Press Release
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Oncopeptides' PORT study shows peripheral administration of Pepaxti being equally safe as central venous administration

Stockholm – March 1, 2024 – Oncopeptides AB (publ), a biotech company focused on difficult-to-treat cancers, today announces that a new article analyzing scientific data on melflufen, marketed in Europe as Pepaxti, was recently published in the peer-reviewed medical journal Clinical Lymphoma, Myeloma & Leukemia. The results provide further evidence that administration via peripheral venous catheter (PVC) is well tolerated with no local infusion-related reactions or new safety signals and may represent an alternative route of administration.

The full article can be found here.

Following the recently finalized Type IB variation process, Pepaxti was recently approved for PVC administration within the EU, which was a feature particularly sought after by doctors in Germany, as it is a preferred method by many patients compared to the previously used central venous catheter (CVC) administration.

The phase 2 PORT study is an open-label, randomized, cross-over study which compared pharmacokinetics, safety and tolerability of peripheral or central intravenous administration of melflufen in combination with dexamethasone in patients with relapsed refractory multiple myeloma who had received at least two lines of prior therapy and were refractory to a proteasome inhibitor and an immunomodulatory drug.

"By allowing more choices for route of administration, we allow patients and their doctors more flexibility when using Pepaxti, supporting our ambition to provide as many patients as possible with a safe, efficient drug that maintains a high level of quality of life," says Stefan Norin, Chief Medical Officer at Oncopeptides.

For more information, please see questions and answers for investors, below.

Questions and Answers for investors

What is this?
Oncopeptides, like most other biotech companies conducting medical research, from time to time publish medical data in established scientific journals, such as Clinical Lymphoma, Myeloma & Leukemia, or at medical congresses. These articles and presentations are primarily aimed at healthcare professionals.

The article referenced above is referencing a clinical study showing that CVC and peripheral venous catheter (PVC) administration of melflufen were bioequivalent.

What does this data mean for physicians?
Providing multiple administration options for drugs to treat severe conditions like multiple myeloma can improve patient care by offering more personalized, safer, and convenient treatment pathways, ultimately contributing to better treatment adherence and outcomes.

What does this data mean to Oncopeptides?
The company has received feedback from particularly German doctors asking for the possibility to add PVC as an administration option. This could potentially mean that more patients can be treated with their preferred way of administration, and with time support a higher patient uptake.

What are medical journals?
Medical journals refer to written documents that present research findings, case studies, reviews, and other scientific information in the field of medicine. They are often published in scientific journals after undergoing a rigorous peer-review process.

Why are they important for a biotech company such as Oncopeptides?
Medical publications help to establish credibility, promote transparency, and provide valuable evidence for the efficacy and safety of treatments or interventions. By sharing research findings and clinical experiences, companies can contribute to the broader medical knowledge base, influencing patient care and industry standards.

What was the type IB process you refer to?
As Oncopeptides communicated on September 28, 2023, the company has decided to not extend its indication for Pepaxti into earlier lines of treatment. Despite the company not having an intention to expand the indication, the European Commission approved the application to do so. To address this, Oncopeptides in December submitted a so called type IB-variation to remove the new indication from the product information, ultimately leading to the same intended outcome. This process has now been finalized, with the added benefit that peripheral administration is a method of administration in the officially approved conditions of use a medicine, a feature sought after by doctors in Germany.

Do these publications affect product development?
The data from research and clinical trials, when published, can provide insights into the development of new drugs or new indications for existing ones. They can also guide the direction of future research projects.

How do healthcare professionals use these publications?
Healthcare professionals rely on medical publications to stay updated on the latest research, innovative techniques, and best practices. This knowledge helps them make informed decisions about patient care and treatment choices.

Can the general public access these publications?
It depends on the publication. While many medical journals require subscriptions, there are open-access journals and resources where research is freely available. The article in question is free to access.

Why is the peer-review process in medical publications crucial?
Peer review ensures that the research presented in the publication is of high quality, scientifically sound, and free from biases. Experts in the field evaluate the research, which helps maintain the credibility and trustworthiness of the findings.

How do medical publications benefit patients?
By driving advancements in medical science, these publications play a role in the development of newer, safer, and more effective treatments. When healthcare companies share their findings, it speeds up the dissemination of crucial information, ultimately leading to better patient outcomes.

Where can I find more information?
The article is available through this link.

For more information, please contact:

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About Oncopeptides

Oncopeptides is a biotech company focused on research, development, and commercialization of therapies for difficult-to-treat hematological diseases. The company uses its proprietary Peptide Drug Candidate platform (PDC) to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells.

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.

Oncopeptides is developing several new compounds based on its proprietary technology platforms and is listed on Nasdaq Stockholm with the ticker ONCO. For more information see: www.oncopeptides.com

Attachments

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