

Press release - 20 January 2022

A French nasal vaccine project against COVID-19 blocks all transmission of the virus – another step taken

The development of a protein vaccine candidate for nasal administration has taken another step. Led by the BioMAP research team, from the Infectiology and Public Health (ISP) joint research unit run by INRAE and the Université de Tours, this project, supported by the Ministry of Higher Education, Research and Innovation, and accompanied by the ANRS | Maladies infectieuses émergentes, is moving up a gear. As new pre-clinical results obtained with the Delta variant this winter demonstrate the robustness of the concept of this vaccine blocking the contagiousness of SARS-CoV-2, the French start-up LoValTech, labelled Deeptech by BPI France, has been created. To accelerate the development of the project and consolidate the investment announcements, this new company now holds an exclusive worldwide licence to exploit the patent on the vaccine, granted by the Université de Tours and INRAE. Its objective is to manage the project from the development phases of the vaccine formulation through to clinical trials leading to a market launch at the end of 2023, beginning of 2024. Within an ecosystem of academic, hospital and innovation partners, and subject to compliance with a tight schedule and sufficient external investment, this project can contribute to overcoming the pandemic crisis.

Since June 2020, the BioMAP research team of the INRAE-Université de Tours Infectiology and Public Health (ISP) joint research unit, a member of the Carnot Institute's *France Futur Elevage* network, has been working on the development of a nasal vaccine against the SARS-CoV-2 virus, with the support of several teams from universities, academia and INRAE.

An original and robust vaccine concept, supported by ANRS | Maladies infectieuses émergentes

Pre-clinical tests had demonstrated the efficacy of the vaccine candidate after two nasal immunisations delivered three weeks apart, both in terms of the immune response and early neutralisation of the original virus and its variants, greatly decreasing the risk of contamination by a vaccinated individual¹. The results of

¹ This vaccine was first tested *in vivo* in a pre-clinical murine model. Two nasal applications, three weeks apart, induced a strong humoral immune response – in particular of the mucosal immunoglobulin A (IgA) with a neutralising and polyspecific activity, i.e. effective against the different variants of SARS-CoV-2 – along with a strong cellular response in the nasal cavities and lungs.

this non-adjuvanted protein vaccine were confirmed at the end of 2021 by new pre-clinical trials on rodents validating its effectiveness against the Delta variant. The vaccine, consisting of the spike protein and non-mutated viral proteins, would therefore protect against the currently circulating strain of SARS-CoV2 despite multiple mutations.

The support of the ANRS | Maladies infectieuses émergentes² on this vaccine candidate will allow the consolidation of the design as well as monitoring all the phases to be carried out until market launch.

Decisive next steps: fund-raising, production of vaccine batches and first clinical trials

Founded by Isabelle Dimier-Poisson from the UMR ISP and head of the BioMAP research team at the origin of the project and Patrick Barillot, former development director at Recipharm, the start-up LoValTech (for Loire Valley Technology) has held an exclusive licence to exploit the vaccine candidate since its creation in January 2022, granted jointly by the Université de Tours and INRAE. Mathieu Epardaud (INRAE researcher) and Nicolas Aubrey (associate professor at the Université de Tours), both members of BioMAP, are also part of the adventure as partners and will be scientific consultants for the startup. The ANR and the Centre-Val-de-Loire region provided an initial funding of €500,000 for scientific development. The Ministry of Higher Education, Research and Innovation allocated a further €1.5 million and the ANRS | Maladies infectieuses émergentes 0.9 million, for a total of €2.4 million, to the Université de Tours in order to carry out the production of the vaccine proteins in a GMP (Good Manufacturing Practice) environment, essential for clinical trials. From the first quarter of 2022, the challenge will be to produce this biomedicine through the Toulouse-based company GTP Bioways and to launch the production of clinical batches for clinical trials in the second quarter.

At the same time, the specific instillation systems - a novel design - of this vaccine in the nose are the subject of collaborative exchanges with two specialised companies, Resyca and Aptar Pharma.

Lastly, discussions on the design of the clinical trials and the drafting of the phase I protocol will be initiated over the next few weeks with the support and expertise of the ANRS | Maladies infectieuses émergentes, sponsor of these future clinical trials. The Clinical Investigation Centre of the CHRU (the Tours Regional University Hospital, a joint structure of the University Hospital, the University and Inserm) has already committed to conducting these clinical trials with other investigators.

Non-invasive and requiring minimal logistics, this vaccination system will allow for a wider distribution:

- to countries with a satisfactory vaccination coverage rate as a booster vaccination in order to strengthen the immune response - particularly the mucosal one - to protect the vaccinated population from symptomatic forms of the disease and, above all, to avoid transmission of the virus.
- to countries where the population is not vaccinated as a first dose.

Official and financial support



² Created on 1 January 2021, the ANRS/ Maladies infectieuses émergentes is the new autonomous agency of INSERM, created by the merger of the REACTing consortium and the National Agency for AIDS Research (ANRS) under the joint impetus of its two supervisory ministries, the Ministry of Higher Education, Research and Innovation and the Ministry for Solidarity and Health.



Industry partners



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About

About INRAE

Created on January 1, 2020, the French National Research Institute for Agriculture, Food, and Environment (INRAE) is a major player in research and innovation. INRAE carries out targeted research and resulted from the merger of INRA and IRSTEA. It is a community of 12,000 people with 268 research, experimental research, and support units located in 18 regional centres throughout France. Internationally, INRAE is among the top research organisations in the agricultural and food sciences, plant and animal sciences, as well as in ecology and environmental science. It is the world's leading research organisation specialising in agriculture, food and the environment. INRAE's goal is to be a key player in the transitions necessary to address major global challenges.

Faced with a growing world population, climate change, resource scarcity, and declining biodiversity, the institute is developing solutions that involve multiperformance agriculture, high-quality food, and the sustainable management of resources and ecosystems.

About Université de Tours

Multidisciplinary (Arts & Humanities, Law, Economics & Social Sciences, Literature & Languages, Medicine, Sciences & Technology, 2 Institutes of Technology (IUT), 1 Centre for Advanced Renaissance Studies, 1 Graduate School of Engineering), the University is located in the heart of Tours but also in Blois.

With over 36 research laboratories, it is the leading public research institution in the Centre Val de Loire region.

<https://international.univ-tours.fr/>

LoValTech, SAS, is located in the MAME incubator in Tours. Created on 17 January 2022, the LoValTech start-up aims to continue the development of the MUCOVID vaccine, stemming from university research in Tours, and to bring it to market. The LoValTech team is an ideal bridge between academic research represented by Isabelle Dimier-Poisson, associate professor at the Université de Tours, and future general manager of LoValTech, Mathieu Epardaud, INRAE researcher and Nicolas Aubrey, associate professor at the Université de Tours, and industry represented by Patrick Barillot, former development director at Recipharm and President of LoValTech.

ANRS | Maladies infectieuses émergentes

Created on 1 January 2021, ANRS | Maladies infectieuses émergentes is an autonomous agency of Inserm. Its mission is to lead, evaluate, coordinate and fund research on HIV/AIDS, viral hepatitis, sexually transmitted infections, tuberculosis as well as emerging and re-emerging infectious diseases (in particular emerging respiratory infections, including Covid-19, viral haemorrhagic fevers and arboviral diseases). The agency covers all fields of research: basic, clinical, public health as well as human and social sciences; its organisation emphasises innovation and the strengthening of international partnerships. With a One Health approach, addressing human and animal health and the impact of humans on the environment, the agency is preparing the response to the scientific challenges posed by emerging diseases and its deployment in times of crisis. The ANRS | Maladies infectieuses émergentes is placed under

the aegis of the Ministry of Higher Education, Research and Innovation and the Ministry for Solidarity and Health. Its director is Professor Yazdan Yazdanapanah.

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