

**SPIKIMM, A BIOTECHNOLOGY COMPANY FOUNDED BY
TRUFFLE CAPITAL UNDER LICENSE FROM THE INSTITUT
PASTEUR, ANNOUNCES THAT THE CLINICAL TRIALS FOR
SPK001, ITS MONOCLONAL ANTIBODY AGAINST SARS-COV-2,
HAVE BEGUN**

**THIS CLINICAL TRIAL HAS BEEN AWARDED NATIONAL PRIORITY RESEARCH
STATUS BY THE FRENCH GOVERNMENT**

Paris, October 20th, 2022

SPK001, the first anti-SARS Cov2 monoclonal antibody candidate of SpikImm, a French biotechnology company founded by Truffle Capital, originally discovered by Institut Pasteur's Human Immunology Laboratory, directed by Dr. Hugo Mouquet (Inserm Joint Research Unit), has been tested on three initial cohorts of healthy volunteers, and has demonstrated excellent tolerance, in the context of the Phase 1 clinical study, recently labeled as a "national priority" by CAPNET (National Steering Committee for Therapeutic Trials and other Research on COVID-19).

SPK001 is a monoclonal antibody developed for the prevention of COVID-19 "pre-exposure prophylaxis" in immunocompromised patients such as organ transplant patients, patients with hematological cancers or autoimmune diseases, who are often unresponsive or poorly responsive to a complete vaccination regimen (approximately 300,000 patients in France, 10 million in Europe and the United States). These patients represent 30 to 40% of all patients hospitalized for COVID-19 with a much higher level of severe forms and mortality than in the general population (risk multiplied by 2 to 4).

SpikImm is developing two antibodies in parallel, SPK001 and SPK002, which have demonstrated potent neutralizing activity in vitro against SARS-CoV-2 and its variants of concern, and excellent therapeutic efficacy in vivo in reference animal models. Also, SpikImm has entered into a non-exclusive in-license agreement with Xencor, Inc (NASDAQ: XNCR) on the Xtend™ technology, designed to increase the half-life of its SPK001 and SPK002 antibodies and therefore, reduce the frequency of administration for optimal and convenient patient prophylaxis.

SPK001 and SPK002 are among the most promising monoclonal antibodies against SARS-CoV2 in the world. Recruitment of the four volunteer cohorts is scheduled to be completed by the end of October 2022. SpikImm plans to evaluate the medical benefit of SPK001 and SPK002 in a Phase 2 trial in immunocompromised patients (antibody pharmacokinetics and virus immunoneutralization). Depending on the results, SpikImm could seek early access and emergency use¹ approval as early as the second quarter of 2023.

Philippe Pouletty, MD, Chairman of SpikImm and CEO & co-founder of Truffle Capital, states:

"At Truffle Capital, creating biotech companies like SpikImm with world-class research organizations such as Institut Pasteur that can have a major impact on patients' lives and public health is our DNA."

Dr. Hugo Mouquet, head of the laboratory of Humoral Immunology at Institut Pasteur, and Scientific Director of SpikImm, states:

"The excellent tolerability demonstrated by the first cohorts of volunteers tested is very encouraging for further clinical trials of SPK001. With the broad spectrum and potent neutralizing activity of SPK001 and SPK002, SpikImm has one of the most promising antibody portfolios competing with very limited prophylactic and therapeutic monoclonal antibody options worldwide since the advent of Omicron."

Pr. Karine Lacombe, University Professor and Chief Medical Officer of SpikImm states:

"We are already well advanced in preparing for the Phase 2 clinical trial, which could begin in the first quarter of 2023. Immunocompromised patients need effective prevention, given high morbidity and new variants. "

¹ Early access : <https://ansm.sante.fr/actualites/autorisation-dacces-precoce-aux-medicaments-un-premier-bilan-positif-et-des-principes-devaluation-affines#:~:text=Depuis%20le%201er%20juillet,d'efficacit%C3%A9%20et%20de%20s%C3%A9curit%C3%A9>.

Emergency use: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

Antoine Pau, acting CEO of SpikImm and Senior Partner of Truffle Capital states:

"With SPK001 and SPK002, SpikImm has two complementary antibodies to potentially best cover today's and tomorrow's COVID-19 variants. With its experienced team and its partnership with Institut Pasteur, SpikImm has a strong platform for accelerated antibody development to address emerging respiratory diseases.

About SpikImm

SpikImm was founded and financed by Truffle Capital with its BioMedTech fund. This is the second collaboration between Institut Pasteur and Truffle Capital. SPK001 and SPK002, SpikImm's drug candidates, were discovered by the Institut Pasteur's Human Immunology Laboratory, headed by Dr. Hugo Mouquet (INSERM Joint Research Unit, <https://research.pasteur.fr/fr/team/humoral-immunology/>). SpikImm benefits from an exclusive and worldwide license from the Institut Pasteur on these antibodies. SpikImm aims to develop SPK001 and SPK002 in an accelerated manner to allow their preventive use "pre-exposure prophylaxis" in immunocompromised patients, a key medical need in the fight against the COVID-19 pandemic. SpikImm has recently been designated winner of the call for expressions of interest "Emerging Infectious Diseases and CBRN Threats, France 2030".

More information: <https://SpikImm.com/>

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