Immunogenicity Assessment in Patients with Acromegaly Treated with Ready-to-use, Prolonged-release, Octreotide Subcutaneous Depot (Oczyesa®)

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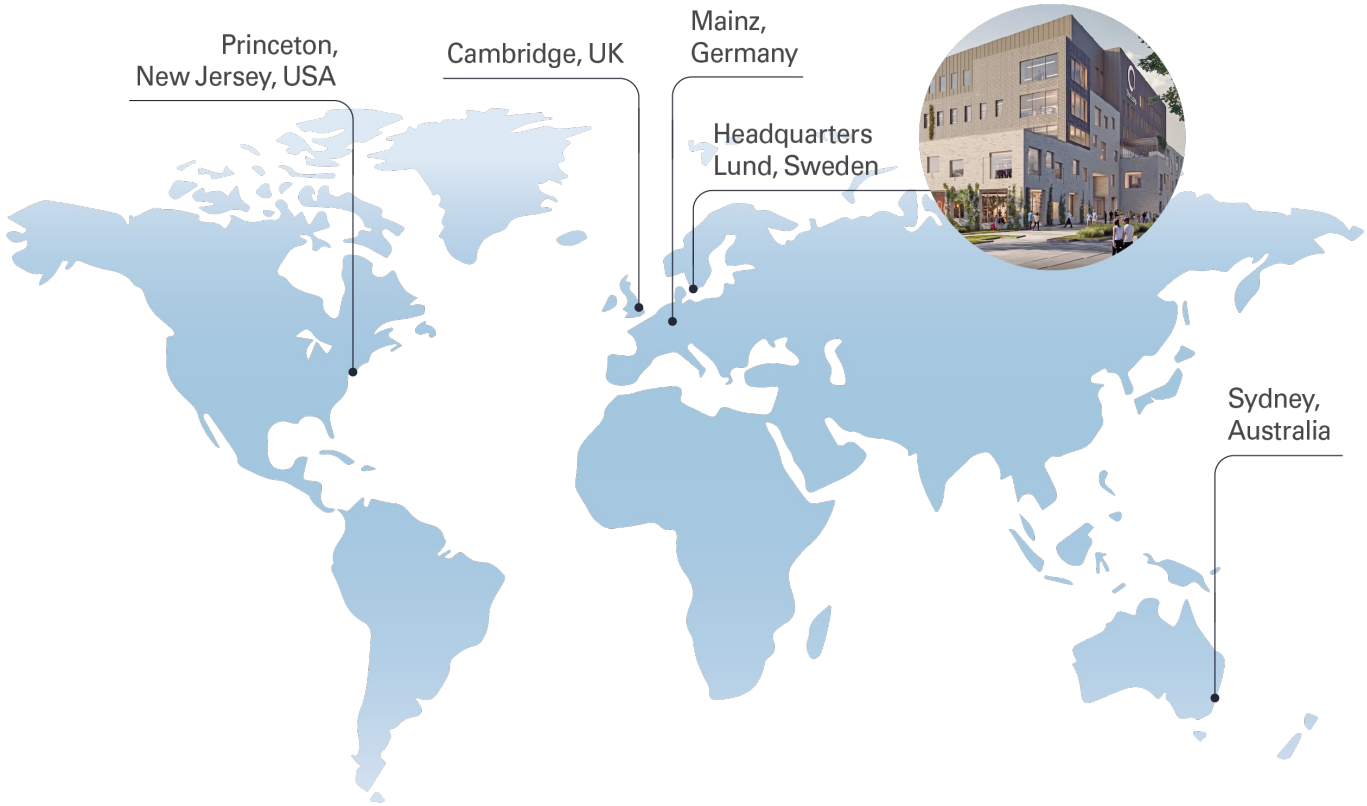
Camurus' International Presence

Map showing Camurus' headquarters and larger regional offices



Products Currently on the Market by Camurus

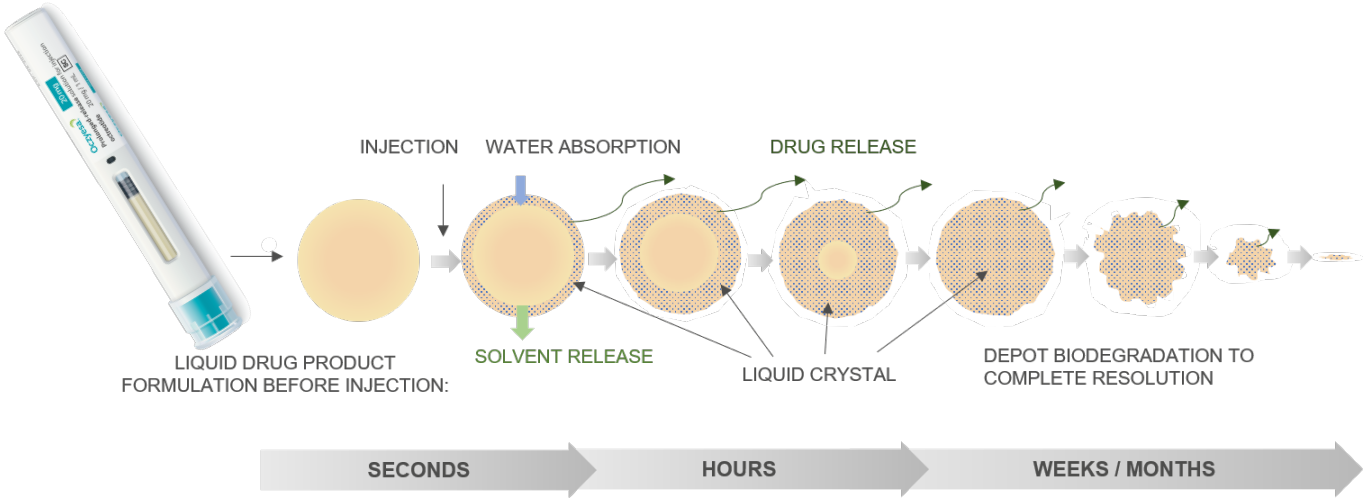
Long-acting treatments

- Oczyesa® (API: octreotide) - prolonged-release treatment for people with acromegaly. Internal name: CAM2029.

- Buvidal®, US: Brixadi® (API: buprenorphine) - prolonged-release treatment for people with opioid dependence. Internal name: CAM2038.

Background & Objective

Background:
FluidCrystal® Injection Depot Technology

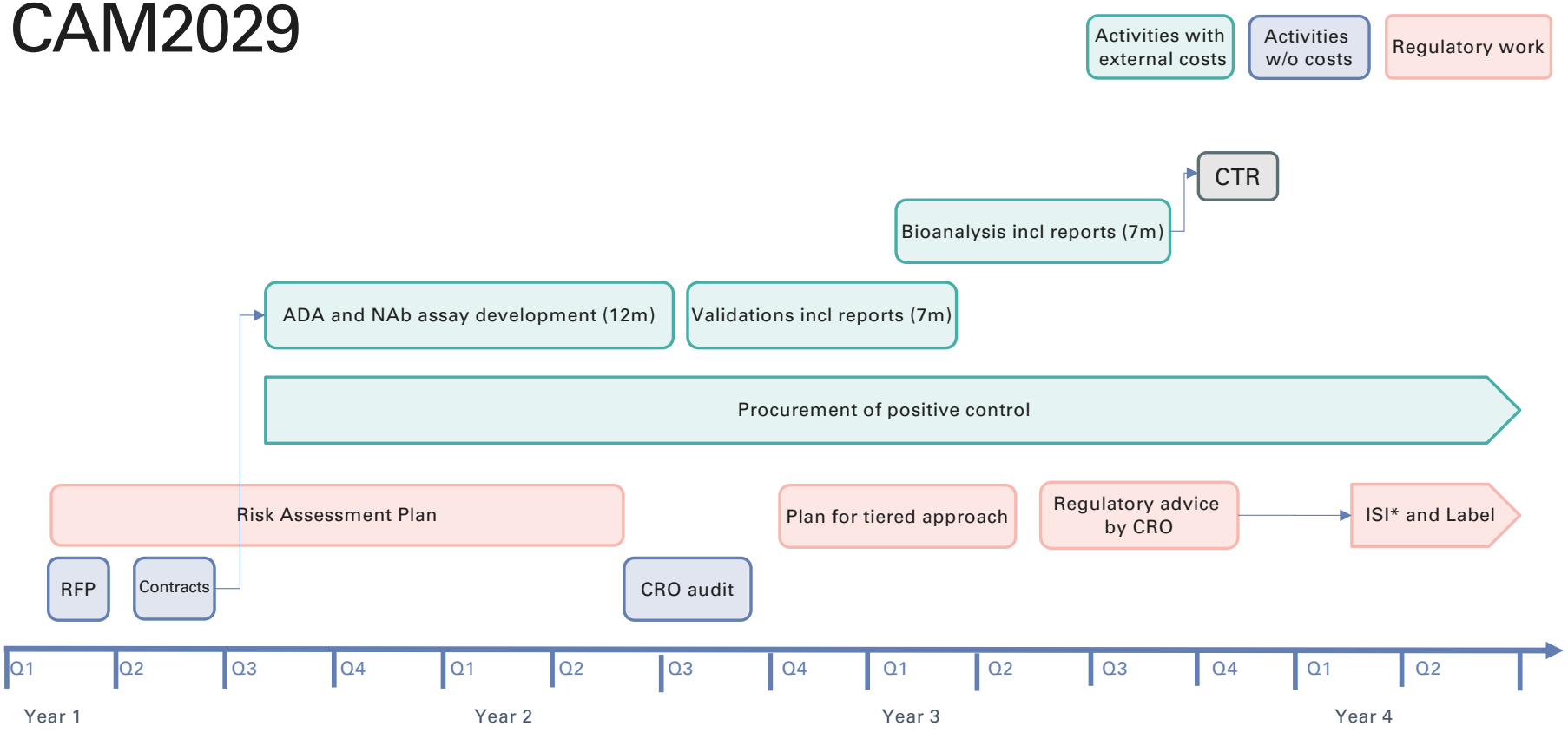


Objective

- To describe the immunogenicity assessment in patients with acromegaly treated with the ready-to-use, prolonged-release octreotide subcutaneous depot, CAM2029 (brand name Oczyesa® in the EU and UK).

Plan/Process for CAM2029 Immunogenicity Assessment

Immunogenicity Assessment CAM2029

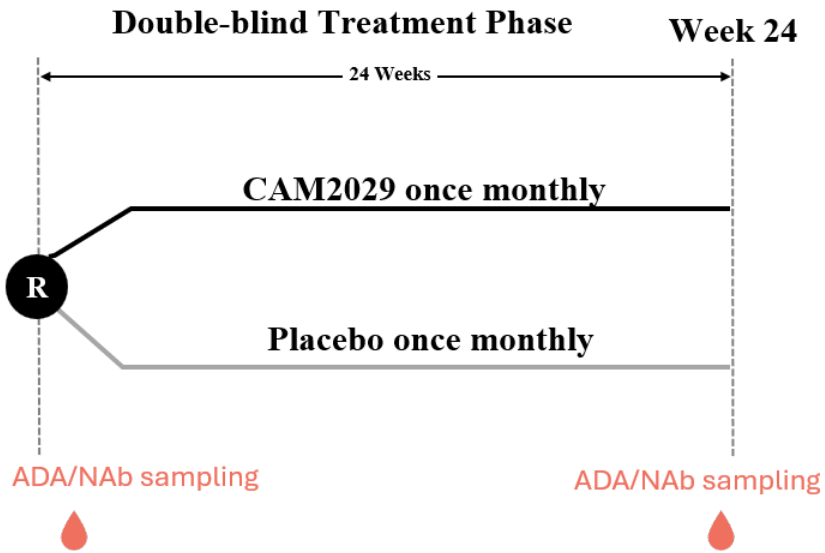


**Integrated Summary of Immunogenicity completed prior to MAA or NDA submission.*
Additional abbreviations: Request for proposal (RFP), Clinical Trial Report (CTR), Contract research organization (CRO), Marketing Authorization Application (MAA), New Drug Application (NDA), Anti-drug antibody (ADA), Neutralising antibody (NAb)

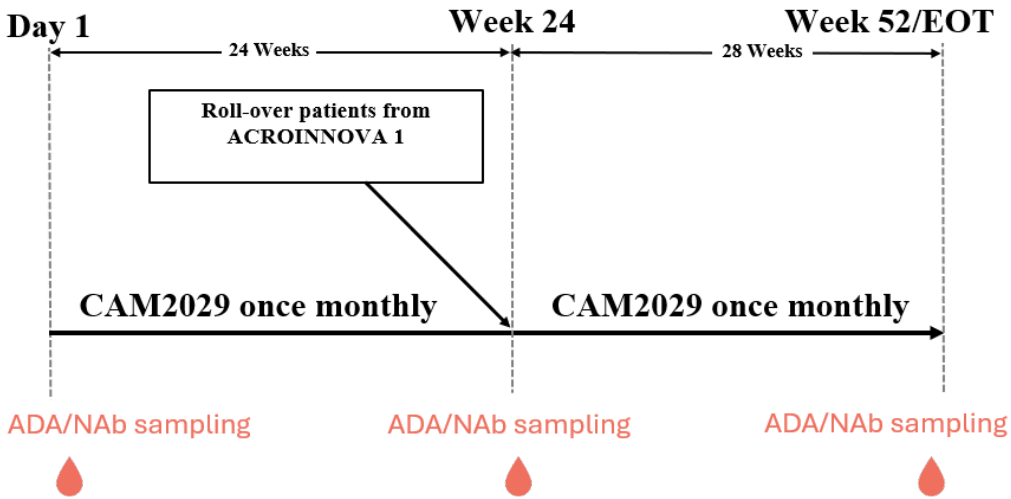
Methods

Clinical Trials and ADA/NAb Sampling CAM2029

ACROINNOVA 1

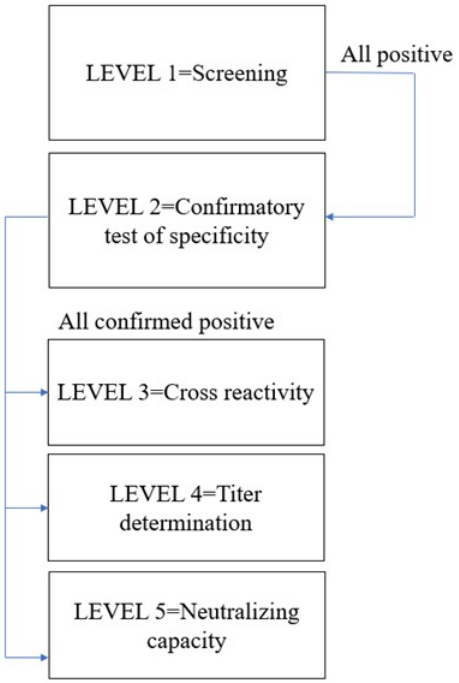


ACROINNOVA 2



Hierarchical Test Scheme

Used in both ACROINNOVA 1 and ACROINNOVA 2

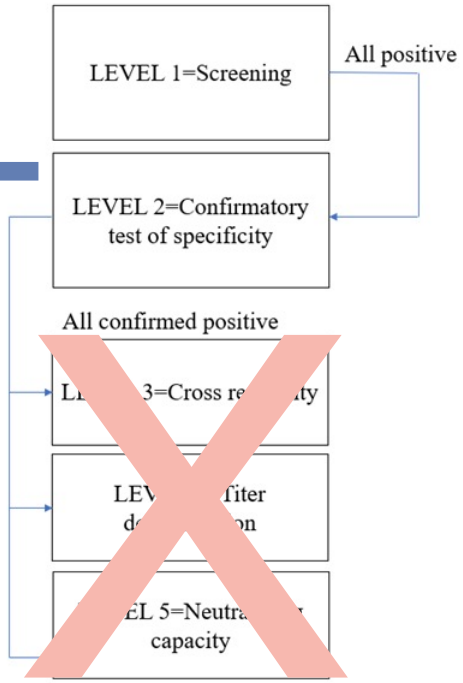


Results

Hierarchical Test Scheme

Used in both ACROINNOVA 1 and ACROINNOVA 2

No confirmed positive hits!



Summary of ADA Results

Clinical trials: ACROINNOVA 1 and ACROINNOVA 2

Clinical Trial	Sample Type	Number of Samples	Number of ADA Positive Samples	Number of False ADA Positive Samples	False Positive Rate (%)
ACROINNOVA 1	Pre-Treatment	70	1	1	1.4%
ACROINNOVA 1	Post-Treatment	64	1	1	1.6%
ACROINNOVA 1	Overall	134	2	2	1.5%
ACROINNOVA 2	Pre-Treatment	79	5	5	6.3%
ACROINNOVA 2	Post-Treatment	162	4	4	2.5%
ACROINNOVA 2	Overall	241	9	9	3.7%

Reference: ISI submitted with Camurus' MAA 2023 (eCTD module 5.3.5.3)

Results Drug Interference in the ADA Assay

Clinical trials: ACROINNOVA 1 and ACROINNOVA 2

- In the validation of the ADA assay, no drug interference was found at a concentration of 4.0 ng octreotide/mL for positive control levels of 100 ng/mL and 500 ng/mL (predicted octreotide $C_{trough,ss}$ of 0.82 ng/mL).

- The actual drug (OCT) concentration in the blood serum samples obtained 4 weeks post administration of CAM2029 was not above 4.0 ng octreotide/mL in any of the samples obtained from ACROINNOVA 1 and did therefore not interfere with the assay. In ACROINNOVA 2 only four samples at week 52/EOT contained an octreotide concentration above 4.0 ng/mL.

Conclusions

Conclusions

Clinical trials: ACROINNOVA 1 and ACROINNOVA 2

- At Camurus, immunogenicity assessment was performed in patients with acromegaly treated with the ready-to-use, prolonged-release octreotide subcutaneous depot, CAM2029.

- Both the ADA assay and the NAb assay were successfully validated according to EMA and FDA guidelines and relevant whitepapers. No confirmed positive hits were obtained in the ADA analysis.

- The result was summarized in the ISI included in section 5.3.5.3. of the eCTD package submitted prior to obtaining Marketing Authorization for CAM2029 in the EU and UK during 2025.

Thank you for listening!

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