Arcalyst® (rilonacept) – New orphan indication

- On March 18, 2021, Kiniksa Pharmaceuticals announced the FDA approval of Arcalyst (rilonacept), for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older.

- Arcalyst is also approved for:

  - Treatment of Cryopyrin-Associated Periodic Syndromes, including Familial Cold Auto-inflammatory Syndrome, and Muckle-Wells Syndrome in adults and pediatric patients 12 years and older.
  - Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist in adults and pediatric patients weighing at least 10 kg.

- Recurrent pericarditis is an autoinflammatory cardiovascular disease that typically presents with chest pain and is often associated with changes in electrical conduction and sometimes buildup of fluid around the heart. Patients who have additional pericarditis episodes following a symptom-free period of 4 to 6 weeks are identified as having recurrent pericarditis. Recurrent pericarditis can lead to frequent emergency department visits and hospitalizations.

  - Approximately 40,000 patients in the U.S. seek and receive treatment for recurrent pericarditis each year. Of that group, approximately 14,000 patients experience a second or subsequent event (recurrence) due to persistent underlying disease or inadequate response to conventional therapies, such as nonsteroidal anti-inflammatory drugs, colchicine, and corticosteroids.

- The approval of Arcalyst for the new indication was based on the RHAPSODY study in 86 patients with symptomatic pericarditis recurrence. The study consisted of a 12-week run-in followed by a double-blind, placebo-controlled, randomized withdrawal period. The primary endpoint was time to first adjudicated pericarditis recurrence in the event-driven withdrawal period.

  - Of 61 randomized, 74% in the placebo arm had a recurrence compared with 7% in the Arcalyst arm who temporarily discontinued treatment for 1 to 3 doses.
  - The median time-to-recurrence on Arcalyst could not be estimated because too few events occurred and was 8.6 weeks (95% CI: 4.0, 11.7) on placebo with a hazard ratio of 0.04 ($p < 0.0001$). Arcalyst reduced the risk of recurrence by 96%.

- The recommended initial dose of Arcalyst in adults for RP is a loading dose of 320 mg delivered as two subcutaneous (SC) injections of 160 mg each, administered on the same day at two different injection sites. Dosing should be continued with a once-weekly injection of 160 mg administered as a single SC injection.

- The recommended initial dose of Arcalyst in pediatric patients 12 years to 17 years is a loading dose of 4.4 mg/kg, up to a maximum dose of 320 mg, administered as one or two SC injections, not to exceed single-injection volume of 2 mL per injection site. If the initial dose is given as two injections, administer on the same day at two different sites. Dosing should be continued with a once-weekly injection of 2.2 mg/kg, up to a maximum of 160 mg, administered as a single SC injection.

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- Refer to the Arcalyst drug label for dosing for its other indications.