

Oncopeptides secures fast-track designation for Window-of-Opportunity study in glioblastoma

Stockholm, March 9, 2026 – Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a biotech company specializing in difficult-to-treat cancers, today announces that it has achieved key regulatory agreement with both the Swedish and Norwegian Medical Products Agencies (Läkemedelsverket, MPA and Direktoratet for medisinske produkter, DMP) regarding the design of its planned “Window-of-Opportunity” (WoO) study evaluating a Peptide Drug Conjugate (PDC) in glioblastoma. The study will be conducted in Norway, where DMP has granted fast-track designation.

This WoO study represents the first clinical evaluation of a PDC in glioblastoma, marking a significant and strategic milestone for Oncopeptides as the company expands the application of its proprietary PDC platform beyond multiple myeloma.

Fast-track designation, which applies to the assessment of the upcoming Clinical Trial Application, is reserved for therapies that address life-threatening conditions with high unmet medical needs and enables an accelerated regulatory review process.

The study will utilize Oncopeptides’ already approved drug in approximately 10 patients with glioblastoma, to provide rapid human proof-of-concept for brain penetration. This efficient study design aims to validate the mechanism in a cost-efficient manner before advancing a PDC into dose-finding and larger trials, for a global glioblastoma market estimated to be worth more than 8 billion USD in 2035 and with high unmet medical need.

“Reaching regulatory agreement with authorities in both Sweden and Norway is a significant milestone for Oncopeptides” **said Sofia Heigis, CEO of Oncopeptides.** “The planned Window of Opportunity study is the first time our PDC platform will be evaluated in glioblastoma, and it marks a significant step in expanding the potential of our technology beyond multiple myeloma. The constructive dialogue with MPA and DMP, together with the fast#track designation granted in Norway, reinforces our confidence in the scientific rationale and clinical relevance of this program. We believe this study will generate important insights and further support our ambition to bring innovative, targeted therapies to patients with high unmet medical need.”

Glioblastoma is the most aggressive form of brain cancer, characterized by rapid growth, invariable relapse, and lack of curative treatment options. With a median survival of only 12–15 months, there is a profound unmet medical need for therapies capable of crossing the blood-brain barrier (BBB) - the primary obstacle that causes most drugs to fail in this indication. Agents from the Oncopeptides’ PDC platform can bypass this barrier due to their lipophilicity and enter cells freely. This novel Mode of Action, results in cytotoxic activity directly within tumor cells.

“The Window of Opportunity study is an innovative and strategically designed approach to bridge the common gap between preclinical promise and clinical reality in glioblastoma,” says **Prof. Petter Brandal, MD, PhD, Oslo University Hospital, and primary investigator in the WoO study**. “By capturing drug activity directly within the tumor tissue, we gain critical insight into the distribution of a PDC in glioblastoma. We welcome DMP’s decision to expedite the review of this application, providing hope to patients with very limited treatment options and a high unmet medical need.”

For more information, including questions and answers for investors, 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

Attachments

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