March 2023

Kim Angel
Executive Director, Canadian MPS Society

Dear Kim,

Takeda would like to inform the MPS II Hunter syndrome community that the National Institutes of Health website, www.clinicaltrials.gov, has been updated with information regarding the planned Post-Trial Access (PTA) program for patients currently enrolled in extension trials for TAK-609. The website lists this as "Post-Trial Access Program Idursulfase-IT (HGT-2310) in Conjunction with Intravenous Elaprase in Pediatric Patients with Hunter Syndrome and Cognitive Impairment."

This PTA program will allow continued access for people who participated and are benefitting from treatment on the existing studies for TAK-609: HGT-HIT-046 (NCT01506141) or SHP609-302 (NCT02412787). Takeda would like to clarify for MPS II Hunter syndrome families that this listing on clinicaltrials.gov is not a new recruiting clinical trial. The PTA is for patients currently enrolled in either study and no new patients are being enrolled.

Additionally, families of children who will be moved from the studies to the PTA program should not be concerned with eligibility criteria on the clinicaltrials.gov site. Including these criteria is a regulatory requirement. Takeda is committed to continuing to provide access to patients in TAK-609 clinical trials.

For children currently enrolled in TAK-609 trials, the transition into the PTA program will be coordinated with the child's care team at clinical trial sites. To participate, patients need only be currently enrolled in the study. Patients' parent(s) or legal guardian(s) will be asked to provide written informed consent for themselves or the child to participate (with assent from the child, when appropriate) prior to treatment.

We will continue to follow up with investigators and advocacy leadership soon with more information on the logistics of transitioning to the PTA. Families enrolled in the TAK-609 clinical trials who have questions regarding the PTA should continue to speak to their clinical trial site or patient advocacy group. Takeda will endeavor to ensure the transition is as smooth as possible for families. Thank you for your patience and understanding.

Sincerely,

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