Rapid increase in anti-HBsAg titers and higher seroprotection rates in adults immunized with Sci-B-Vac® compared to a monovalent hepatitis B vaccine:

Results from PROTECT – a double-blind, randomized, controlled, phase 3 study

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INTRODUCTION

• Although licensed Hepatitis B virus (HBV) vaccines are effective in preventing HBV in children and healthy young adults, there is reduced vaccine efficacy in older persons, and those with diabetes, obesity or who smoke cigarettes 1.
• Sci-B-Vac®:
  • A trivalent HBV vaccine that contains S antigen and pre-S1 and pre-S2 components of the HBV surface antigen (HBsAg).
  • Adjuvanted with alum
  • Manufactured in mammalian cells
  • Pre-S1 antigen induces key neutralizing antibodies that block virus-receptor binding and T cell response to pre-S1 and pre-S2 antigens could further boost responses to the S antigens, resulting in a more immunogenic response 3,4.

OBJECTIVES

Co-primary objectives:
• Non-inferiority of seroprotection rates (SPRs) (>10 IU/mL) of Sci-B-Vac® vs. Engerix® in all participants age ≥ 18 years, 4 weeks after 3rd vaccination (at day 196)
• Superiority of SPR of Sci-B-Vac® vs. Engerix® in participants age ≥ 45 years, 4 weeks after 3rd vaccination (at day 196)

Secondary and Exploratory objectives:
• Non-inferiority of SPRs of Sci-B-Vac® after receiving the 2nd vaccination compared with Engerix® after receiving the 3rd vaccination.
• Reactogenicity (day 1-6), adverse events (AEs) at day 1-28 postvaccination and serious AEs, medically significant events or new onset of chronic illness (NOCI) during day 336.
• Comparison of geometric Mean Concentration (GMC) of anti-HBs at day 196

STUDY DESIGN

Immunogenicity

Figure 1:
Both PROTECT Co-Primary Endpoints Met

Nonsignificant differences were observed between Sci-B-Vac® and Engerix® in GMTs of anti-HBs levels (Figure 1), with no age-related differences found in GMTs of anti-HBs levels.

RESULTS

Figure 3:
SPRs for Sci-B-Vac® show a rapid increase in anti-HBsAg titers in all participants age 18+

Safety & Tolerability

Percentage of local AEs:

- Engerix®: 143/761 (19%) vs. Sci-B-Vac®: 146/761 (19%)
- Engerix®: 146/761 (19%) vs. Sci-B-Vac®: 143/761 (19%)

Figure 2:
(5-Hx) (GMC) was observed with Sci-B-Vac® after 3rd vaccination, across key subgroups

- Engerix®: 106 (14%) vs. Sci-B-Vac®: 107 (14%)
- Engerix®: 106 (14%) vs. Sci-B-Vac®: 107 (14%)

CONCLUSIONS

• SPR of Sci-B-Vac® was non-inferior to Engerix® in adults ≥18 years and superior in adults ≥45 years.
• Sci-B-Vac® demonstrated more rapid increase in seroprotection after the 1st and 2nd vaccinations; however it did not meet the secondary objective of non-inferiority of SPRs of Sci-B-Vac® after the 2nd vaccination compared with SPR of Engerix® after the 3rd vaccination.
• Sci-B-Vac® induced 5.8X higher antibody GMC compared to Engerix®.
• Higher rates of injection site pain, tenderness, and myalgia per injection were noted with Sci-B-Vac® compared to Engerix®; however, AEs were mostly mild-to-moderate in intensity. No safety signals were observed, and safety and tolerability were consistent with the known profile of Sci-B-Vac®.

PROTECT Study Participant Disposition

SCREENED: 2,472
Selection: 868 (35%)
RANDOMIZED: 1,607
26 clinical study sites in U.S., Europe, and Canada

FULL ANALYSIS SET:
Sci-B-Vac®: 796
Engerix®: 811

DISCLOSURE

We thank all clinicians, nurses, and volunteers who contributed to the study. The contribution of scientists and technologists at VBI Vaccines Inc. is greatly appreciated.

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REFERENCES

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