Dear Duchenne Community,

We would like to provide you with an update regarding FibroGen's LELANTOS-2 (094) Phase 3 clinical trial of pamrevlumab for the treatment of ambulatory patients with Duchenne muscular dystrophy. We are very saddened to share that pamrevlumab did not meet the primary endpoint of change in the North Star Ambulatory Assessment (NSAA) total score from baseline to week 52 when compared to placebo. Secondary endpoints were also not met, as measured by change from baseline at week 52 in: 4-stair climb velocity, 10-meter walk/run test, time to stand, time to loss of ambulation, and proportion of patients with greater than 10 seconds in the 10-meter walk/run test.

Preliminary safety data showed that pamrevlumab was generally safe and well tolerated. The majority of treatment emergent adverse events were mild or moderate. Treatment-emergent serious adverse events were observed in 8.3% of patients in the pamrevlumab group and 2.8% of patients in the placebo group.

A news release was issued on August 29th announcing the results and can be referenced here.

ABOUT LELANTOS-2

A total of 73 boys with ambulatory DMD ages 6 to <12 years were enrolled in LELANTOS-2, a global, Phase 3, randomized, double-blind trial of pamrevlumab or placebo in combination with systemic corticosteroids. The primary endpoint of the study was ambulatory function measured by change in the North Star Ambulatory Assessment (NSAA) total score from baseline to Week 52. Secondary endpoints assessed from baseline to Week 52 included changes in 4-stair climb velocity, 10-meter walk/run test, time to stand, time to loss of ambulation, and proportion of patients with greater than 10 seconds in the 10-meter walk/run test. In LELANTOS-2, patients were dosed with pamrevlumab (35 mg/kg IV on Day 1 and every two weeks thereafter with last dose at Week 52) or placebo.

We are extremely grateful for the courageous efforts of the boys, their caregivers, the advocacy community, and the trial investigators who have contributed to this important clinical study.

NEXT STEPS

FibroGen is in the process of evaluating the totality of the data, including other pre-specified endpoints, to determine the next steps for the program.

We are currently engaging with the LELANTOS-2 investigators and their sites regarding the trial results.

Regarding our overall Duchenne program, we are committed to the following next steps:

- The LEANTOS-2 (094) Open Label Extension (OLE) trial will continue while we conduct further analysis of the patient subgroups and exploratory endpoints. Families who participated in the LELANTOS-2 trial should reach out to their study site directly with questions.

- We plan to have further discussions with the Duchenne community regarding the trial results and answer as many of your questions as we can.

- The full results for LELANTOS-2 will be published or presented at an upcoming medical meeting or congress.

We will continue to update you on any news related to our programs.

Thank you,

Thane Wettig
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Pamrevlumab is an investigational drug and not approved for marketing by any regulatory authority. For more information about our pamrevlumab studies please visit www.clinicaltrials.gov.