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	EudraCT- Submission note
Protocol Study Title	Omission of surgery and sentinel lymph node dissection in clinically low-risk HER2positive breast cancer with high HER2 addiction and a complete response following standard anti-HER2-based neoadjuvant therapy (ELPIS trial)
Protocol code	HCB-ONC001 ELPIS (ML41519)
EudraCT Number	2019-005019-18
Study Product	Paclitaxel/trastuzumab/pertuzumab (TDM-1 if residual disease)
Sponsor	Fundació de Recerca Clínic Barcelona – Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS)
Trial end	17th July 2024

16th January 2025

Dear Sir or Madam,

The sponsor, **Fundació de Recerca Clínic Barcelona- Institut d'Investigacions Biomèdiques August Pi i Sunyer (FRCB-IDIBAPS)**, hereby submit the **Statistical Analysis Report (SAR)** of the ELPIS trial.

This report contains the análisis of the study *"Omission of surgery and sentinel lymph node dissection in clinically low-risk HER2positive breast cancer with high HER2 addiction and a complete response following standard anti- HER2-based neoadjuvant therapy"*.

The purpose of this document is to provide the statistical analysis, results, tables and listings. The report also includes all information required in the EudraCT summary of results, specifically:

- ✓ Study objectives and design
- ✓ Patient population and inclusion/exclusion criteria
- ✓ Treatment arms and interventions
- ✓ Primary and secondary outcomes

- ✓ Statistical analysis and results
- ✓ Safety data and adverse events
- ✓ Conclusions and clinical implications

The sponsor confirms that the **ELPIS clinical trial (EudraCT Number 2019-005019-18), was prematurely terminated on 17th July 2024, due to low patient accrual**.
Despite efforts to optimize recruitment, the enrollment rate remained insufficient to meet the predefined targets, and continuation was deemed unfeasible.
A total of 5 patients were recruited out of the 25 originally planned.

In accordance with EudraCT guidance, when a study is prematurely ended and does not meet its planned enrollment, sponsors may submit a summary attachment in lieu of the full data set. The attached report is a peer-reviewed publication that meets the standards outlined in Annex 1 of the ICH E3 guideline.

We confirm that we hold the rights to submit this document and that it accurately reflects the outcomes of the clinical trial ELPIS (EudraCT Number: 2019-005019-18).

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

Sincerely,

Sara Campos
Application Submitter CTU
FRCB – IDIBAPS