Mallinckrodt Reaches Agreement to Divest Experimental Drug Adrabetadex to Mandos, LLC

Company plans to produce up to an additional two years’ supply of drug for eligible patients

Agreement is subject to approval by U.S. Bankruptcy Court in Delaware

Mallinckrodt Pharmaceuticals has reached an agreement to divest and transfer the Investigational New Drug (IND) application for experimental drug adrabetadex (VTS-270) to Mandos, LLC (“Mandos”). Additionally, Mallinckrodt plans to work with Mandos in an effort to secure production of additional drug supply for children who are suffering from the ultra-rare and devastating Niemann-Pick Type C1 disease (“NPC1”).

The planned supply is expected to allow access to adrabetadex for potentially up to two years for patients who are eligible to continue treatment under expanded access or other future potential development programs. The decision to plan for additional drug supply comes after Mallinckrodt’s careful consideration of the needs and concerns of children with NPC1 and the ability to make drug supply available for the continuous treatment of NPC1 patients in the near-term, as allowable.

Under the agreement, Mallinckrodt will transfer sponsorship of its IND application for adrabetadex, which is filed with the U.S. Food and Drug Administration, to Mandos at closing. The agreement and the closing of the transaction is subject to approval of the U.S. Bankruptcy Court for the District of Delaware as part of Mallinckrodt’s Chapter 11 filing.

Mallinckrodt announced in January of this year that it would discontinue the development of adrabetadex following a comprehensive analysis of clinical data that did not show clear evidence of benefit for NPC1 patients. However the Company is aware of and acknowledges that some parents and treating physicians report observing benefit in children being treated with adrabetadex.

“Recognizing both the critical need for new treatment options for Niemann-Pick disease and the concerns of the NPC patient community – who we have worked closely with since acquiring adrabetadex in 2018 – MNK has worked judiciously to identify an entity that would seek to find a path forward for the drug,” said Steven Romano, M.D., Executive Vice President and Chief Scientific Officer at Mallinckrodt. “We are hopeful Mandos will further advance both the understanding of the disease and the potential to develop the drug as a future treatment option for NPC patients.”

Mallinckrodt’s team would like to thank the patients, families, treating physicians and NPC community for their support over the last several clinical study years. We have come to know these families and the community personally, and hope this announcement provides some initial comfort as potential options are considered for the program’s path forward. If the transaction is approved, Mallinckrodt will assist Mandos in the closure of the existing clinical program and fully transition the expanded access over the course of the next several months in support of Mandos.
and the patient community. The Company will provide additional updates on the progress of the approval of the transaction and the agreement with Mandos at the close of the transaction.