Unidad de Ensayos Clínicos
Agencia Española del Medicamento y Productos Sanitarios (AEMPS)
Parque Empresarial Las Mercedes, Edificio 8
C. Campezo, 1
28922 Madrid

European Medicines Agency (EMA)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject	To state reasons for the trial premature interruption
Study Title	Study of genetic Alzheimer's disease mutation carriers in preclinical stages of the disease: 18F-Florbetaben Positron Emission Tomography study.
Protocol code	FBB-FAD-2014
EudraCT Number	2014-000763-41
Product	PET-tracer 18F-FlorbetabenNeuraceq® 300 MBq/ml solution for injection
Sponsor	Fundació Clínic per a la Recerca Biomèdica
Trial end	29-Jan-2019

28th March 2025

Dear sir/madam,

The trial was a single centre study conducted in Spain.

This trial was approved by the Spanish authorities but ended prematurely.

This study was not a Low Intervention Trial.

The active site was: Hospital Clínic de Barcelona, C/ Villarroel 170, 08036 (Barcelona)

Harmonised Protocol (version 1.0, 26-May-2014):

Member State	Date of approval		
	National Competent Authority	Ethics Committee	Name of Ethics Committee
SPAIN	20-Aug-2014	03-Jul-14	CEIm Hospital Clínic de Barcelona

Declaration

The sponsor, Fundació de Recerca Clínic Barcelona- Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), hereby declares that the clinical trial with EudraCT Number 2014-000763-41 ended prematurely on 29-Jan-2019.

Reasons for the premature termination:

- Supply issues with 18 F-Florbetaben.
- The planned sample size of 40 patients was not reached; only 25 patients were enrolled.

Impact on results:

Due to the early termination and limited sample size, only partial results could be obtained.

Please do not hesitate in contacting us should you need further information.

Yours faithfully,

Sara Campos
Application Submitter CTU CLINIC