# VACCINES

## DRUG DEVELOPMENT SOLUTIONS

SGS

# FROM MOLECULE TO MARKET

## SGS PROVIDES A COMPLETE SERVICE PACKAGE TO SUPPORT THE CLINICAL DEVELOPMENT OF YOUR VACCINE COMPOUND

Developing vaccine therapies for the market requires a special kind of expertise and a comprehensive range of specialized analytical and clinical capabilities. SGS understands the challenges of vaccine development and has over 35 years of experience as a global contract service organization. SGS provides integrated vaccine solutions from preclinical activities to phase I-IV clinical trials, including biosafety, bioanalytical and quality control testing.

Guided by a consultative approach, SGS enables clients to efficiently and successfully achieve their vaccine program objectives with services including:

### CLINICAL RESEARCH

- Exploratory trials
- Healthy volunteer and patient studies
- Scientific and regulatory consultancy
- Clinical pharmacology units (172 beds) and global network of investigator sites
- Trial monitoring and project management
- Biometrics (data management, statistics, PK/PD analysis, secure data office, medical writing)
- Medical affairs and pharmacovigilance

### ANALYTICAL TESTING

- Biosafety testing including virology, electron microscopy, molecular biology and microbiology tests
- Biopharmaceutical testing and protein characterization
- Quality control testing
- Biomarkers & immunogenicity testing including ELISA, multiplex and flow cytometry

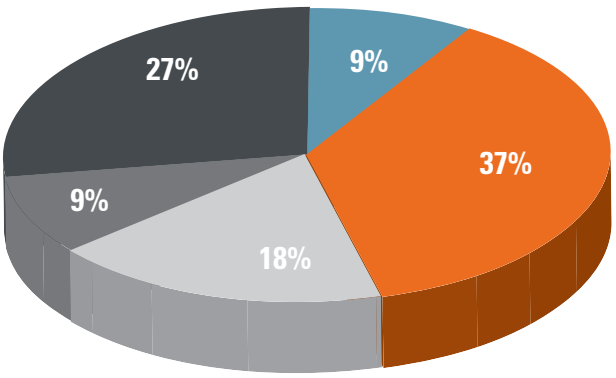
### PREVENTION TO THERAPEUTIC

While the original goal of vaccination was prevention of viral and bacterial infections, this paradigm is shifting towards therapeutic vaccination in indications such as oncology, auto-immune diseases, allergy, diabetes and infectious diseases. In addition, the platforms used to generate vaccines have shifted from the traditional protein targets to more efficient platforms using genome based approaches and nanotechnologies, including immunomodulation.

SGS's experience spans the full spectrum of services from Phase I through Phase IV, with two of Europe's largest Phase I centers and a Bioanalytical testing laboratory providing immunoassay and streamlined support for First in Human Trials. SGS has the capacity and expertise to develop and deliver the most complex trials requiring supportive molecular screening techniques as well as large, international scale patient trials.

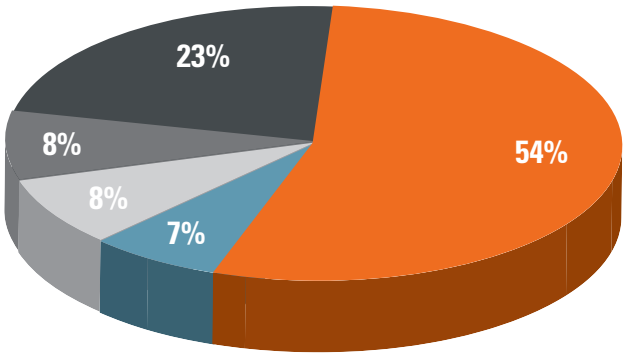
The evolution from pediatric/adult, preventive, combination vaccines to adult therapeutic vaccines by using new platforms, technologies, delivery and manufacturing solutions, is also demonstrated by the growing experience in therapeutic vaccines within SGS.

### VACCINE PROJECTS BY STUDY PHASE




- Phase 1
- Phase 2a
- Phase 2b
- Phase 3
- Phase 4

### VACCINE PROJECTS BY DISEASE CONDITION




- Influenza
- Hepatitis
- Other Viral
- Therapeutic
- Bacterial

Total number of vaccine projects = 13

## VOLUNTEERS, SPECIAL POPULATIONS AND PATIENTS

- Extensive database of volunteers and patients for fast recruitment of large populations (groups of up to 400 participants at a single site)
  - o Including access to special populations: elderly, renal impaired, etc.
- Expansion to larger populations (up to 1,000 participants) via our SMO network

## EXTENSIVE PROJECT MANAGEMENT EXPERIENCE

- Aggressive recruitment timelines in all trial phases
- SGS maintains operational control – ensuring consistency across the sites
- All study-related procedures can be performed by SGS staff, together with the sites' investigator, reducing training time and increasing protocol adherence
- Close collaboration with KOL's and immediate access to specialists and the necessary equipment
- Large experience in complex sample handling on site

## THERAPEUTIC EXPERIENCE

- HIV
- HCV
- HBV
- Influenza
- Anti-enterotoxigenic E. coli
- Lyme disease
- Tick borne encephalitis
- Epstein Barr Virus
- Nicotine (smoking cessation)
- Meningococcus Band Influenza

## FACILITIES

- Favorable regulatory environment enables fast study start-up
- Two FDA-inspected Clinical Pharmacology Units (172 beds) in Belgium and France
- Global Clinical Trial Monitoring and Management covered by seven offices in Europe and North America
- International network of 19 analytical laboratories across, Europe, America and Asia

## CASE STUDIES

### PHASE I THERAPEUTIC VACCINE

A Phase 1, First-in-Human, randomized, double-blind, placebo-controlled study to assess the safety and pharmacodynamics of increasing subcutaneous doses of a nanobody vaccine in healthy non-smoker and smoker adults.

The primary objective was to assess the safety and pharmacodynamics (PD) of a prime, a boost (28 days apart) and a second boost (on day 85) subcutaneous injection, of the vaccine in healthy volunteers aged ≥18 years and ≤ 60 years, both non-smokers and smokers. The secondary objective was to measure anti-nicotine antibody (Ab) concentrations as an indication of activity during 9 months (approximately) after the first injection. The study was conducted in 48 smoker and 62 non-smoker subjects.

The major challenge was in the regulatory aspects of the new GMO-based technology. The CPU has the necessary class II environmental license in Belgium allowing handling such products and has been working this way for the past 10 years.

The new technology, a nanobody-based vaccine, is a new platform, allowing very quick development of new vaccines against a large number of different epitopes. In this case nicotine was chosen because of the simplicity of the epitope. The difficulty to obtain approval lies in the limited preclinical toxicologic data because of the nature of the particle (only GLP compliant toxicology in cynomolgous monkeys), and the limited IMPD. Scientific and technical advice was requested from the authorities and finally they agreed to conduct the study without additional preclinical data.

### PHASE III PREVENTIVE VACCINE

A Phase III pivitol clinical trial in healthy adults for influenza was conducted across 37 sites with approximately 7,500 participants.

- Electronic Data Capture (EDC), Interactive Voice Response System (IVRS) and an electronic patient reported outcome (i.e., electronic diary) (ePRO) systems were implementated to execute randomization, study drug release and data collection
- To meet competitive enrollment targets of full enrollment within 7-10 business days, SGS had rigorous requirements for site participation, and site-specific enrollment plans.
- All site initiation visits were coordinated to occur within two days of each other.
- Each site had their own dedicated lead Clinical Research Associate (CRA), with at least one secondary CRA, which were on location during Day 1 at each investigator site to ensure quick resolution and direction for site-generated questions as well as immediate correction of any missteps by the site regarding protocol procedures.
- Daily site enrollment reports proved very valuable to track actual versus planned enrollments. with shifting of targeted enrollments by site.

## SGS IS THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY

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WHEN YOU NEED TO BE SURE

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