Arcalyst® (rilonacept) – New indication

- On December 18, 2020, the FDA approved Regeneron's Arcalyst (rilonacept), for the maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg.

- Arcalyst is also approved for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS).

- The approval of Arcalyst for the new indication was based on a 2-year, open label study of 6 pediatric patients who previously experienced clinical benefit from daily injections of Kineret® (anakinra). Patients had a median age at baseline of 4.8 years and stopped Kineret treatment 24 hours before initiation of Arcalyst. Remission was defined using the following criteria: diary score of < 0.5 (reflecting no fever, skin rash and bone pain), acute phase reactants (< 0.5 mg/dL C-reactive protein [CRP]), absence of objective skin rash, and no radiological evidence of active bone lesions.

    — All patients met the primary endpoint of the study, remission at 6 months and sustained the remission for the remainder of the 2-year study. No patient required steroid use during the study.

- In adult patients 18 years and older, the recommended dose of Arcalyst for DIRA is 320 mg once-weekly, administered as two subcutaneous (SC) injections on the same day at two different sites with a maximum single-injection volume of 2 mL.

- In pediatric patients weight at least 10 kg, the recommended dose of Arcalyst is 4.4 mg/kg (up to a maximum of 320 mg), once weekly, administered as one or two SC injections with a maximum single-injection volume of 2 mL. If the dose is given as two injections, they should be given on the same day at two different sites.

- When switching from another interleukin-1 (IL-1) blocker, discontinue the IL-1 blocker and begin Arcalyst treatment at the time of the next dose.

- Refer to the Arcalyst drug label for dosing for CAPS.