



VBI VACCINES

A horizontal band with a warm orange and brown color palette. It features a blurred, microscopic image of cells, possibly showing cellular structures and membranes, which is typical for a vaccine-related presentation.

Sci-B-Vac[®] PROTECT Phase III Top-Line Data

Forward-Looking Statements

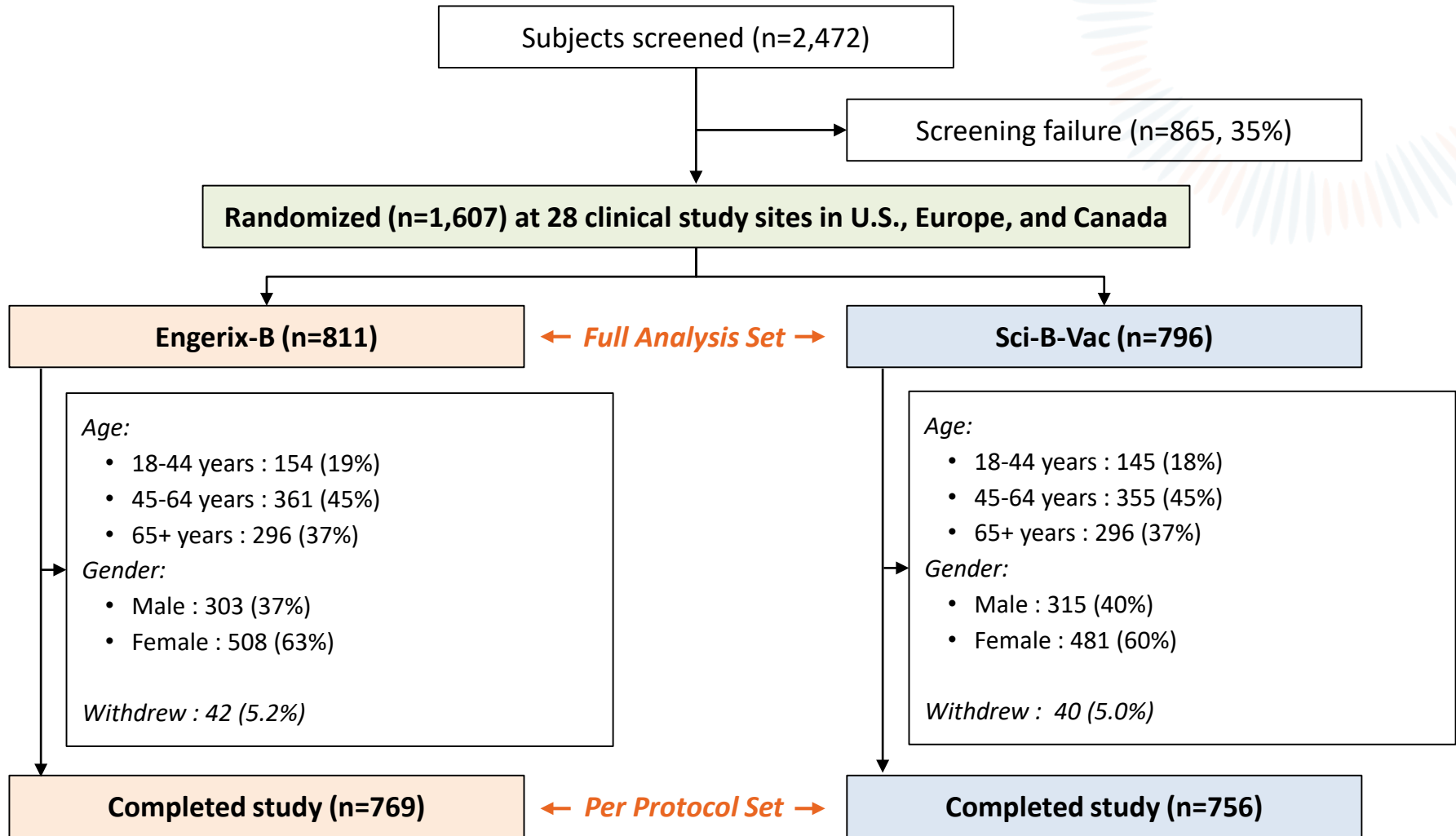
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Sci-B-Vac[®]: Two Ongoing Phase III Studies to Support Approval in U.S., Europe, and Canada

Phase III Study	PROTECT <i>2-arm safety and immunogenicity study</i>	CONSTANT <i>4-arm lot-to-lot consistency study</i>
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 \geq age 18 ii. Superiority in adults \geq 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 \geq 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

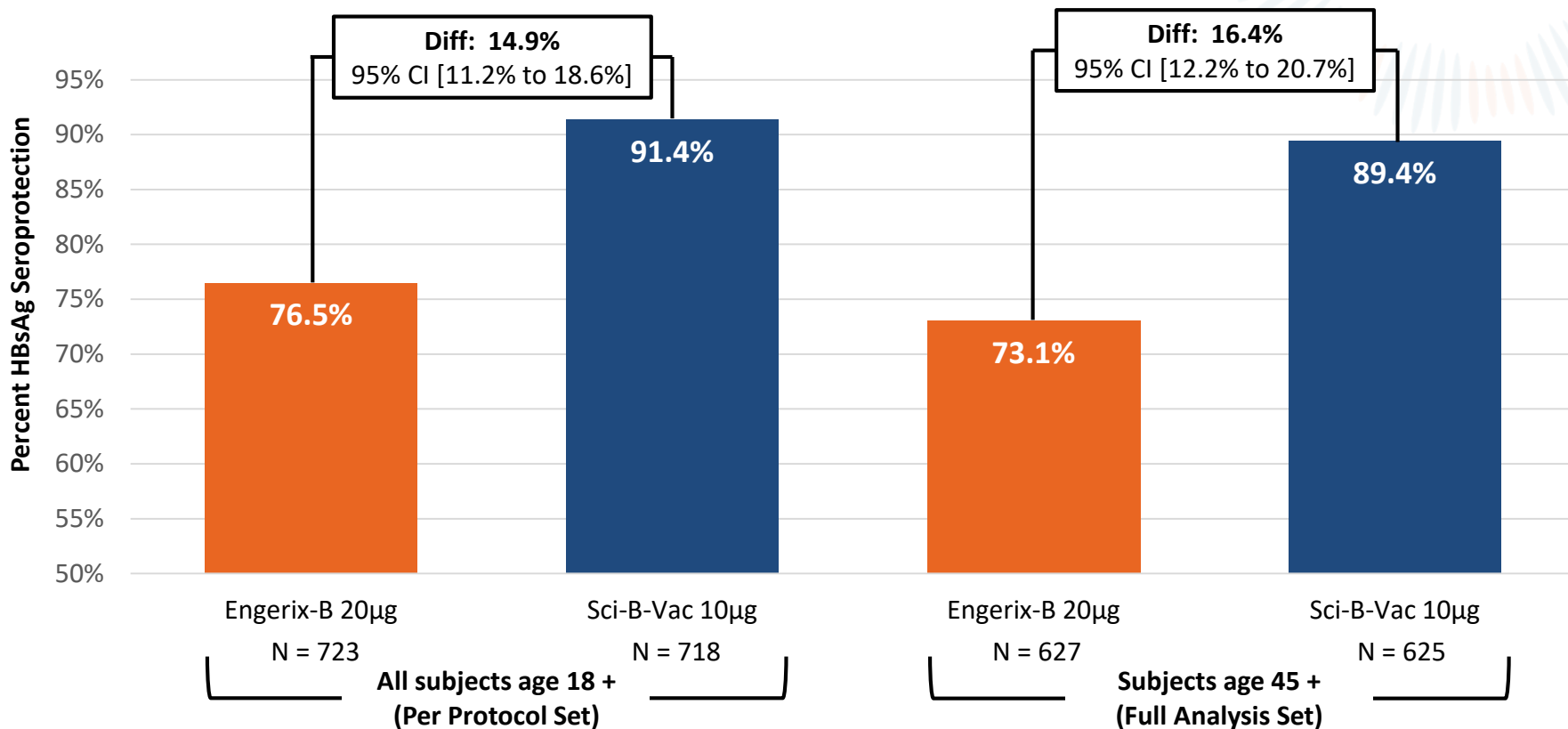


Both PROTECT Co-Primary Endpoints Successfully Met

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

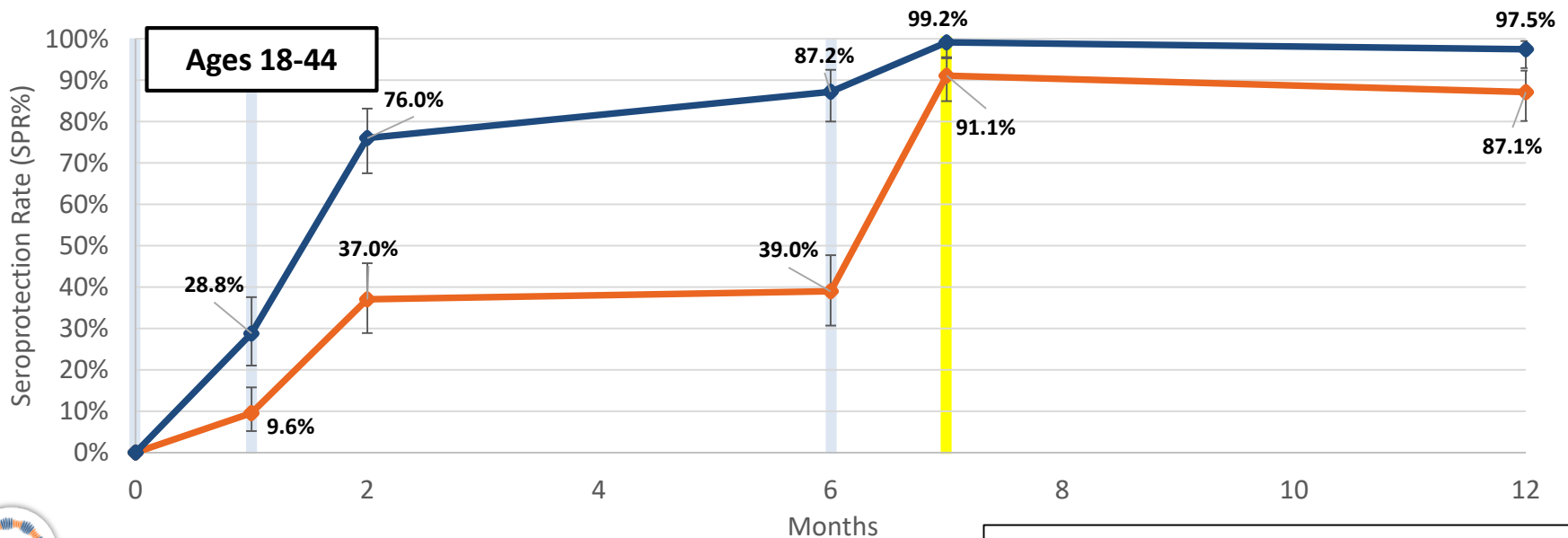
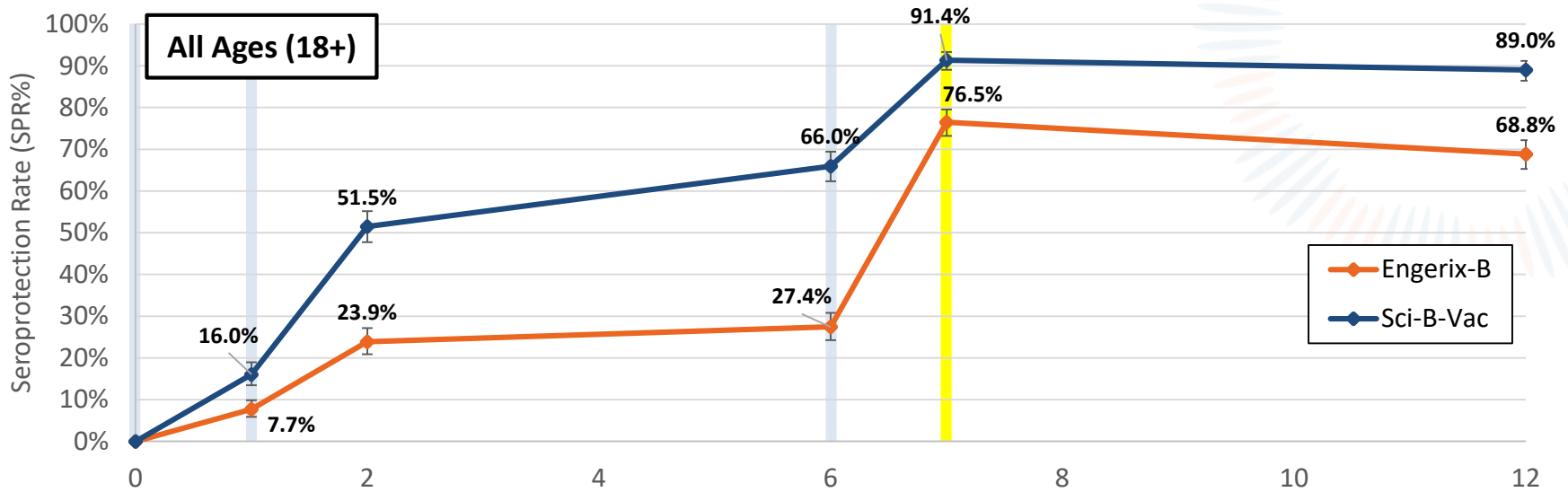
1. Non-Inferiority of seroprotection rate (SPR) achieved in all subjects age 18+

2. Statistical and clinical superiority, as defined in the protocol, achieved in subjects age 45+



- *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



■ - Vaccinations
 ■ - Time of analysis of co-primary endpoints



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%]

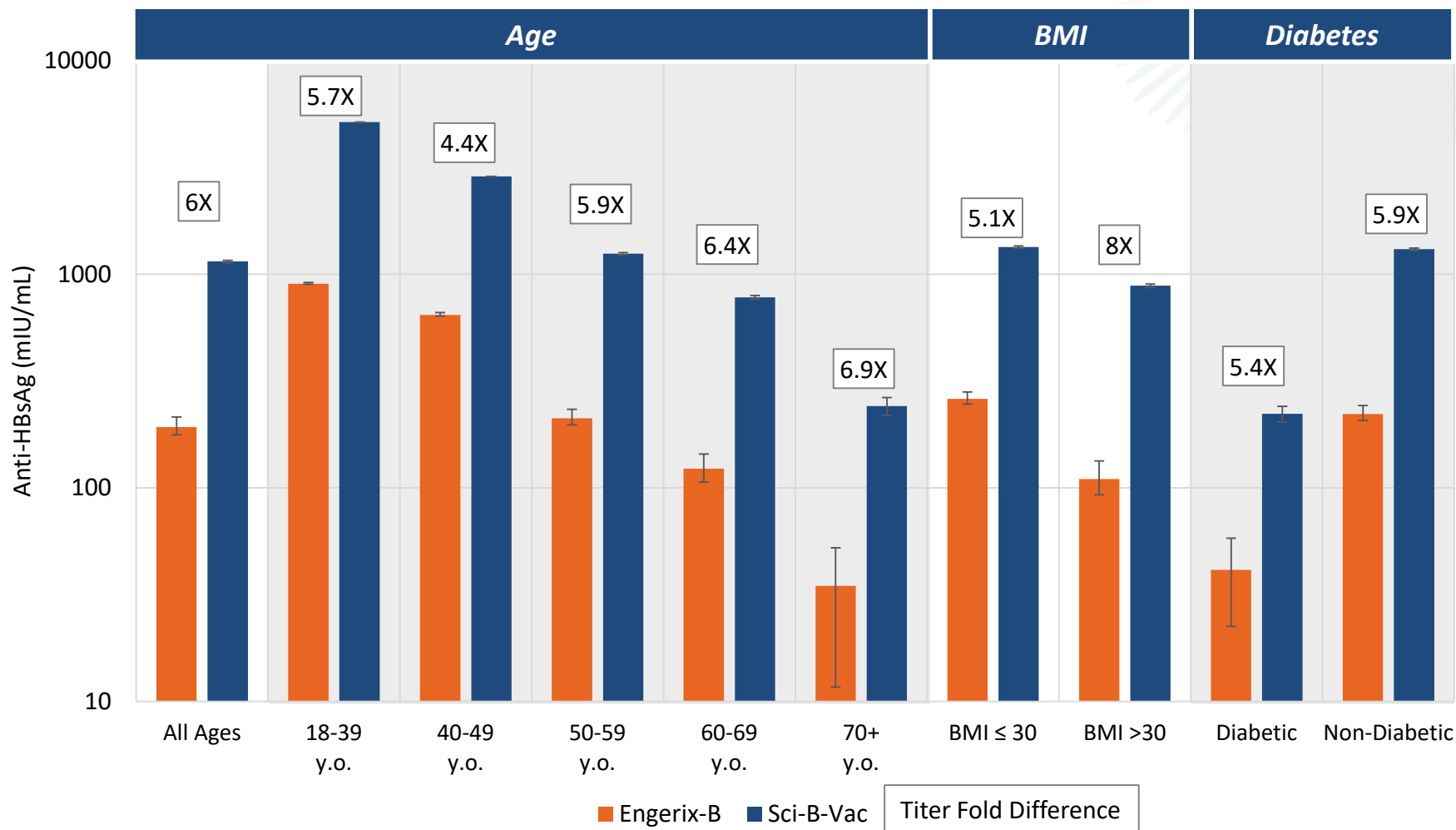
**Subjects with a Body
Mass Index (BMI) > 30**

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)

	Engerix-B®	Sci-B-Vac®
Total SAEs (63)	21 (2.6%)	32 (4.0%)
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%)

- 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)

Unsolicited Adverse Events (AEs)

	Engerix-B®	Sci-B-Vac®
1+ AEs reported (% of sub.)	54.5%	52.5%
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%

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



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