Ilaris® (canakinumab) – New Indications

- On September 23, 2016, the FDA announced the approval of Novartis' Ilaris (canakinumab) for the following indications in adult and pediatric patients:
  - Treatment of tumor necrosis factor (TNF) receptor associated periodic syndrome (TRAPS)
  - Treatment of hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS)/mevalonate kinase deficiency (MKD)
  - Treatment of familial mediterranean fever (FMF)
- The new indications are distinct types of periodic fever syndromes. They are hereditary diseases characterized by periodic attacks of fever and inflammation, as well as severe muscle pain.
  - The most common syndrome, FMF, mainly affects people of Eastern Mediterranean ancestry. It affects 1 in 250 to 1 in 1,000 individuals in these populations, many of whom are children.
- Ilaris was previously approved for cryopyrin-associated periodic syndromes (CAPS), in adults and children 4 years of age and older, including familial cold autoinflammatory syndrome and muckle-wells syndrome. It was also approved for active systemic juvenile idiopathic arthritis in patients aged 2 years and older.
- Approval of the new indications is based on results from the CLUSTER clinical study consisting of three separate disease cohorts (TRAPS, HIDS/MKD and FMF) in 185 patients. The primary endpoint measured the proportion of patients within each disease cohort that experienced resolution of disease flare symptoms at day 15 and did not experience a new disease flare during the remaining 16 week treatment period.
  - A statistically significant proportion of patients in the Ilaris group achieved the primary endpoint vs. placebo (45.5%, 35.1% and 61.3% vs 8.3%, 5.7%, and 6.3% for TRAPS, HIDS/MKD and FMF, respectively; $p = 0.005$ for TRAPS, $p = 0.002$ for HIDS/MKD and $p < 0.0001$ for FMF).
- In patients with TRAPS, HIDS/MKD, and FMF, the most common adverse events (> 10%) with Ilaris use were injection site reactions and nasopharyngitis.
- The recommended dose of Ilaris for TRAPS, HIDS/MKD and FMF is 2 mg/kg administered subcutaneously every 4 weeks for patients with a body weight ≤ 40 kg and 150 mg every 4 weeks if the body weight is > 40 kg. The dose may be increased if the clinical response is not adequate.
- Refer to the drug label for specific dose adjustments and for dosing related to other FDA-approved indications.

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