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Innate Immunity Potentiation and Adaptive Immunity Stimulation in Human Volunteers with Mucosal Vaccine Candidates Heber Nasvac and Mambisa

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ABSTRACT

With the first case of COVID-19 on April 11, Cuba began an extensive research program to control the epidemic. As everywhere else, the quickest route was to select among the products already available from other indications or in clinical development those that due to their mechanism of action, proven safety, or clinical evidence could affect the new coronavirus. The concept of training immunity with vaccines originally developed for other diseases has gained attraction during the epidemic. Several clinical trials and epidemiological analyses of populations previously immunized with BCG and other vaccines are the focus of scientific discussions.

Here we show the activation of innate immunity markers both at mucosal and systemic level with a mucosal vaccine CIGB2020 (HeberNasvac™) containing virus-like particle and nucleocapsid particle of the hepatitis B virus. In a proof-of-concept clinical evaluation in human volunteers, CIGB2020 administered as a nasal spray and sublingual drops, activate interferon-induced genes and Toll-Like Receptors 3, 7, and 8 at the level of oropharyngeal mucosa and peripheral blood. Likewise, in peripheral blood are activated monocyte and lymphocyte populations expressing HLA-DR.

The immune potentiating capacity of the nucleocapsid antigen was also used to formulate a specific mucosal vaccine candidate against SARS-CoV-2 with RBD protein expressed in yeast. One dose administration by nasal route in previously naturally infected individuals with SARS-CoV-2 induces high levels of specific IgG antibodies with RBD-ACE2 binding inhibition capacity and neutralization activity against live virus.

Keywords: Mucosal vaccine, Innate immunity, COVID-19, Virus-Like Particle, RBD

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