of ACAM2000 (Group 2). Peak neutralizing antibody GMTs were significantly higher following 2 MVA-BN doses (153.5) compared with ACAM2000 (79.3), with a ratio of 1.935 (95% CI: 1.562, 2.397). At Day 14, neutralizing antibody GMTs were equal following a single dose of either MVA BN or ACAM2000 (16.2, ratio of 0.997, 95% CI: 0.738, 1.348), with similar seroconversion rates (90.4% vs. 91.8%, respectively). The median MIA induced by ACAM2000 was significantly reduced when subjects received prior MVA BN in Group 1 (0 mm²) compared with Group 2 (76.0 mm²), suggesting protection against orthopoxvi- ruses. MVA BN was well tolerated, demonstrating a better safety profile than ACAM2000.

Conclusion. Two doses of MVA BN induce significantly higher peak neutralizing antibody responses compared with ACAM2000. A single dose induces an early neutralizing antibody response equal to ACAM2000 at Day 14, demonstrating the suitability of MVA BN in both pre- and post-outbreak scenarios. This study was partly funded by BARDA under contract HHSO100200700034C.

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LB13. Trivalent Hepatitis B (HepB) Vaccine Yields Superior Seroprotection Rates in Adults: Results from the Phase 3 Double-Blind, Randomized Study Comparing Immunogenicity and Safety of a 3-Dose Regimen of Sci-B-Vac® and Engerix B® (PROTECT)

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Background. Many adults fail to achieve seroprotection after receiving 3 doses of monovalent HepB vaccines such as Engerix B® and the response decreases with age and with common co-morbidities. Sci-B-Vac® is a trivalent HepB vaccine produced in mammalian cells, adjuvanted with aluminum hydroxide, which in addition to small S antigen, contains preS1 and preS2 antigens expressing highly immunogenic T- and B-cell epitopes that may enhance seroprotection rates (SPR) in adults.

Methods. In a multicentre study, the immunogenicity of 10 µg dose of Sci- B-Vac® compared with a 20-µg dose of Engerix-B® vaccine was evaluated in adults aged ≥18 years in 3 subgroups: (1) non-inferiority in adults ≥21 years and (2) superiority in adults ≥245 years of SPR, 4 weeks after the third dose.

Results. Of 1,607 randomized subjects, 42.3% were from United States, 41.6% EU, and 16.1% Canada. Males (38.5%) and females (61.5%) were enrolled to 18–44 (18.6%), 45–64 (44.6%), and ≥65 year (36.8%) age groups. Both co-primary endpoints were met. In the non-inferiority analysis, SPR in Sci-B-Vac® recipients aged ≥21 years was 91.4% vs. 76.5% for Engerix-B®; SPR difference: 14.9%: 95% confidence interval [11.2%, 18.6%]. Superiority analysis showed that SPR in Sci-B-Vac® recipients aged ≥245 years was 89.4% vs. 71.3% for Engerix-B®; SPR difference: 18.1% 95% CI [12.2%, 20.7%] (figure). Significantly higher SPR for Sci-B-Vac® vs. Engerix-B® was noted in subgroups (gender, BMI, diabetes, smoking and particularly age—SPR difference for 45–64 (14.7% [9.8–18.8%]) and 65 ≥18.9% [11.6–26.1%]) years). No major safety signals were observed; solicited and unsolicited adverse events were consistent with the known vaccine safety profiles.

Conclusion. Sci-B-Vac® met immunogenicity endpoints for non-inferiority in adults aged ≥21 years and was superior in adults aged ≥245 years, compared with the monovalent vaccine, Engerix-B®. Sci-B-Vac® SPR was higher compared with Engerix-B® in key subgroups. No safety signals were observed and safety and tolerability were consistent with the known profile of Sci-B-Vac®.

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LB14. Cerebrospinal Fluid Profiling of the Human Host Response Reveals Species-Specific Enteroviruses Signature in Acute Flaccid Myelitis Cases Francisco Diaz-Mitoma, MD, PhD1; Yael Sagris, PhD2; Manfred Grabb, PhD3; Asmeta Achari, MS4; Guixia Yu, BS5; Steve Miller, MD, PhD6; Scot Federman, BA7; Shaun Arevalo, BS8; Hannah Sample, BS9; Kelsey Zorn, MHS, BA10; Kathleen Harrus, PhD, MPH, RN11; Samuel Dominguez, MD, PhD12; Samuel Dominguez, MD, PhD12; Carol Glaser, MD, DVM13; Debra Wadford, PhD14; Kevin Messacar, MD15; Kevin Messacar, MD16; Michael Wilson, MD17; Charles Chiu, MD, PhD18; Charles Chiu, MD, PhD18. University of California, San Francisco, San Francisco, CA.

Background. Human enteroviruses (HEVs) are associated with acute flaccid paralysis (AFP) and long-term neurological sequelae, including acute flaccid myelitis (AFM). A novel outbreak of AFM identified a unique enterovirus D68 (EV-D68) epidemic in 2014. Research has revealed the importance of enteroviruses in AFM pathogenesis, but no study has systematically profiled the cerebrospinal fluid (CSF) of AFM patients to investigate the role of enteroviruses.

Methods. This study profiled the CSF of 11 patients with AFM using a multiplex droplet digital PCR (ddPCR) assay targeting common enterovirus genera and species, along with common co-infections. CSF samples were obtained at the time of admission and at discharge. EV-D68 and co-infections were identified by ddPCR and confirmed by qRT-PCR.

Results. We identified EV-D68 in the CSF of 6 (55%) patients, and in 5 of these 6 we also identified a co-infection. Co-infections were human rhinovirus (HRV) in 5 patients, EV-A91 in 2 patients, and EV-A61 in 1 patient. The co-infections were detected in both the admission and discharge CSF samples. EV-D68 was detected in all 6 patients with EV-D68-only infection, and in 5 of 6 patients with co-infection.

Conclusion. Our study provides the first systematic profiling of the CSF in AFM patients and highlights the role of enteroviruses in AFM pathogenesis.

Disclosures. Francisco Diaz-Mitoma, MD, VBI Vaccines (Employee, Shareholder)