DATE:	February 25, 2022
TO:	All Media Outlets
FROM:	Alport Syndrome Foundation
CONTACT:	Lisa Bonebrake (Info@alportsyndrome.org)
RE:	FDA Decision on Bardoxolone Methyl

For Immediate Release:
The board and staff of Alport Syndrome Foundation (ASF) want to ensure the community of Alport patients and families are aware of the FDA's recent decision not to approve bardoxolone methyl as a treatment for Alport syndrome.

ASF remains in touch with the study sponsor, Reata Pharmaceuticals, and will do all we can to provide updates to the patient community as the company makes decisions about the future of bardoxolone methyl. Questions from patients about the FDA's decision can be directed to info@alportsyndrome.org. Inquiries ASF is not in a position to answer will be shared with our liaison at Reata Pharmaceuticals so we can respond accurately and appropriately.

Though the outcome is not what we anticipated or hoped for as the result of the first clinical trial in Alport syndrome, it is important for our community to put this experience in context. Clinical trials can lead to long and arduous paths, but they are the only way toward finding better treatment options and/or a cure. Progress was still made, including the study being a catalyst for a new and more accessible genetic testing option that led to thousands of patients being accurately diagnosed and becoming aware of their specific genetic mutations. This is not the only current clinical trial in Alport syndrome. The availability of other clinical study options is valuable and not always the case with rare diseases.

Executive Director, Lisa Bonebrake, notes "ASF wants to reiterate to the patient community how important it is that we not lose momentum for innovation or science. The announcement from the FDA underlines the importance of ASF's current investment in a new patient registry in partnership with the National Kidney Foundation, and a new ancillary study to collect bio-samples and natural history data with NEPTUNE at the University of Michigan. These major projects provide the kinds of data that directly support a regulatory pathway for potential new drug therapies."

We extend our deep gratitude to the patients who participated in the CARDINAL and EAGLE Studies. Additionally, we recognize and appreciate the physicians who participated as principal investigators only adding to their own workload with no compensation – to help move research forward for Alport syndrome patients. We also want to thank Reata Pharmaceuticals for being the first company to bring a clinical trial in Alport syndrome to fruition, and for their investment in the exploration of a treatment for our rare and orphan disease.

The CARDINAL Study and the EAGLE Extension Study proved Alport syndrome patients are willing to participate in clinical trials, and that our doctors are confident in enrolling engaged patients like us. This is a huge hurdle to overcome in a rare disease community, and we are grateful to all those who help support ASF's vision of conquering Alport syndrome.

We are moving forward with gratitude and hope, and remain committed to changing the stories and outcomes for Alport syndrome patients and families. ****** END