Amsterdam, DD MM YYYY

Ref:

[Committee for Advanced Therapies]

[Committee for Medicinal Products for Human Use]

Consultation of GMO authorities under Article 6(3) of Regulation (EU) No 726/2004

As previously communicated by EMA, a marketing authorisation application for [name of product] has been received by the European Medicines Agency. The [Committee for Advanced Therapies] [Committee for Medicinal Products for Human Use] considers that the product contains or consists of genetically modified organisms (“GMOs”).

Please find attached a copy of the ERA Rapporteur assessment report for your consideration together with Module 1.6.2.

The Rapporteur is of the opinion that the considerations laid down in *[*the specific ERA developed under the Good Practice on the assessment of GMO-related aspects in the context of clinical trials with human cells genetically modified by means of retro/lentiviral vectors[[1]](#footnote-1) *] [*the specific ERA developed underthe Good Practice on the assessment of GMO related aspects in the context of clinical trials with AAV clinical vectors*]* are applicable to this product*.*

If you consider that the principles under the above-referred ERA are not applicable to this product, please state your reasons. Please explain also what measures should, in your view, be implemented by the applicant to address your identified concerns.

Deadline for the consultation: [add date]

1. <https://ec.europa.eu/health/sites/health/files/files/advtherapies/2018_gmcells_gp_en.pdf> [↑](#footnote-ref-1)