Shire Human Genetic Therapies, Inc.
Progress Report on Enzyme Replacement Therapy Clinical Trial
August 20, 2009

Shire has an active development program in metachromatic leukodystrophy (MLD) and we are currently preparing to conduct a global phase II/III clinical trial with an experimental enzyme replacement therapy (ERT). Shire is currently working very closely with the contract manufacturer, which is the only company to ever make this ERT, to produce this experimental enzyme for clinical trials. Moreover, Shire is also evaluating all avenues to increase production capacity for this ERT, including the opportunity to bring manufacturing in-house. We plan to begin enrollment to the trial in the second half of 2009.

Shire is also working with regulatory agencies as well as individual medical institutions prior to initiating our phase II/III clinical trial. A submission to regulatory agencies and approval by medical institutions of a trial protocol is standard industry practice prior to beginning any clinical trial. This process is in place to ensure the protection of the safety and rights of the trial participants, and to help ensure that the trial design will address the questions that regulatory agencies might have regarding the experimental therapy. Shire will post the details of the clinical trial, including entry criteria and locations, on www.clinicaltrials.gov, keyword MLD, after we have incorporated any changes and received the required approvals.

We understand that this trial creates great expectations for patients and their families and that our inability, at this time, to offer access to our experimental ERT to new patients outside of clinical trials may be disheartening and frustrating. We at Shire are working diligently to bring a much needed therapy to MLD patients as soon as possible.

In addition, Shire is committed to communicating in an open and transparent manner so that you can have appropriate expectations regarding access to this experimental ERT.

For any questions or clarification, please contact:

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