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CyTuVax presents positive results of HBAI20 vaccine trial

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CyTuVax B.V.has released the results of the HBAI20 Phase 2 “BE-Responder” trial. This trial focused on so-called non-responders to hepatitis B vaccination, persons who have been vaccinated with at least one complete vaccination course (3 injections of a licensed hepatitis B vaccine) without achieving a protective immune response. In this study population of hepatitis B vaccine non-responders, the HBAI20 vaccine is able to reduce the percentage of non-responders to 8% compared to 21% in the HBVaxPro-10 group ($p = .068$ Fisher).

Statistical evaluation using a generalized linear mixed model demonstrates that subjects who have received the HBAI20 vaccine are 3.5 times more likely to attain seroprotection at the end of the study compared with subjects who received the licensed HBVaxPro-10 vaccine ($p < .05$).

With the HBAI20 vaccine, seroprotection was achieved earlier than with the HBVAxPro-10 vaccine. 83% of the non-responders attained seroprotection after only 2 vaccinations. In contrast, with the licensed HBVaxPro-10 vaccine, even after 3 injections only 79% of the non-responders achieved seroprotection.

The safety profile of HBAI20, as compared to HBVaxPro-10, showed a temporary higher number of transient mild and moderate local side effects: impaired arm movement, redness, and pain at injection site indicating that HBAI20 induces a stronger immune response. No differences regarding systemic side effects were observed.

The “BE-Responder” study was a double-blind randomized controlled phase 2 clinical trial, and enrolled 133 adults subjects in 2 arms with a ratio of 3:1 (HBAI20 : HBVaxPro-10). Subjects were recruited at 3 sites: MUMC (Maastricht), ZOL/UH (Genk), and VAXINFECTIO (Antwerp). Both vaccines were administered 3 times in a 0, 1, and 2 months schedule. CyTuVax adjuvant for the HBAI20 vaccine consisted 20 µg of depot-formulated Interleukin-2 aggregates.