

SPIKIMM, A BIOTECH COMPANY FOUNDED BY TRUFFLE CAPITAL AND INSTITUT PASTEUR, ANNOUNCE THAT SPK001, ITS MONOCLONAL ANTIBODY HAS DEMONSTRATED A POTENT AND BROAD NEUTRALIZATION ACTIVITY ACROSS ALL SARS-CoV-2 VARIANTS OF CONCERN, INCLUDING OMICRON (BA.1 AND BA.2)

- RESULTS ARE AVAILABLE AS PREPRINT AND HAVE BEEN SUBMITTED IN AN INTERNATIONAL PEER-REVIEWED JOURNAL.
[HTTPS://WWW.BIORXIV.ORG/CONTENT/10.1101/2022.04.01.486719V1](https://www.biorxiv.org/content/10.1101/2022.04.01.486719v1)
- SPIKIMM EXPECTS TO INITIATE CLINICAL TRIALS MID-2022

Paris, April 12th, 2022

The monoclonal antibody SPK001, SpikImm's lead candidate originally developed in the *Humoral Immunology* lab headed by Dr Hugo Mouquet at the Institut Pasteur (joint research unit Inserm), has demonstrated a potent and broad neutralization activity *in vitro* against SARS-CoV-2 and all variants of concern (including Delta and Omicron), as well as *in vivo* prophylactic and therapeutic efficacies in mouse and hamster models. As most monoclonal antibodies commercially-available and in clinics partially or completely lost their effectiveness against omicron variants BA.1 and BA.2 (dominant worldwide since Dec 2021), SPK001 now appears as one of the most promising mAbs.

SPK001, is developed as a long-acting antibody with a convenient, intramuscular administration for the prevention of COVID19 (pre-exposure prophylaxis) in immunocompromised patients unable to mount a protective antibody response after vaccination. There is a major unmet medical need for the prevention of COVID19 in immunocompromised patients such as transplant patients, patients with hematologic cancer or autoimmune diseases (around 300,000 patients in France, 3 M in Europe and 7 M in the US). These patients represent 30 to 40% of all patients hospitalized for COVID19 with high mortality risk, since a significant portion of them cannot mount sufficient immune responses after vaccination.

SpikImm expects to initiate clinical trials mid-2022 and then, to demonstrate the medical benefit in a phase 2 in immunocompromised patients. Depending on the results, SPK001 may seek Emergency Use Authorization (EUA) as from Q2 2023.

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

"Antibody responses to the SARS-CoV-2 spike protein strongly contribute to long-term immune protection against severe COVID19. SPK001 was selected among hundreds of screened anti-SARS-CoV-2 monoclonals, and cross-neutralizes all SARS-CoV-2 variants of concern including Delta, Omicron BA.1 and BA.2. With its breadth and potency, documented by strong structural data, SPK001 appears as a prime candidate for COVID19 prevention in immunocompromised patients".

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

"We are thrilled with the promising results of SPK001 and would like to thank the Institut Pasteur and SpikImm teams for the hard work accomplished. SpikImm will continue, along with its partners to focus on its accelerated development plan, initiating clinical trials and making SPK001 available as soon as possible to patients."

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

"Monoclonal antibody therapy is one of the most efficient and safe approach to prevent COVID19 in immunocompromised patients unable to respond to vaccination. With these important results, SpikImm is now very well positioned to become a major player in COVID19 prevention for immunocompromised

patients and will also explore potential strategic partnerships that could accelerate its development and support broad commercialization.”

About SpikImm

SpikImm was founded by Truffle Capital and Institut Pasteur to develop human monoclonal antibodies (mAbs) to prevent COVID19 infection. SPK001, SpikImm's lead candidate, has been originally developed in the laboratory of *Humoral Immunology* (Institut Pasteur & Inserm U1222; <https://research.pasteur.fr/en/team/humoral-immunology/>) headed by Dr Hugo MOUQUET. SpikImm was recently named laureate of “Emerging infectious diseases” Innovation Healthcare 2030 acceleration strategy by the French State.

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

About the Institut Pasteur and the Institut Pasteur International Network

The Institut Pasteur, a non-profit foundation with recognized charitable status set up by Louis Pasteur in 1887, is today an internationally renowned center for biomedical research with a network of 33 members worldwide. In the pursuit of its mission to prevent and control diseases in France and throughout the world, the Institut Pasteur operates in four main areas: research, public health, education and training, and development of research applications. More than 2,800 people work on its Paris campus. The Institut Pasteur is a globally recognized leader in infectious diseases, microbiology, and immunology. Other avenues of investigation include cancer, genetic and neurodegenerative diseases, genomics and developmental biology. This research aims to expand our knowledge of the living world in a bid to lay the foundations for new prevention strategies and novel therapeutics. Since its inception, 10 Institut Pasteur scientists have been awarded the Nobel Prize for Medicine, including two in 2008 for the 1983 discovery of the human immunodeficiency virus (HIV) that causes AIDS.

More information: www.pasteur.fr/en

About Truffle Capital

Founded in 2001, Truffle Capital is an independent European Venture Capital firm specializing in Life Sciences (MedTech and BioTech) and disruptive technologies in the I.T. sector (FinTech and InsurTech). Truffle Capital's mission is to support the creation and development of young innovative companies capable of becoming tomorrow's leaders. Chaired by Patrick Kron and managed by Dr. Philippe Pouletty and Bernard-Louis Roques, co-founders and CEOs, Truffle Capital has €700 million in assets under management. It has raised more than €1.1 billion since its creation and has supported more than 70 companies in the digital technology and life sciences sectors. In 2019, Truffle Capital has announced the raising of nearly €400 million in new institutional funds, including €250 million in BioMedTech.

More information: www.truffle.com — Twitter: @trufflecapital

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