

Bio-Manguinhos / Fiocruz national vaccine against new coronavirus enter pre-clinical study phase

Brazilian vaccine projects advance to in vivo studies

The Institute of Technology on Immunobiologicals, belonging to the Oswaldo Cruz Foundation, BioManguinhos / Fiocruz, started in July 2020 two *in vivo* preclinical studies for two vaccine candidates against Sars-CoV-2. One synthetic vaccine based on antigenic peptides from B and T cells developed in house against Sars-CoV-2, and one subunit vaccine using antigen fragments to stimulate a better immune response.

For the synthetic approach, Bio-Manguinhos researchers identified antigenic peptides using a computational model (*in silico*). These peptides from the Spike protein and the SARS-COV-2 nucleoprotein, obtained through chemical synthesis, have already been validated *in vitro* using patients serum. The peptides have been coupled to nanoparticles, functioning as a "delivery" system, so that they are able to improve the immune system's response and activate its defense against Sars-CoV-2.

Synthetic vaccines speed the vaccine development process, compared to traditional methodologies. The development process can be initiated without the need of the actual virus and the biosafety requirements are less stringent, without the need for BSL level 3 laboratories during the first stages of development (BSL3 are necessary only in pre-clinical studies). Furthermore, we expect that these constructs present improved stability, important for vaccine storage as well as lower production costs. This is a new technology in terms of use in vaccine development, and a number of producers/developers are currently investing in this technology.

The second vaccine candidate, a subunit vaccine, also in preclinical studies, is based on a more mature technology platform. Bio-Manguinhos researchers produced and are testing different S and N protein constructs, as vaccine antigens which can provoke an immune response, both in terms of protective/neutralizing antibody production as well as eliciting a protective T-cell response.

After preclinical studies, the candidate vaccines will move on to the phase of clinical studies of phases I, II and III. Bio-Manguinhos's R&D Vice-director, Sotiris Missailidis, pointed out that there are enormous expectations about which vaccines –there will certainly be more than one – among the several candidates currently in development globally in different platforms, will effectively reach regulatory approval and registration. If preclinical and clinical studies are successful, Bio-Manguinhos / Fiocruz' vaccine could be registered by 2022.

"These R&D projects are part of a wider institutional strategy in the search for a vaccine against COVID-19. The Brazilian Ministry of Health has already indicated Fiocruz, through Bio-Manguinhos, as the primary institution to evaluate technologies and vaccine candidates, aiming at establishing partnerships for clinical development and manufacturing for future distribution to assure access to quality and safe vaccines for the society", said Bio-Manguinhos director, Mauricio Zuma.

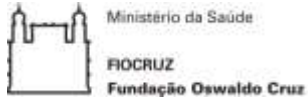
Through these and other initiatives in diagnostic and biopharmaceutical development and clinical analyses in the effort of combating COVID-19, Bio-Manguinhos reinforces its strategic role as a governmental institution in contributing to national self-sufficiency for manufacturing of health goods.

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