Sanofi’s mission is to discover and develop safe and effective innovative medicines for patients who need them. Clinical trials are crucial to producing data that help regulatory authorities determine whether an investigational treatment is safe and effective. Until this determination is made and marketing authorization is granted, potential treatments remain investigational and experimental, and generally are not made widely available to patients outside of clinical trials.

At this time, Sanofi’s primary focus is to ensure that appropriate supply of olipudase alfa is available to meet our commitment to the patients currently enrolled in the ongoing ASCEND and ASCEND-Peds extension trials. It is also Sanofi’s priority to prepare the clinical and data packages needed for regulatory submission, which includes demonstration of potential commercial reproducibility of olipudase alfa to meet the commercial manufacturing requirements. Sanofi remains committed to this work with the ultimate ambition of making olipudase alfa available to patients as quickly as possible.

We understand that many patients and their families may have an interest in accessing olipudase alfa. As Sanofi Genzyme continues to work toward the potential of an expanded access program, and consistent with humanitarian needs and the olipudase alfa development program, our medical team is addressing physician requests for compassionate use on an individual basis. More information about our company’s expanded access program is available online at Sanofi.com.

We are grateful to the ASMD community for the ongoing support of the olipudase alfa development program and will continue to provide updates as new information becomes available.