

UNDER EMBARGO / until March 14, 2025 - 12 noon

PRESS RELEASE / March 14, 2025

**/FIRST IN HUMAN/  
First administration in humans  
Lovaltech nasal vaccine against COVID-19 :  
Tours University Hospital launches MUCOBOOST clinical trial**

*Press conference - Friday, March 14, 2025 at 12 noon at CHRU Tours, Hôpital Bretonneau*

A major milestone in the development of a nasal vaccine against COVID-19 has just been reached: five years after the pandemic, Tours University Hospital (TUH) and ANRS - Emerging Infectious Diseases (ANRS MIE), co-sponsors, have been authorized to start the MUCOBOOST clinical trial. This candidate vaccine, based on a novel technology, could revolutionize the prevention of respiratory infections. This innovation, developed by biotechnology start-up Lovaltech, positions France as a pioneer in next-generation vaccination.

*Administered as a nasal spray, this vaccine should provide total protection against COVID-19. It should provide effective protection against all variants of the virus and block its transmission, thus reducing human-to-human contagiousness and virus circulation.*

**MUCOBOOST First in human, phase I & II clinical trial to begin shortly at the Clinical Investigation Centre (CIC) of the Tours University Hospital followed by the CIC Cochin-Pasteur (Paris).**

After obtaining authorization from the French National Agency for the Safety of Medicines (ANSM) and the French Committee for Protection of Individuals (CPP), the MUCOBOOST Phase I and II clinical trial marks a major step forward in the control of the COVID-19, with the evaluation of this candidate vaccine which reduces both the risk infection and transmission of the virus, providing a complete vaccine response.

**By the end of April - Phase I**

The first Phase I enrolments will start at the end of April at the Clinical Investigation Center at the CHRU in Tours, followed in June by the Clinical Investigation Center at Cochin-Pasteur in Paris (two centers in the I-Reivac network, a French network dedicated to clinical research in vaccinology).

Known as *dose escalation*, this first phase requires the participation of 36 volunteers. Three groups of 12 healthy people, 18 to 55, will be included by the investigating physicians to evaluate three dose levels of intranasal vaccine. The first stratum will start at the lowest dose, then dose escalation rules will be applied.

The protocol provides for 8 visits over 12 months to the CIC: 1 visit to check that the volunteer meets the required criteria and validate participation, 1 visit to administer the vaccine, 6 follow-up visits with biological samples.

**Objective: to assess tolerance and immune response in healthy volunteers in order to determine the re-ordered dose for Phase II. Preliminary results from this first phase are expected in autumn 2025.**

**To be continued, early 2026 - Phase II**

For this second phase, 202 healthy volunteers will be required. To optimize enrollment, 5 centers in the I-Reivac network will participate: Tours, Saint-Etienne, Lyon, Cochin and Dijon.

**Objective: to assess the superiority of the nasal vaccine versus an mRNA vaccine in terms of induction of a local immune response.**

This multi-center clinical trial is being co-promoted by Tours University Hospital and ANRS MIE, an unprecedented alliance between research centers and referral hospitals that guarantees a rigorous scientific framework and optimal evaluation conditions.

**MUCOBOOST IN BRIEF**

**Randomized, controlled, multicenter Phase I/II trial comparing the safety and immunogenicity of a booster dose of an intranasal COVID-19 vaccine expressing recombinant SARS-CoV-2 N/S proteins to a booster dose of a COVID-19 mRNA vaccine in healthy adult volunteers**

**Co-Promoter :** Tours University Hospital/ ANRS MIE

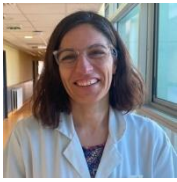
**Scientific Coordinator:** Pr Isabelle DIMIER-POISSON, University of Tours

**Investigator:** Dr Zoha MAAKAROUN-VERMESSE, Tours University Hospital

**Coordinating co-investigator :** Pr Odile LAUNAY, CIC Cochin Pasteur



**Doctor Zoha Maakaroun-Vermesse, infectiologist-vaccinologist at the CHRU de Tours, investigator-coordinator of the MUCOBOOST phase I and II clinical trial.**



« Clinical research in the field of vaccinology at Tours University Hospital has experienced significant growth since the creation of the vaccinology unit in 2021, in close collaboration with Dr. Valérie Gissot, medical coordinator of the CIC 1415 in Tours. Since then, the center has become an expert in this field and joined the I REIVAC network, a national network for clinical research in vaccinology. This collaboration has allowed us to connect with the research teams in Tours and embark on the MUCOBOOST clinical trial as early as 2022. Launching a clinical research project of this scale requires

the participation of many local and national stakeholders across multiple fields. The hope of a new approach to COVID-19 prevention through this project was already very motivating. We truly appreciated the team spirit at every stage of the project. We all leave this experience enriched. »

**One step further on the road to excellence for hospital-university research in Tours.**



« With MUCOBOOST, the Clinical Research and Innovation Department of Tours University Hospital and its Clinical Investigation Center demonstrate their maturity and the excellence of their expertise in promoting Phase 1 clinical trials. For the first time, Tours University Hospital is experimenting with the co-sponsor status alongside ANRS MIE, which is now allowed under European regulations. This decision highlights our commitment to developing collaborations and our openness on a national scale. This innovation – which we are proud to lead – follows in the footsteps of renowned virologists from Tours such as Philippe Maupas and Philippe Roingeard. »

Mathilde-Sigaud-Fils, Director of Research and Innovation, Tours University Hospital.

**MUCOBOOST  
firsts**

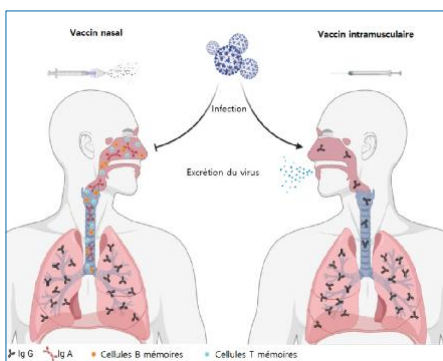
- For the first time in France, a clinical trial has been co-promoted by a referral hospital (Tours University Hospital) and ANRS MIE.
- For the first time, Tours University Hospital is the sponsor a clinical trial with **first administration in humans.**

**Lovaltech's nasal SARS-CoV-2 vaccine paves the way for next-generation vaccination**



Originally developed by the BioMAP team within the "Infectiology and Public Health" joint research unit (INRAE and University of Tours), this vaccine will be administered in the form of a nasal spray, and offers a dual advantage: it directly immunity of the respiratory mucosa, the first barrier against infection, while promoting a more robust global immune response.

**Nasal vaccination : extended protection and a barrier to transmission**



Current vaccines (including mRNA vaccines) are administered intramuscularly and are said to be "systemic": they activate immune cells throughout the body via a pool of cells circulating in the blood, which can then reach infected organs. However effective this systemic immunity may be, it does not allow for a high level of B and T lymphocytes in the nasal cavity and lungs - which would promote rapid, effective protection against the virus, blocking it as soon as it enters the body.

Conversely, intranasal vaccination induces an immune response not only systemically, but also locally - directly, therefore, at the SARS-CoV-2 entry point.

By activating the immune cells in the nasal mucosa, we can avoid the race against time between the virus (which is multiplying in our respiratory system) and our systemic immune system (which must mobilize all the way to the organs most affected): in concrete terms, we can rapidly stop the virus and block its ability to disseminate and replicate in our body.



**A decisive step towards a new vaccine strategy**

« We are particularly proud to reach a decisive step in the development of our nasal vaccine. This authorization reflects the trust of health institutions in our project and rewards the successful scientific and clinical collaboration between ANRS MIE, Tours University Hospital, INRAE, Lovaltech, and the University of Tours. The development of this vaccine addresses strategic public health challenges while positioning France as a leading player in health innovation and next-generation vaccination » explains Isabelle Dimier-Poisson, University Professor of Immunology at the University of Paris.

## Lovaltech, a 3-year-old start-up at the forefront innovation made in Touraine

### Towards French leadership in nasal vaccination

Tours-based biotech start-up Lovaltech is a winner of the i-Lab 2022 and i-DEMO France 2030 national competitions, which reward innovative projects in scientific research. The start-up has also secured public and private funding to accelerate the development of this vaccine and explore new vaccine applications (see infographic below).

The project has received financial support from the French Ministry of Higher Education and Research, ANRS MIE, the French Ministry of Health and the Centre-Val de Loire Region. In addition, APTAR, a world leader in pharmaceutical delivery devices, will manufacture the nasal vaccine delivery systems, guaranteeing production in line with international industrial and regulatory standards.

*"This innovation represents a strategic opportunity to rethink vaccination, improve immunization coverage and meet future global health challenges. Thanks to an excellent research ecosystem and committed partners, Lovaltech aims to transform vaccination and establish French leadership in biotechnology and healthcare innovation"* concludes Patrick Barillot, Chairman and co-founder of Lovaltech.

## A look back at the success story of this Touraine-based start-up

### 2020

#### Submission of the first COVID project

The BioMAP research team of the "Infectiology and Public Health" unit, a joint INRAE / Université de Tours research unit headed by Prof. Isabelle Dimier-Poisson, is developing a nasal subunit vaccine against COVID-19 with the support of a network of academic and industrial collaborations. The anti-SARS-CoV-2 nasal vaccine candidate is based on a process already used in the laboratory for a nasal vaccine designed to protect against toxoplasmosis.

Pre-clinical laboratory tests demonstrated the efficacy of the candidate vaccine concept, consisting of the Spike protein and the non-mutated nucleoprotein, after two nasal immunizations spaced 3 weeks apart, both in terms of immune response and protection against the original virus and its variants.

### 2021

The project has been awarded **€1.5 million** by the French Ministry of Higher Education, Research and Innovation and **€1 million** by ANRS MIE, delivered via the University of Tours; New pre-clinical trials on the hamster reference model efficacy of the vaccine to block contagiousness and inter-individual transmission.

### 2022 > 2025

#### Support of ANRS MIE to the tune of 900 K€.

**January: Creation of Lovaltech**, a biotech start-up based in Tours and awarded the DeepTech label by BPI France, to take over from academic research and continue the industrial development of the nasal vaccine through to market launch.

With initial financial support from MESRI and ANRS MIE, Lovaltech led the GMP development phase of the vaccine protein and muco-excipient (production and pharmaceutical release) via CDMOs GTP Bioways and Stanipharm.

**Winner of the i-Lab 2022 national competition for innovative start-ups and of I-DEMO 2023 France 2030**, Lovaltech has accelerated the development of its vaccine by launching regulatory toxicity and immunogenicity studies to demonstrate safety and efficacy of the candidate vaccine animals prior to administration in humans. These studies, conducted October 2022 by C-Ris Pharma (a French CRO specializing in non-clinical studies), have now been completed and have validated the vaccine's safety.

### 2025

**Launch of the First in Human phase I&II clinical trial, co-promoted by Tours University Hospital and ANRS MIE.**

### LOVALTECH / THE TEAM

#### Patrick Barillot

Chairman and co-founder

#### Isabelle Dimier-Poisson

Scientific Director

and co-founder

#### Mathieu Epardaud

Scientific consultant and

co-founder

#### Omar Hashim

Researcher and Project Manager

#### Muna Aljeli

Researcher and Project Manager

#### Nicolas Aubrey

Scientific Consultant

and Co-founder

#### Gaëtane Rouvray

CMC Manager **Alan**

**Mougeolle** Quality

Manager

[www.lovaltechnology.com](http://www.lovaltechnology.com)

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### Institutional partners



### Industrial partners

