Preclinical *in vivo* efficacy results on Vaxxel's intranasal vaccine candidate against Pneumovirus infections confirmed through study funded by National Institute of Allergy and Infectious Diseases (part of the U.S. National Institutes of Health)

"Mucosal bivalent Live Attenuated Vaccine Metavac®-RSV protects against human MetaPneumoVirus (hMPV) and Respiratory Syncytial Virus (RSV) in cotton rats model"

Press Release
Lyon (FR) – 1st October 2024, 10:00 am CET

Vaxxel, a French start-up developing mucosal vaccines against respiratory viral infections, is proud to announce positive preclinical *in vivo* efficacy results for Metavac®-RSV, its intranasal live-attenuated bivalent vaccine candidate to fight hMPV (human MetaPneumoVirus) and RSV (Respiratory Syncytial Virus) infections. These two pneumoviruses are the source of acute respiratory infections in humans such as bronchiolitis or pneumonia in children below 5 years old and in older adults above 65 years old. There is no vaccine available today against HMPV to protect the 195 million persons at risk (including 46 million children) from these severe infections (US and EU, 2020).

The challenge study was directed and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH), through their preclinical services offered to the scientific community[1]. It has been performed by Sigmovir, a preclinical Contract and Basic Research Organisation, using a cotton rat model and showed protection of animals immunised intranasally with Metavac®-RSV and subsequently challenged with wild type hMPV or RSV. Sterilising immunity in cotton rats' lungs against both hMPV and RSV has been demonstrated, as well as induction of strong IgG and broad neutralizing antibody responses against hMPV and different RSV strains.

The NIAID challenge study confirms the extended efficacy of Vaxxel's vaccine candidate, which was already validated in challenged mouse model, as published earlier this year in Nature's portfolio npj Vaccines.

The objective of Vaxxel's technology is to mimic natural infection without causing the disease, and to activate both humoral and mucosal prolonged immunity. The bivalent vaccine candidate is based on Metavac®, Vaxxel's proprietary recombinant hMPV virus attenuated through reverse genetics.

Vaxxel anticipates start of phase I clinical trial in Q3 2026.

[1] DMID Preclinical Services Program, contract # HHSN272201700028I/75N93023F00001/A88HHSN272201700028I/75N93023F00001/A88.

"*We are very pleased with these new results confirming the high value of Metavac®-RSV and we are very grateful to NIAID for their support and their trust. This study confirms the broad efficacy of Vaxxel's vaccine candidate in a second animal model of infection, an outcome we are very pleased with."* says **Denis Cavert, CEO of Vaxxel.** *"Metavac®-RSV is the first intranasal vaccine candidate against both hMPV and RSV infections. It is mimicking the natural infection without the associated pathogenicity and is delivered intranasally without adjuvant. We are eager to contribute to protect children and older adults at risk every year of RSV and hMPV infections and reduce significant burden of disease.*"

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About Vaxxel

Vaxxel Is a spin off from the International Research Laboratory RESPIVIR France – Canada (CIRI - Centre International de Recherche en Infectiologie, INSERM - Institut National de la Santé et de la Recherche Médicale, CNRS - Centre National de la Recherche Scientifique, UCBL - Université Claude Bernard Lyon 1, Ecole Normale Supérieure de Lyon, France), headed by Dr. Manuel Rosa-Calatrava (Lyon) and Pr. Guy Boivin (Université Laval, Québec, Canada), and is led by Denis Cavert, CEO of Vaxxel. Vaxxel develops Live-Attenuated Viruses as vaccine-candidates against human Metapneumovirus and against Respiratory Syncytial Virus based on the versatile mucosal LAV Metavac® vaccine platform. This platform has been funded and licensed by Pulsalys Technology Transfer Office and Lyon Ingénierie Projets (LIP), a subsidiary of Université Claude Bernard Lyon 1. Preclinical Proof of Concept of the first bivalent vaccine candidate against Metapneumovirus an Respiratory Syncytial Virus has been demonstrated on both reconstructed human epithelium airway epithelium and animal preclinical models. The company is a recipient of the 2019 i-Lab award, organised by the Ministry of Higher Education, Research and Innovation in partnership with Bpifrance, and has also received the French "Deeptech" label.

About Vaxxel vaccine candidates

Vaxxel develops two mucosal Live-Attenuated viral vaccine candidates against respiratory infections: a monovalent vaccine called Metavac® against human Metapneumovirus (hMPV), and a bivalent vaccine against both hMPV and Respiratory Syncytial Virus (hRSV) called Metavac®-RSV. These two pneumoviruses are the source of acute respiratory infections such as bronchiolitis or pneumonia in children below 5 years old and in older adults above 65 years old. There is no HMPV vaccine available today to protect the 195 million persons at risk (including 46 million children) from these severe infections (US and EU, 2020). The addressable market is more than 5 billion Euros. Vaxxel's intranasal Live-Attenuated Vaccine candidates are based on a proprietary technology: Metavac®, a recombinant hMPV seed attenuated through reverse genetic, suitable for production from GMP-grade cell line grown on microcarriers with demonstrated capability to be used at industrial scale. The objective of Vaxxel's technology is to mimic natural infection without causing the disease and to activate both humoral and mucosal immunity.