



Notification of Extension of CSR Submission and Posting of Study Results

Protocol title:	A Phase I/II Open Label, Single-dose, Gene Transfer Study of scAAV9.U1a.hSGSH (ABO-102) in Patients with Middle and Advanced Phases of MPS IIIA Disease
Protocol code:	ABT-003
EudraCT number:	2018-000504-42


Dear Sir/Madam,

In reference to the Early Termination notification for the clinical study protocol referenced above, submitted to the AEMPS on 23-Feb-2022, the trial enrolled pediatric patients globally, and the Global End of Trial date was 10-Mar-2022.

Based on EU Directive 2001/20/EC, the Sponsor is obligated to provide the Clinical Study Report (CSR) and to post study results within 6 months following Global End of Trial. Due to a change in Sponsor, and subsequently, the additional time necessary for the transfer of clinical data to the new Sponsor, the Sponsor will be unable to meet the 6-month deadline for posting results on EudraCT and will post the study results within 12 months of the Global End of Trial date. The Change in Sponsor will be communicated shortly to the Agency in a separate submission.

Abeona Therapeutics Inc. is a clinical-stage biopharmaceutical company developing gene and cell therapies for serious diseases. For more information regarding the company, visit www.abeonatherapeutics.com.

Sincerely,


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