22-Oct-2026

Dear SCA Colleagues,

We are pleased to announce that Biohaven's New Drug Application (NDA) re-submission for Vyglyxia (troriluzole) in spinocerebellar ataxia has been accepted for review by the FDA, and we have been granted an Advisory Committee Meeting (AdComm).

We wanted to thank everyone for all your hard work and support over the last several years generating the data that went into this submission. As you know, we had previously been granted an AdComm but due to policy change under the former FDA leadership the AdComm was cancelled at the last minute. Under new leadership, the FDA has expressed increased support for the use of regulatory flexibility in rare diseases and the policy against convening AdComms is no longer in place. We view this as positive for the review of our resubmission as the AdComm process generally includes the opinions of experts in the SCA field, the patient and caregiver voice, and a role for advocacy. We feel this is a critical step to a fair and balanced review.

In anticipation of the AdComm, your involvement and that of patients will be critical to a fair review and positive outcome. Please feel free to reach out anytime for an update or with any questions. I'm happy to discuss via phone or with a meeting.

Again, none of this would have been possible without your continued collaboration and support. It is a privilege to work with each and every one of you. We would not be here without your deep commitment to patients and families living with SCA.

Warm Regards,

Melissa Beiner and the Biohaven SCA Team