Peptomyc announces the beginning of a Phase 2 clinical trial of OMO-103 in advanced osteosarcoma

Barcelona, 16th of January 2025

Peptomyc SL, a clinical-stage biotech company focused on developing new mini-protein therapeutics targeting MYC, the most dysregulated oncogene in human cancer, announced the approval of a Phase 2 trial of OMO-103, the Company’s lead candidate, in pediatric and adult patients with advanced osteosarcoma.

This investigator-initiated trial conducted by the **Vall d’Hebron Institute of Oncology (VHIO)** in Barcelona, Spain, is sponsored by the **Osteosarcoma Institute** (OSI; https://osinst.org/), whose mission is to dramatically increase treatment options and survival rates in osteosarcoma patients through identifying and funding the most promising and breakthrough osteosarcoma clinical trials and science. **Dr. Lee Helman, Director of the OSI**, commented that “MYC amplification/overexpression occurs in a subset of patients with osteosarcoma and there is mounting evidence that this may be associated with a poor outcome. We are grateful for the opportunity to support a study evaluating the use of a MYC inhibitor in collaboration with VHIO and Peptomyc.” The OSI is a science-driven organization whose strategy is guided by its active and engaged Strategic Advisory Board (SAB) of preeminent physicians and other researchers from academia and industry. We would like to acknowledge OSI SAB members William Tap, MD; Katherine Janeway, MD, MMSc; Brian Crompton, MD, Lara Davis, MD, and Chand Khanna, DVM, PhD for their expert contributions to the development of this clinical trial. The trial is also supported in collaboration with Curing Kids Cancer, The Morgan Adams Foundation, and The Kristen Ann Carr Fund.

“We are extremely grateful to the OSI and VHIO for this study and we are thrilled to expand our OMO-103 clinical program with the initiation of a third clinical trial for this candidate, underscoring OMO-103’s potential versatility across a broad range of solid tumors,” commented **Dr. Laura Soucek, Chief Executive Officer of Peptomyc**. “Patients with advanced osteosarcoma, a rare type of bone cancer affecting predominantly children, adolescents, and young adults have an extremely poor prognosis, highlighting the need for novel treatment regimens to combat this highly aggressive disease. With MYC representing a bad prognostic for osteosarcoma patients – potentially resulting in resistance to standard of care treatment – we believe that inhibiting MYC could have a significant anti-tumor effect in this dismal disease.”

**Dr. Claudia Morales Valverde,** Senior Researcher of the Genitourinary, Central Nervous System (CNS) Tumors, Sarcoma and Cancer of Unknown Primary Site Group at the Vall d’Hebron Institute of Oncology (VHIO) in Barcelona and **Principal Investigator of the trial** said, “This is the first use of a MYC inhibitor in osteosarcoma patients and we are eager to conduct this seminal study at the Vall d’Hebron University Hospital. MYC is especially amplified in osteosarcomas and our study will include at least 30% of patients below the age of 18, highlighting the importance of pediatric, adolescent, and adult specialists’ collaboration.”

**Dr. Manuela Niewel, Chief Medical Officer of Peptomyc**, added, “I am really excited to test OMO-103 in this underserved patient population and hopefully make a change in their disease outcome. “

The Phase 2 trial (OSTEOMYC) aims at evaluating the safety and clinical activity, pharmacodynamics, and pharmacokinetics of OMO-103 in advanced osteosarcoma. The primary efficacy endpoint is progression-free survival (PFS) at 16 weeks per RECIST criteria. Secondary endpoints include Overall Response Rate (ORR) per RECIST and overall survival. The trial is enrolling patients at Vall d’Hebron University Hospital in Barcelona, Spain. More information about the trial is available at:

<https://clinicaltrials.gov/study/NCT06650514>

**About Osteosarcoma**

Osteosarcoma, while rare, is the most common type of bone cancer and is often associated with a high degree of malignancy, early metastasis, rapid progression, and poor prognosis. This cancer occurs primarily in children, adolescents, and young adults ranging from 10 to 30 years of age. The risk of diagnosis decreases in adulthood but rises again in older adults, usually over the age of 60. Approximately 3 new cases/million population are diagnosed each year. Treatment typically includes surgery and chemotherapy, with chemotherapy administered before and after surgery to help lower the risk of relapse. Even though curative therapy is available for the primary tumor, long-term outcomes for osteosarcoma patients continue to be impacted by metastatic progression and few improvements have been achieved in the last 40 years.

**About MYC**

MYC is the most dysregulated oncogene in human cancer, controlling multiple transcriptional programs associated to most hallmarks of cancers, including increased proliferation, metastatic potential, immune suppression, and resistance to treatment.

**About OMO-103**

OMO-103 is a first-in-class and best-in-class mini-protein against MYC. It has successfully been tested in a Phase Ia study in all-comers solid tumors and is currently in a Phase Ib study in metastatic pancreatic ductal adenocarcinoma (mPDAC) patients in combination with standard of care chemotherapy.

**About Peptomyc**

Peptomyc (www.peptomyc.com) is a spin-off from VHIO – the Vall d’Hebron Institute of Oncology – and ICREA – the Catalan Institute of Research and Advanced Studies, founded in December 2014 in Barcelona, Spain. The company is focused on the development of innovative cell penetrating mini-proteins targeting the MYC oncoprotein for cancer treatment and based on Dr. Soucek’s scientific research in Omomyc (the best direct MYC inhibitor known to date). It is the first company to have successfully completed a Phase 1 clinical trial with a direct MYC inhibitor.

***Disclosures Regarding Forward-Looking Statements***

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