

COMy: New clinical and real-world evidence for Pepaxti demonstrating strong data and expanded positioning

STOCKHOLM – May 13, 2026 – Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a biotech company focused on difficult-to-treat cancers, today announces that new data supporting the clinical utility of Pepaxti (melflufen) in relapsed refractory multiple myeloma (RRMM) will be presented at the 12th World Congress on Controversies in Multiple Myeloma (COMy), taking place in Paris, France, May 14–17, 2026.

Three e-poster presentations of data related to Pepaxti will be held during the conference. These include an independent large-scale real-world series from the Spanish Registry, a comprehensive pooled analysis of renal safety and an update on the LAGOON study in Spain. All e-posters are already available to download, some along with videos by the presenting authors. For more information, refer to the table below.

“We are pleased to present a robust set of data at COMy that confirms our own clinical trial evidence with real-world insights,” says **Stefan Norin, Chief Medical Officer at Oncopeptides**. “The stability of renal function observed in our pooled analysis, combined with the encouraging activity seen in the Spanish Registry—even in patients previously treated with BCMA-targeting agents—continues to validate Pepaxti as an important treatment option for patients with high unmet medical needs.”

Real-World evidence: The Spanish Registry

Supplementing Oncopeptides’ clinical data is a descriptive study from the Spanish Registry, evaluating 60 patients treated with melflufen and dexamethasone in clinical practice. This represents the largest real-world cohort of its kind to date and notably includes 33 patients (55%) previously treated with novel immunotherapies, such as anti-BCMA or anti-GPRC5D agents.

Key findings from the registry include:

- **Response rates:** The ORR was 40% for the full cohort and increased to 45.4% for patients previously exposed to novel immunotherapies.
- **Bridge to CAR-T:** Notably, melflufen served as an effective bridge to CAR-T therapy for two patients, both of whom achieved a partial response.
- **Survival outcomes:** Despite the heavily pretreated nature of this cohort—where 57% of patients were penta-refractory and had received a median of 4–5 prior lines of therapy – the study reported a median progression-free survival (mPFS) of 4.2 months and a median overall survival (mOS) of 12.3 months. This is in line with the HORIZON study where ORR was 29% mPFS was 4.2 months, and mOS was 11.6 months.

Maintained renal function in RRMM

Another highlight at COMy focuses on pooled data from three clinical studies (the Phase 1 /2 O-12-M1, Phase 2 HORIZON, and Phase 3 OCEAN trials), assessing the impact of melflufen on renal function in 430 patients.

The analysis demonstrates that renal function remained stable throughout melflufen treatment, and that renal adverse events were uncommon, reinforcing that melflufen can be safely administered to RRMM patients with mild to moderate renal impairment.

Observing melflufen in clinical practice: the LAGOON study

Furthermore, a poster regarding LAGOON (OP-115), a prospective, non-interventional study (NIS) currently being conducted in Spain, is presented. The study aims to observe the effectiveness and safety of Pepaxti in combination with dexamethasone when used in accordance with the approved label in standard clinical practice.

LAGOON is enrolling 50 adult patients with RRMM who have received at least three prior lines of therapy. The study will track outcomes such as overall response rate (ORR), progression-free survival (PFS), safety and tolerability and overall survival (OS), providing vital data on how melflufen performs within the current European treatment landscape.

Poster presentation details

All posters and corresponding presentation videos are available online via the [E-Posters - COMy 2026](#) portal. Oncopeptides' clinical posters (LAGOON and Renal Analysis) feature video summaries by the presenting authors.

Poster Title	Presenting Author	Full Author List	Link
LAGOON (OP-115): A non-interventional study of melphalan flufenamide (melflufen) in combination with dexamethasone in patients with relapsed and/or refractory multiple myeloma (RRMM) in Spain according to the approved label	Enrique M. Ocio	E.M. Ocio, E. González García, A. Perez Montaña, X. Gutiérrez, V. Cabañas, E. Carrillo Cruz, P. Omberg, S. Norin, M.V. Mateos	View Presentation
Maintained renal function with melflufen therapy in RRMM: results from analysis of pooled clinical data	Paul G Richardson	F. Schjesvold, S. Bringhen, M.A. Dimopoulos, L. Pour, M.V. Mateos, A. Oriol, A. Larocca, M.T. Krauth, M. Thuresson, S. Norin, P. Sonneveld, P.G. Richardson	View Presentation
Melflufen and dexamethasone in heavily pretreated RRMM patients: A real-world descriptive study from the Spanish Registry (Title to be confirmed from final poster)	Javier de la Rubia (Tentative)	(Full list available on the COMy portal)	View Presentation

For more information, please visit www.oncopeptides.com

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About Oncopeptides

Oncopeptides is a Swedish biotech company focusing on research, development and commercialization of targeted therapies for difficult-to-treat cancers.

The company uses its proprietary Peptide Drug Conjugate platform (PDC) to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. Its flagship drug is currently being commercialized in Europe with partnership agreements for South Korea, the Middle East and Africa and elsewhere.

Oncopeptides is also developing several new compounds based on its two proprietary technology platforms PDC and SPiKE.

The company was founded in 2000, has about 80 employees with operations in Sweden, Germany, Austria, Spain and Italy. Oncopeptides is listed on Nasdaq Stockholm with the ticker ONCO.

For more information see: www.oncopeptides.com

About Pepaxti

Pepaxti® (melphalan flufenamide, also called melflufen) has been granted Marketing Authorization, in the European Union, the EEA-countries Iceland, Lichtenstein and Norway, as well as in the UK. Pepaxti is indicated in combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapies, whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody, and who have demonstrated disease progression on or after the last therapy. For patients with a prior autologous stem cell transplantation, the time to progression should be at least 3 years from transplantation.

Attachments

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