Sci-B-Vac® PROTECT Phase III Top-Line Data
Forward-Looking Statements

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### Sci-B-Vac®: Two Ongoing Phase III Studies to Support Approval in U.S., Europe, and Canada

| Phase III Study | PROTECT  
| 2-arm safety and immunogenicity study | CONSTANT  
| 4-arm lot-to-lot consistency study |
|---|---|
| **N size** | 1,607 | ~2,900 |
| **Control Vaccine** | Engerix-B® (GSK) | Engerix-B® (GSK) |
| **Primary Endpoint(s)** | Based on seroprotection rates (SPR):  
  i. Non-inferiority in adults ≥ age 18  
  ii. Superiority in adults ≥ age 45 | Consistency of immune response as measured by Geometric Mean Concentration (GMC) of antibodies across three consecutively manufactured lots of Sci-B-Vac® |
| ** Secondary Endpoint(s)** | i. Safety and tolerability  
  ii. Non-inferiority of SPR in adults ≥ age 18 after 2 doses of Sci-B-Vac® vs. 3 doses of Engerix-B® | Safety, tolerability, and SPR |
| **Expected Top-Line Data Readout** | Today (6/17/2019) | Around year-end 2019 |
PROTECT Study Subject Disposition

Subjects screened (n=2,472)

Screening failure (n=865, 35%)

Randomized (n=1,607) at 28 clinical study sites in U.S., Europe, and Canada

Engerix-B (n=811)
- Age:
  - 18-44 years: 154 (19%)
  - 45-64 years: 361 (45%)
  - 65+ years: 296 (37%)
- Gender:
  - Male: 303 (37%)
  - Female: 508 (63%)
- Withdrew: 42 (5.2%)

Completed study (n=769)

Full Analysis Set

Sci-B-Vac (n=796)
- Age:
  - 18-44 years: 145 (18%)
  - 45-64 years: 355 (45%)
  - 65+ years: 296 (37%)
- Gender:
  - Male: 315 (40%)
  - Female: 481 (60%)
- Withdrew: 40 (5.0%)

Completed study (n=756)

Per Protocol Set
Both PROTECT Co-Primary Endpoints Successfully Met

Co-Primary Endpoints at Day 196, 4 weeks post-3rd vaccination:

1. Non-Inferiority of seroprotection rate (SPR) achieved in all subjects age 18+
2. Statistical and clinical superiority, as defined in the protocol, achieved in subjects age 45+

- **Engerix-B 20µg Sci-B-Vac 10µg**
- N = 723
- N = 718

**Percent HBsAg Seroprotection**

- **91.4%**
- **76.5%**
- **Diff: 14.9%**
- 95% CI [11.2% to 18.6%]

- **Sci-B-Vac 10µg**
- **95% CI [11.2% to 18.6%]**

- **Engerix-B 20µg Sci-B-Vac 10µg**
- N = 627
- N = 625

**Subjects age 45 + (Full Analysis Set)**

- **89.4%**
- **73.1%**
- **Diff: 16.4%**
- 95% CI [12.2% to 20.7%]

- **Engerix-B 20µg Sci-B-Vac 10µg**
- **95% CI [12.2% to 20.7%]**

**Non-inferiority:** If the lower bound of the 95% confidence interval (CI) of the difference between the SPR in the Sci-B-Vac arm minus the SPR in the Engerix-B arm is > -5%, Sci-B-Vac will be declared non-inferior to Engerix-B.

**Statistical superiority:** If the lower bound of the same 95% CI is greater than 0%, Sci-B-Vac will be declared statistically superior to Engerix-B.

**Clinical superiority:** If the lower bound of the same 95% CI is > 5%, Sci-B-Vac will be declared clinically superior to Engerix-B.
Kinetics of Seroprotection Rates by Age Groups

**All Ages (18+)**

- Engerix-B
- Sci-B-Vac

**Ages 18-44**

- Engerix-B
- Sci-B-Vac
Seroprotection Rates in Subgroup Populations

SPR of Sci-B-Vac® vs. Engerix-B® was statistically significantly higher in all key subgroup analyses of adults age ≥ 18 years, at Day 196, 4 weeks post-3rd vaccination, including:

- **Diabetics**
  - 58.3% Engerix-B® vs. 83.3% Sci-B-Vac®
  - SPR difference: 25.0%; 95% CI [8.4%, 40.4%]

- **Subjects with a Body Mass Index (BMI) > 30**
  - 68.1% Engerix-B® vs. 89.2% Sci-B-Vac®
  - SPR difference: 21.1%; 95% CI [14.3%, 28.0%]
Anti-HBsAg Titers in Subgroup Populations

5-8x fold higher antibody GMC is maintained for patients who received Sci-B-Vac vs. Engerix-B regardless of age, BMI, or diabetes status

Error bars = SD; The GMC and SD are calculated based on log10-transformed data, then transformed back to Anti-HBsAg Antibody titer
Summary of Safety Data (1)

OVERALL:

• No safety signals observed in PROTECT
• Sci-B-Vac safety profile consistent with previous studies and post-marketing use (Israel)
• High rate of completion of vaccinations, 96.8% and 95.2% for Engerix-B and Sci-B-Vac, respectively
• Low rate of vaccine discontinuation due to non-serious adverse events (AEs) of 0.4% vs. 0.4% and due to SAEs of 0.2% vs. 0.3% for Engerix-B and Sci-B-Vac, respectively

REACTOGENICITY – SOLICITED AEs:

• Higher rates of mild-to-moderate injection site pain, tenderness and myalgia reported by subjects receiving Sci-B-Vac compared to Engerix-B
• Reactogenicity symptoms generally resolved without intervention within 1-7 days
• No increase in reactogenicity symptoms over the 3-dose vaccination schedule
## Summary of Safety Data (2)

### Serious Adverse Events (SAEs)

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<th>Engerix-B®</th>
<th>Sci-B-Vac®</th>
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<td>Total SAEs (63)</td>
<td>21 (2.6%)</td>
<td>32 (4.0%)</td>
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**SAEs occurring in ≥ 2 subjects:**

- **Atrial Fibrillation**: 2 (0.2%) 1 (0.1%)
- **Cardiac failure congestive**: - 2 (0.3%)
- **Colon cancer**: 2 (0.2%) -
- **Cholelithiasis**: 1 (0.1%) 1 (0.1%)
- **Ankle fracture**: 1 (0.1%) 1 (0.1%)
- **Osteoarthritis**: 1 (0.1%) 1 (0.1%)
- **Cerebrovascular accident**: 1 (0.1%) 1 (0.1%)

### Unsolicited Adverse Events (AEs)

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<th>Engerix-B®</th>
<th>Sci-B-Vac®</th>
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<td>1+ AEs reported (% of sub.)</td>
<td>54.5%</td>
<td>52.5%</td>
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**AEs reported by ≥ 1% of subjects:**

- Headache: 8.3% 8.5%
- URI: 6.7% 6.3%
- Fatigue: 4.9% 4.1%
- Nasopharyngitis: 3.5% 3.9%
- Injection site pain: 1.6% 2.9%
- Back pain: 2.8% 4.4%
- Arthralgia: 2.5% 2.1%
- Diarrhea: 2.6% 1.3%
- UTI: 2.1% 2.1%
- Oropharyngeal pain: 2.2% 1.9%
- Dizziness: 1.2% 1.5%
- Sinusitis: 2.1% 1.4%
- Hypertension: 1.6% 1.3%
- Respiratory rate increase: 0.9% 1.3%
- Gastroenteritis: 0.5% 1.3%
- Nausea: 1.2% 0.4%
- Cough: 1.0% 1.1%
- Neck pain: 1.1% 0.8%
- Bronchitis: 0.7% 1.0%
- Muscle strain: 0.7% 1.0%

- Only one SAE, viral gastroenteritis, reported by site investigator as probably related to study vaccine (Sci-B-Vac®)
- No clusters or unusual patterns of SAEs – generally consistent with characteristics of study population (age 18-90 years)
Conclusions & Next Steps

• PROTECT top-line data showed Sci-B-Vac® to have higher rates of protection in all adults, when compared with Engerix-B®, with statistical and clinical superiority in adults age 45 years and older

• This data reaffirms the clean safety profile of the vaccine, with no safety signals observed

• Subgroup analyses show that Sci-B-Vac® elicits statistically significantly higher SPR compared with Engerix-B® in key immunocompromised populations including obese individuals, diabetics, and elderly

• Data from CONSTANT is expected to expand the safety data base as well as provide additional efficacy data in the adult population age 18-45 years

NEXT STEPS:

• Around year-end 2019: CONSTANT top-line data expected

Subject to successful completion of CONSTANT:

• Beginning mid-year 2020: Expected submissions of applications for regulatory approvals in the U.S., Europe, and Canada