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Oncovita receives FDA Orphan Drug Designation for its lead oncolytic virus candidate MVdeltaC in the treatment of pleural mesothelioma

Paris, France, June 4th, 2025. Oncovita, a biotechnology company developing innovative virus-based immunotherapies for cancer treatment, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to its lead investigational therapy, MVdeltaC, for the treatment of pleural mesothelioma—a rare and aggressive cancer with high unmet medical need and limited therapeutic options.

MVdeltaC is a novel immunotherapy based on a genetically modified attenuated Schwarz strain measles virus, engineered to selectively replicate in tumour cells and stimulate a potent anti-cancer immune response. This approach combines direct tumor cell lysis and immune system activation, with the goal of improving outcomes for patients with advanced solid tumors, including pleural mesothelioma.

"*Receiving Orphan Drug Designation from the FDA for MVdeltaC marks a major milestone for Oncovita and validates our approach of harnessing the potential of measles vaccine viruses to treat solid tumors, particularly rare and devastating cancers such as pleural mesothelioma*," said **Stéphane Altaba, CEO of Oncovita**. "*This regulatory support strengthens our strategy to advance innovative immunotherapies as we prepare to enter clinical development with MVdeltaC by 2026*."

"*With this designation, Oncovita is now well-positioned to enter the U.S. market with its modified attenuated measles virus for the treatment of pleural mesothelioma. This recognition highlights the promise of this novel approach against one of the most aggressive cancers in medicine*," added **Dr. Stéphane Champiat, MD, PhD, Head of Medical Affairs at Oncovita.**

The FDA's Office of Orphan Products Development grants Orphan Drug Designation to support the development of therapies for rare diseases affecting fewer than 200,000 people per year in the United States. This designation provides several benefits for the development of such therapies, including tax credits for eligible clinical trials, waiver of FDA application fees, and up to seven years of market exclusivity following product approval.

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About Pleural Mesothelioma

Pleural mesothelioma is a rare and aggressive form of cancer that develops in the pleura, the membrane surrounding the lungs. It is often linked to prolonged exposure to asbestos. Approximately 3,000 new cases are diagnosed each year in the United States. The disease is associated with a poor prognosis and limited treatment options, particularly in cases of relapse or resistance to existing therapies.

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About Oncovita

Oncovita is a biotechnology spin-off from the Institut Pasteur, specializing in the development of virus-based immunotherapies for cancer, with a particular focus on platforms using the oncolytic measles virus. The company's lead candidate, MVdeltaC, a genetically modified measles virus (Schwarz strain) engineered to act as a targeted immunotherapeutic agent, is currently at the pre-IND/CTA stage. Oncovita aims to leverage its proprietary Measovir® platform to develop safer, scalable, and effective treatments for solid tumors.tumors. For more information: www.oncovita.com