

## PRESS RELEASE

# Camurus announces approval of Oczyesa® for the treatment of acromegaly in the UK

**Lund, Sweden — 28 August 2025** — Camurus (NASDAQ STO: CAMX) today announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has approved Oczyesa®, octreotide subcutaneous depot, marketing authorization for the maintenance treatment in adult patients with acromegaly who have responded to and tolerated treatment with somatostatin analogs.<sup>1</sup>

"Oczyesa, the first once-monthly subcutaneous octreotide treatment, has shown effective and sustained control of acromegaly and can be self-administered by patients using an autoinjector pen", says Fredrik Tiberg, President & CEO, CSO at Camurus. "Camurus plans to launch the treatment in the UK in the fourth quarter of 2025."

The MHRA's marketing authorization of Oczyesa is based on the results from a comprehensive clinical program comprising seven clinical studies, including two Phase 3 studies within the ACROINNOVA program.

Oczyesa is formulated using Camurus' proprietary FluidCrystal® technology. The product is designed for convenient once-monthly, subcutaneous self-administration using a pre-filled autoinjector pen with a hidden, thin needle.

Oczyesa was granted marketing authorization in the EU by the European Commission on 30 June 2025.

### For more information

Fredrik Tiberg, President & CEO

Tel. +46 (0)46 286 46 92

[fredrik.tiberg@camurus.com](mailto:fredrik.tiberg@camurus.com)

Fredrik Joabsson, Chief Business Development Officer

Tel. +46 (0)70 776 17 37

[ir@camurus.com](mailto:ir@camurus.com)

### About acromegaly

*Acromegaly is a rare, progressive disease, typically caused by a tumor of the pituitary gland producing excess growth hormone and stimulating increased insulin growth factor-1 (IGF-1) levels. This results in abnormal growth of bone and tissue, enlarged hands, feet, facial features and inner organs, and symptoms such as fatigue, joint pain, headache, visual field defects, excessive sweating, and paresthesia.<sup>2</sup> Inadequate biochemical and symptom control can have detrimental impacts on quality of life and mortality of patients with acromegaly.<sup>3,4</sup> The prevalence of acromegaly is estimated to about 60 cases per million.<sup>5</sup>*

### About Oczyesa® (CAM2029)

*Oczyesa® (CAM2029) is a ready-to-use, long-acting subcutaneous depot of octreotide indicated for maintenance treatment in adult patients with acromegaly who have responded to and tolerated treatment with somatostatin analogs.<sup>1</sup> The product is stored at room temperature and should not be refrigerated.*

*The CAM2029 clinical program for acromegaly comprises seven clinical trials, including four Phase 1 studies, one Phase 2 study, and two Phase 3 studies within the ACROINNOVA clinical program. CAM2029 has demonstrated an approximate five-fold higher bioavailability compared to the currently approved, long-acting, intramuscular (IM) octreotide.<sup>6</sup> The ACROINNOVA 1 study demonstrated that treatment with Oczyesa results in a significantly higher proportion of patients achieving normalized insulin growth-factor-1 (IGF-1) levels compared to placebo. The persistence of mean IGF-1 values and reduction of symptoms were confirmed over 52 weeks in the ACROINNOVA 2 study. Furthermore, the study showed improvements in symptoms, quality of life, and treatment satisfaction scores after 52 weeks of treatment with Oczyesa compared to standard of care (SoC) at baseline.<sup>7,8</sup> The most common side effects included gastrointestinal disorders,*

nervous system disorders, hepatobiliary disorders, metabolism and nutritional disorders, and injection site reactions.<sup>1</sup>

CAM2029 is under development for two additional chronic and severe disease indications: gastroenteropancreatic neuroendocrine tumors (GEP-NET) and polycystic liver disease (PLD).

### About Camurus

Camurus is an international, science-led biopharmaceutical company committed to developing and commercializing innovative, long-acting medicines for improving the lives of patients with severe and chronic diseases. New drug products with best-in-class potential are conceived based on the company's proprietary FluidCrystal<sup>®</sup> technology and its extensive R&D expertise. The R&D pipeline includes products for the treatment of dependence, pain, cancer, and endocrine diseases. Camurus has operations across Europe, the US, and Australia, with headquarters in Lund, Sweden. The company's shares are listed on Nasdaq Stockholm under the ticker CAMX. For more information, visit [www.camurus.com](http://www.camurus.com) and [LinkedIn](#).

### References

1. Oczyesa<sup>®</sup> SmPC.
2. Colao A., et al. Acromegaly. *Nat Rev Dis Primers*. 2019;5(1):20.
3. Webb SM, et al. Quality of Life in Acromegaly. *Neuroendocrinology*. 2016;103(1):106-111.
4. Fleseriu M., et al Acromegaly: pathogenesis, diagnosis, and management. *Lancet Diabetes Endocrinol*. 2022 Nov;10(11):804-826.
5. Crisafulli S., et al. Global epidemiology of acromegaly: a systematic review and meta-analysis. *Eur J Endocrinology*. 2021; 185:251-63.
6. Summary of Product Characteristics, Sandostatin LAR 20 mg: [https://assets.hpra.ie/products/Human/22656/Licence\\_PA0896-028-005\\_03012024152159.pdf](https://assets.hpra.ie/products/Human/22656/Licence_PA0896-028-005_03012024152159.pdf)
7. Ferone, D., et al. *J Clin Endocrinol Metab*. Published 8 October, 2024.
8. Press release 15 July, 2024: <https://www.camurus.com/media/press-releases/2024/camurus-announces-positive-phase-3-results-from-the-acroinnova-2-study-of-octreotide-sc-depot-cam2029-in-acromegaly-patients/>

This information was submitted for publication at 4.45 pm CET on 28 August 2025.