April 25, 2022

RE: CTA Submission for ALLN-177-302 (URIROX-2)

EudraCT Number 20018-000921-29

Reloxaliase (oxalate decarboxylase)

Termination of Trial – No Results Published or CSR Submission Planned

Protocol ALLN-177-302 (URIROX-2) was terminated by Allena Pharmaceuticals, Inc. Allena therefore, does not plan to prepare a clinical study report nor will the results of the trial be published.

This decision is based on the previously planned, first of two Sample Size Reestimations (SSR1) conducted by an independent data safety monitoring board (DSMB) statistician. SSR1 was designed to assess the effect of reloxaliase vs. placebo on the reduction of urinary oxalate (UOx) levels over the first 28 days of the trial, the primary endpoint to support a potential US Biologics License Approval filing using the Accelerated Approval pathway.

The trial was initially sized at 200 subjects, which would provide more than 90% power for the primary UOx endpoint based on an assumption of a 15% greater effect size of reloxaliase over placebo. The DSMB was provided with data for the first 78 subjects enrolled in the trial. Based on the results of its unblinded analysis, the DSMB statistician has recommended that the trial size be increased from the initial 200 subjects to the maximum allowed number of 400 subjects under the pre-specified rules. However, even with this maximum recommended sample size increase, the power to detect an effect of reloxaliase vs. placebo would still be less than 80% based on the available data.

Based upon this recommendation from the DSMB statistician, Allena believes that the separation between the reloxaliase and placebo groups for the UOx primary endpoint is lower than expected, and therefore, the likelihood of success for the long-term endpoint of reduction in kidney stone disease progression is also lower than expected. As such, Allena has decided to terminate the URIROX-2 study. This decision is not based on any safety concerns related to reloxaliase. No further clinical studies of reloxaliase will be conducted and clinical development of reloxaliase has been terminated.

If you have additional questions or require further information regarding this submission, please don't hesitate to contact me by telephone (978) 427-2098 or via email at jsubramanyam@allenapharma.com.

Sincerely,

Janaki M. Subramanyam

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