

U.S. Food and Drug Administration removes clinical hold of Oncopeptides' pipeline drug OPD5

Stockholm – April 1, 2025 – Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a biotech company focused on difficult-to-treat cancers, today announces the U.S. Food and Drug Administration (FDA) has lifted the clinical hold previously placed on Oncopeptides' next-gen drug OPD5.

Based on the company's proprietary Peptide Drug Conjugate (PDC) platform, OPD5 is a follow-on molecule to Oncopeptides' flagship drug melflufen (branded in Europe as Pepaxti) with a potentially improved risk/benefit profile and enhanced intellectual property protection. OPD5 would initially target multiple myeloma and could potentially be expanded with other indications and diseases over time.

"We continue to see a strong medical need for a PDC in the U.S. confirmed by leading experts in the country," says Sofia Heigis, CEO of Oncopeptides. "With the go-ahead from the regulator, we are now able to move ahead with plans for clinical development."

As a next step, Oncopeptides will continue to prepare for a new clinical study, OP-502, to assess the safety, tolerability and efficacy of OPD5. Given its similarities to melflufen and the experience gained from its' U.S. approval process, Oncopeptides believes that OPD5 can fulfill an important medical need in U.S. as well as in the EU. To support continued development including a phase 1 study, the company is assessing various financing options, including partnerships.

For more information including a Q&A for investors, please visit [Oncopeptides.com](https://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

Attachments

[U.S. Food and Drug Administration removes clinical hold of Oncopeptides' pipeline drug OPD5](#)