

Press Release

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Mendus announces collaboration with Institut Bergonié to study ilixadencel in soft tissue sarcomas

Mendus AB (“Mendus” publ; IMMU.ST) announces that it has entered into a collaboration with Institut Bergonié, a leading cancer center in Bordeaux, France to study the Mendus’ intratumoral immune primer ilixadencel in soft tissue sarcomas as part of the REGOMUNE trial, a multicenter, prospective open-labeled phase 1/2 trial combining regorafenib and avelumab in solid tumors.

Based on promising signs of clinical efficacy in a wide range of solid tumors and following the successful implementation of manufacturing process improvements, Mendus had previously communicated its decision to move the ilixadencel program forward in hard-to-treat solid tumors, with soft tissue sarcomas as a prioritized indication. Mendus announces today a collaboration with Institut Bergonié, Bordeaux, France to study ilixadencel as a novel immunotherapy in combination with the tyrosine kinase inhibitor (TKI) regorafenib and the immune checkpoint inhibitor avelumab as part of the REGOMUNE trial, which is coordinated by Institut Bergonié. Bayer AG supplies regorafenib and Merck KGaA supplies avelumab as study drug for the trial.

“To study ilixadencel in soft tissue sarcomas provides for the opportunity to assess the relevance of intratumoral immune priming with ilixadencel in hard-to-treat tumors that are poorly responding to currently available therapies”, says Jeroen Rovers, Chief Medical Officer at Mendus. “Based on our completed clinical trials we are confident that ilixadencel can be safely combined and may act synergistically with tyrosine kinase inhibitors and immune checkpoint inhibitors. This provides for a solid basis to study the combination with regorafenib and avelumab in collaboration with Institut Bergonié as part of the REGOMUNE trial.”

The REGOMUNE trial (ClinicalTrials.gov ID: NCT03475953) is a prospective open-labeled phase 1/2 trial combining regorafenib and avelumab in multiple solid tumors, led by Dr Sophie Cousin and Prof Dr Antoine Italiano. Following a phase 1b dose escalation study design, the combination of regorafenib with avelumab is being evaluated in 17 cohorts of advanced or metastatic tumors in independent phase 2 trials. The trial is recruiting patients in 7 specialized cancer hospitals throughout France. As part of the trial, Mendus will supply ilixadencel as study drug to treat up to 43 patients suffering from soft tissue sarcomas (STS).

Institut Bergonié is a comprehensive cancer center which, is the regional reference center for oncology in the Nouvelle-Aquitaine region of France. The center has a long history in cancer research and recently celebrated its centennial anniversary. Institut Bergonié is part of UNICANCER, a national hospital network of 20 French Comprehensive Cancer Centers (FCCC) which are entirely devoted to fighting cancer with the same unique model based on patient care, research and oncology education.

“Institut Bergonié is committed to provide access to all areas of cancer research to patients”, says Prof Dr Antoine Italiano, principal investigator of the REGOMUNE trial and head of the Department of Medicine at Institut Bergonié. “Through our own research and in collaboration with external partners, we develop innovative treatments where they are most needed and the REGOMUNE trial is an excellent example of how we bring together promising new combination therapies to address hard-to-treat tumors. Based on its promising signs of efficacy and excellent safety profile, we look forward to add ilixadencel to the combination of regorafenib and avelumab for treatment of soft tissue sarcomas in the REGOMUNE trial.”

Mendus and Institut Bergonié expect to complete the preparations for the ilixadencel treatment arm within the REGOMUNE trial in the second half of 2024 and first patient data to be available first half of 2026.

“Our continued research efforts and manufacturing process improvements allow us to bring ilixadencel back into clinical development and we feel privileged to work with Institut Bergonié as one of the leading cancer centers in Europe based on clinical and medical-scientific expertise”, says Mendus CSO Alex Karlsson Parra. “A next wave of innovation in immuno-oncology is expected to come from novel combination approaches for tumors that are poorly responding to currently available therapies and this is where we have focused our preclinical and clinical research with ilixadencel. The REGOMUNE trial provides for an excellent opportunity to evaluate intratumoral immune priming with ilixadencel as a treatment which can have a meaningful impact in the lives of people suffering from hard-to-treat tumors.”

For more information, please contact:

Erik Manting
Chief Executive Officer
E-mail: ir@mendus.com

About Mendus AB (publ)

Mendus is dedicated to changing the course of cancer treatment by addressing tumor recurrence and improving survival outcomes for cancer patients, while preserving quality of life. We are leveraging our unparalleled expertise in allogeneic dendritic cell biology to develop an advanced clinical pipeline of novel, off-the-shelf, cell-based immunotherapies which combine clinical efficacy with a benign safety profile. Based in Sweden and The Netherlands, Mendus is publicly traded on the Nasdaq Stockholm under the ticker IMMU.ST. <https://www.mendus.com/>