

## Arcalyst® (rilonacept) – New indication

- On December 18, 2020, the FDA approved Regeneron's <u>Arcalyst (rilonacept)</u>, 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 <a href="Kineret">Kineret</a>® (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.</p>
  - 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 onceweekly, 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.



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

 $\mbox{RxNews}^{\tiny{\textcircled{\tiny{\scriptsize 0}}}}$  is published by the OptumRx Clinical Services Department.

©2020 Optum, Inc. All rights reserved.