Ilaris® (canakinumab) – New indication

- On August 25, 2023, the FDA approved Novartis' Ilaris (canakinumab), for the symptomatic treatment of adult patients with gout flares in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

- Ilaris is also approved for several autoinflammatory periodic fever syndromes, including: cryopyrin-associated periodic syndromes, tumor necrosis factor receptor associated periodic syndrome, Hyperimmunoglobulin D syndrome/mevalonate kinase deficiency, and familial Mediterranean fever.

- Additionally, Ilaris is approved Still's disease, including adult-onset Still's disease and systemic juvenile idiopathic arthritis.

- The approval of Ilaris for the new indication was based on two 12-week, randomized, double-blind, active-controlled studies in patients with gout flares for whom NSAIDs and/or colchicine were contraindicated, not tolerated or ineffective, and who had experienced at least three gout flares in the previous year (Studies 1 and 2). In both studies, patients were randomized to Ilaris or triamcinolone at baseline and thereafter treated upon a new flare. In both studies, the co-primary endpoints were: (1) patient's assessment of gout flare pain intensity at the most affected joint at 72 hours post-dose measured on a 0 to 100 mm visual analogue scale (VAS) and (2) the time to first new gout flare. A total of 610 patients were included in the efficacy analysis.

- In addition to Studies 1 and 2, Ilaris was also evaluated in Study 3, a 12-week, randomized, double-blind, active-controlled study in 397 patients. Pain intensity at the most affected joint, assessed on a 0 to 100 mm VAS at 72-hours post-dose was the primary endpoint, and time to first new gout flare was a secondary endpoint. Approximately 44% of patients were unable to use NSAIDs and colchicine (due to contraindications, intolerance, or inadequate response) in this study.

- Analyses of both endpoints were conducted for Studies 1, 2, and 3 for the subpopulation of patients unable to use NSAIDs and colchicine and overall population of patients unable to use NSAIDs and/or colchicine.

    - In all studies, pain intensity of the most affected joint at 72 hours post-dose was consistently lower for patients treated with Ilaris compared with triamcinolone acetonide in the subpopulation of patients unable to use NSAIDs and colchicine. This benefit of Ilaris on pain intensity was comparable to the overall patient populations.
    - In the subpopulation of patients in Studies 1, 2 and 3 unable to use NSAIDs and colchicine, time to new flare over 12 weeks from randomization showed a reduction in the risk of a new flare when treated with Ilaris compared with triamcinolone acetonide. This risk reduction for a new flare after Ilaris treatment vs. triamcinolone acetonide was comparable to the overall patient population over 12 weeks in all 3 studies.
    - Refer to the Ilaris drug label for complete trial results.

- The most common adverse reactions (> 2%) with Ilaris use for gout were nasopharyngitis, upper respiratory tract infections, urinary tract infections, hypertriglyceridemia, and back pain.
- The recommended dose of Ilaris for adult patients with a gout flare is 150 mg administered subcutaneously. In patients who require re-treatment, there should be an interval of at least 12 weeks before a new dose of Ilaris may be administered.
    - Refer to the Ilaris drug label for dosing for all its other indications.