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# Clinical trials and pharmacology of HeberNasvac, a newly registered therapeutic vaccine for chronic hepatitis B: Crossroad of biotechnology, adjuvant strategies and liver immunology

**Aguilar J C[1], Al-Mahtab M[4], Akbar S M F[3], Uddin H[4], Rahman S[4], Tuero A[1], Aguilar A[1], Freire F[1], Aguiar J[1], Lobaina Y[1], Muzio V[1], Cinza Z[1], Rahman S[1], Penton E[1], Mancini M[2], Michel M L[2]** and **Guillen G[1]**

[1]Center for Genetic Engineering and Biotechnology, Cuba

[2]Pasteur Institute, France

[3]Toshiba Hospital, Japan

[4]Bangabundhu Sheikh Mujib Medical University, Bangladesh

**Introduction:** Chronic hepatitis B (CHB) infection constitutes a major cause of HCC, liver cirrhosis worldwide. HeberNasvac is a novel therapeutic vaccine based on the recombinant HBsAg and HBcAg. These proteins contain adjuvant and immunomodulatory properties that supported the clinical development of HeberNasvac.

**Materials & Methods:** Four clinical trials evaluated the administration of HeberNasvac, three of them in CHB patients. Two studies were carried out in treatment-naive patients and a third was conducted in non-responders to IFN-α therapy. The viral load was monitored as main variable in all the studies involving CHB patients. Serological evaluations for HBe and HBsAg and their corresponding antibodies were also conducted. The transaminases, bilirubin and other liver and hematological markers were evaluated to assess product safety. BALB/c mice, rabbits and AAV HBV transfected/HLA double transgenic mice were used as models to evaluate the capacity of the nasal route of immunization to generate systemic and especially liver immune responses.

**Results:** Clinical trials evidenced a significant reduction of the viral load to undetectable levels and under 104 copies/mL, both at end of treatment and after 24/48 weeks follow-up evaluations, evidencing the sustained control of the virus. Liver function tests and hematological variables evidenced the safety of this product. Serological responses were higher to PEG-IFN treatment. Action mechanism studies related to the route of immunization evidenced the role of the nasal route of immunization in the induction of T cells at the target organ, the liver.

**Conclusions:** The vaccination with HeberNasvac is effective and safe, supporting its use as therapy against CHB infection. The studies of immunogenicity in novel model of CHB infection evidenced the effect of the nasal route of immunization in the liver homing of effector T cells. These results suggest that HeberNasvac may contribute as a novel treatment for CHB.

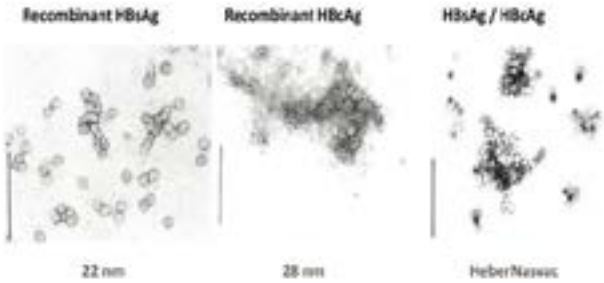


**Figure 1:** HeberNasvac: the drug product and their active ingredients

## Biography

Aguilar J C has completed her PhD in Biological Sciences. He is the main author of 12 patent applications, 2 book chapters, 3 review articles, 55 original research articles, 11 clinical protocols (phase I to Phase IV) and 60 scientific presentations (Oral + Posters) in international meetings. He has experience of writing technical documents in relation to multiple IRB permission and answers to regulatory agencies, 22 SOPs, 8 technical pharmacology reports, 4 physicochemical and immunological reports, 1 Risk analysis reports, 10 clinical trial monitoring reports, IMPD and CTD preparation and revision. He also has written 20 collaboration agreements and more than 10 technical missions. He works as a Scientific Reporter of Elfos Scientiae. He has received 7 Cuban Science Academy Awards, Awards of the National Union of Scientific Workers, 5 Science and Technology Forum Awards. He is the Young Member of the Cuban Academy of Sciences, Cuban Society of Immunology.

julio.aguilar@cigb.edu.cu