September 19, 2023

Dear GAN Community,

We are writing to share that Taysha has made the difficult decision to discontinue development of the investigational gene therapy candidate, TSHA-120, for the treatment of giant axonal neuropathy (GAN). This decision follows the receipt of feedback from the United States (U.S.) Food and Drug Administration (FDA) regarding a registrational path for TSHA-120.

FDA feedback following the recent Type C meeting request indicated that the FDA continues to recommend a randomized, double-blind, placebo-controlled trial as the optimal path to demonstrate efficacy for TSHA-120. The FDA also provided a potential path for a single-arm trial (a trial without a placebo control) that instead would use an external control group matched by multiple prognostic factors (important GAN disease characteristics) with the to-be treated subjects. FDA also recommended longer term follow up to account for potential bias.

Due to challenges related to the feasibility of these recommended study designs to support a potential registrational path for TSHA-120, we have made the difficult decision to discontinue further development of the program.

We understand the disappointment that this news brings for the GAN community, but we want to assure you that Taysha plans to pursue external options for TSHA-120 that may enable further development of TSHA-120 for people living with GAN.

On behalf of all of us at Taysha, we would like to express our sincere appreciation for the patients and families who have participated in the trial, and to the GAN community for your partnership and the input you have shared to support our efforts these past two and a half years.

We will be hosting a community webinar in the near future. We will share the details and Zoom link for the webinar as soon as it is scheduled. We hope to answer as many questions as possible during the webinar. Please submit any questions you may have in advance to patientaffairs@tayshagtx.com.

Sincerely,
The Taysha Patient Affairs Team