSD) in patients aged 2 years and older.

- Ilaris is also approved for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older and various autoinflammatory Periodic Fever Syndromes.

- Ilaris is the first FDA approved treatment for AOSD.

- AOSD is a rare and serious autoinflammatory disease of unknown origin. Characteristics of AOSD have considerable overlap with SJIA, which includes fever, arthritis, rash and elevated markers for inflammation. The overlapping features of AOSD and SJIA suggest this is a disease continuum rather than two separate diseases.

- 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. 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. The efficacy data were generally consistent with the results of a pooled efficacy analysis of SJIA patients.

- The most common adverse reactions (> 10%) with Ilaris use for Still's disease were infections (nasopharyngitis and upper respiratory tract infections), abdominal pain, and injection-site reactions.

- The recommended dose of Ilaris for patients with AOSD with a body weight greater than or equal to 7.5 kg is 4 mg/kg (with a maximum of 300 mg) administered subcutaneously every 4 weeks.

    — Refer to the Ilaris drug label for dosing for all its other indications.