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Dear CLN1 disease community,

We are pleased to share the news that Queen's University in Ontario, Canada, has received Clinical Trial Application (CTA) approval from Health Canada for the Phase 1/2 clinical trial of TSHA-118, Taysha's investigational gene therapy for infants and children living with CLN1 disease (Neuronal Ceroid Lipofuscinosis, Type 1), a form of Batten disease. CTA approval means that the regulatory authorities in Canada have reviewed and approved the clinical trial plans for TSHA-118.

In patients with the CLN1 form of Batten disease, the body doesn't make enough of the enzyme palmitoyl protein thioesterase 1 (PPT1), which is needed to break down a complex substance in the cells made up of protein and fat. TSHA-118 is intended to deliver a healthy copy of the *PPT1* gene, formerly known as the *CLN1* gene, through an AAV9 vector which will be investigated in the clinical trial.

Approval of the TSHA-118 clinical trial plans by Health Canada is an important milestone, and we are encouraged by the progress that Queen's University is making toward initiating this clinical trial.

> "Today's CTA approval would not have been possible without the combined tireless work of Dr. Walia and the Taysha team. CTA approval of a clinical trial is a formative moment, and we are motivated by the community we serve, and the potential of TSHA-118. Thank you to the team at Queen's University for advancing this gene therapy into the clinic, as we study TSHA-118 for infants and children with CLN1 disease."
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> -RA Session II, Founder, President and CEO
> Taysha Gene Therapies

There are two ongoing natural history studies including an observational study in Hamburg to assess the natural history of CLN1 disease and other types of Batten disease as part of the international DEM-CHILD database. Also, part of this DEM-CHILD database, a combined retrospective and prospective study at the University of Rochester characterizes the major symptoms of CLN1 disease at the time of diagnosis and the relationship between age and severity. If interested in learning more about these studies you may reach out to the patient advocacy groups BDSRA, BDSRA Australia or BDFA.

We are grateful for the continued support of the CLN1 disease community, and our Batten advocacy partners. We look forward to providing updates about the Queen's University TSHA-118 clinical trial to the global patient organizations as new information becomes available.

Warm regards,

The Taysha Team