

# **SK Bioscience**

# The Growth Strategy Driven by Two Engines, PCV & IDT









1) SKYVAX : SK Bioscience's in-house developed vaccine portfolio

# Growth Engine 1

# PCV & DT



#### NextGen PCV

# Confidence in the Success of the PCV Vaccine for Extends to the Co-Development of Next-Generation PCV

#### **Importance of PCV**

# Expected to Reach 19T KRW by 2030, become the largest market in the global vaccine industry

'24~'30 Market CAGR ~8%, expected continuous growth

 Approx. 300,000 children die annually from pneumococcal infections, increasing public burden and vaccine demand, with the pediatric market accounting for ~70% of the total



#### NextGen PCV Co-Development

Securing Upside Potential while Minimizing Investment Risks to Maintain and Strengthen Market Presence in the PCV Market



#### Total €350M (Approx. 530B KRW) + Royalty

- ✓ Upfront : €50M (received upon contract signing)
- ✓ Milestone : €300M (received in stages of

Development/Approval/Commercialization)

✓ Royalty: Received as an agreed percentage of net sales





# Secured Competitive Strength Enabling Market Presence upon Launch







- 1Competitive Immunogenicity & Safety2Optimal IPD coverage
- Sanofi Global Marketing Capabilities
- Optimal Manufacturing Preparedness

#### PCV21 Global Phase 2 Study Results

#### Sufficient Immunogenicity Across All Serotypes



Validated PCV platform for over 20 years and confirmed safety in Phase 2 Results

#### **Competence in Key Serotype 3**

- Serotype 3 remains highly prevalent despite being included in existing vaccines
   \*IPD coverage : Approx. 13% in the US and 15% in Europe, ranking 1st or 2nd in prevalence
- Expected competitive advantage with superior immunogenicity based on a 3-dose regimen compared to competing products

#### Designed with Optimal Combinations of Various Carrier Proteins

 Confirmed high immunogenicity of TT-conjugated serotypes (1, 5, 15B, 22F)



# Secured Competitive Advantage in IPD Coverage from Prevention to Cure Through Optimal Serotype Combination

Competitive Immunogenicity & Safety

#### **Optimal IPD coverage**

- **3** Sanofi Global Marketing Capabilities
- Optimal Manufacturing Preparedness

#### Not just a 'Valency Count Competition', but a 'IPD Coverage Competition'

#### What is IPD<sup>1)</sup> coverage?

• A measure of how effectively a specific vaccine prevents Invasive Pneumococcal Disease

(the proportion of total IPD cases covered by serotypes included in the vaccine)

## The importance of serotype selection is increasing due to changes in epidemiology

• IPD coverage varies over time and by region depending on existing vaccine administration

혈청형	4	6B	9∨	14	18C	19F	23F	1	5	7F	3	6A	19A	22F	33F	8	10A	11A	12F	15B 15C	9N
PCV13	4	6B	9∨	14	18C	19F	23F	1	5	7F	3	6A	19A								
PCV15 (MSD)	4	6B	9∨	14	18C	19F	23F	1	5	7F	3	6A	19A	22F	33F						
PCV20 (Pfizer)	4	6B	9∨	14	18C	19F	23F	1	5	7F	3	6A	19A	22F	33F	8	10A	11A	12F	15B	
PCV21/소아 (Sanofi)	4	6B	9∨	14	18C	19F	23F	1	5	7F	3	6A	19A	22F	33F	8	10A	11A	12F	15B	9N

PCV21 includes the 9N serotype in addition to the existing 20-valent vaccine, increasing IPD coverage by 5-7%



#### 9N serotype is …

• The major serotypes with the 3rd to 5th highest incidence recently in the US and EU

Source : US ABC data, ECDC Surveillance Atlas



Rapid Market Share Acquisition with PCV21, from Strengthening Market Presence with NextGen PCV

- 1 Competitive Immunogenicity & Safety
  - Optimal IPD coverage
- 3 Sanofi Global Marketing Capabilities
- Optimal Manufacturing Preparedness

At Launch, PCV21 is Expected to be Best-in-Class in the Pediatric Market



# Sanofi's Global Market Share in Pediatric Vaccines ranges 40~100%

• Experience in supplying vaccines to major NIP<sup>2</sup>) programs and established public/private distribution channels ensure high market share



- 1) '18~'22, all ages, Coverage range in the US and EU
- 2) NIP : National Immunization Program
- 3) Dtap : Diphtheria, Tetanus, and Pertussis, IPV : Inactivated Poliovirus Vaccine, HiB : Hemophilus influenzae type B

## **Readiness for PCV Commercial Production**



- Competitive Immunogenicity & Safety
  - Optimal IPD coverage
- 3 Sanofi Global Marketing Capabilities
- 4 Optimal Manufacturing Preparedness



#### Sanofi Val-de-Reuil (FR)

- EU's largest vaccine production facility with a size of approx. 300,000m<sup>2</sup>
- Al-based innovative production capabilities

1) BSL-3 : Biological Safety Level-3 / cGMP : current Good Manufacturing Practice

y & Safety pabilities aredness

#### Andong L-house (KR)

- EMA EU-GMP certification in 2021
- Proven track record in global vaccine CDMO
- Completed scale-up for PCV21 phase 3 clinical trials
- Commercial production readiness for PCV secured with the construction of G2+ ('25.05)



#### IDT Biologika (DE)

- Proven track record over 100 years
- BSL-3 cGMP<sup>1)</sup> commercial production facility
- Approved by 10+ major regulatory agencies, including FDA, EMA, PMDA<sup>2)</sup> etc.

2) FDA : Food and Drug Administration / EMA : European Medicines Agency / PMDA : Pharmaceuticals and Medical Devices Agency

# Growth Engine 2 PCV & IDT



IDT Biologika

# IDT Targets a Turnaround in '25 Aiming for a 17.4% CAGR Growth by '28





#### **Top line Growth**

#### Sufficient Additional Order Potential Verified, Further Orders in Progress

- Discussing with new clients and securing additional volumes from existing clients to maximize utilization
- Exploring co-investment with clients to secure new DP business opportunities

#### Plan to Secure SK Group Synergy and Drive CGT Expansion

- Opportunities to secure project orders in cooperation with global initiatives and Big Pharma
- Future expansion opportunities in NextGen PCV, CGT<sup>1</sup>, and mRNA

#### **Bottom line Improvement**

#### Achieving a Stable EBITDA Margin of Over 25% by 2028

- Successfully exceeded the 2024 EBITDA improvement target
- Execution of the 5 key optimization project identified through PMI
- Driving FTE management and SG&A expense reduction

# **Next steps**

# mRNA



## Refining the Expansion Strategy Based on the mRNA Platform



#### A Commercially Validated mRNA Platform Secured

Combining proprietary technologies and patents with competitively commercialized technologies through L/I

UTR <sup>1)</sup>	In-houso	<ul> <li>Proprietary pDNA IP,</li> </ul>
Poly A 3' <sup>2)</sup>	III IIUUSE	specific sequence structures secured
5'Cap <sup>3)</sup>	License-in	Trilink, CleanCap
LNP <sup>4)</sup>	License-in	Acuitas

#### Securing/Developing a Validated Pipeline through CEPI<sup>5)</sup> Funding

 Exploring potential contributions to public health and private market entry through global initiative collaborations

	Phase 1 fundin	ng \$40M secur	ed Discus fundin	sing additional g of \$100M			
JEV	(25.02)	Phase 1/2	Planne	Planned to be pursued			
Lassa Fever Vaccine	Antigen selection	'26 initiation target	Panden	nic preparedness ready			
	Pre-clinical/ PD	Phase 1/2	Phase 3	Approval commercialization			



Target to be specified based on platform (~'25.1H)

1) UTR : Untranslated region

- 2) Poly A 3': A long chain of adenine nucleotides
- 3) 5'Cap : Plays a crucial role in enhancing intracellular stability and facilitating the initiation of translation
- 4) LNP : Lipid nano particle, Carrier that delivers mRNA molecules into cells
   5) CERL Control of Control o
- 5) CEPI : Coalition for Epidemic Preparedness Innovations



bioscience

from Prevention to Cure

# 5 Pillars Progress Updates

5 Pillars

## **5 Pillars Progress Updates**



#### SKBS 3.0

Pillar 1	Pillar 2	Pillar 3	Pillar 4	Pillar 5
Expansion of Vaccine Portfolio	Strengthening of R&D/ Manufacturing Infra	Execution of SKYShield	Next Pandemic Preparedness	New Bio Biz Expansion
<ul> <li>Initiating differentiated flu phase 1 clinical trial within this year</li> <li>HPV9+ clinical trial initiation in '26</li> <li>Pan Sarbeco<sup>1)</sup> phase 1/2 clinical trial within this year</li> <li>Initiating phase 1/2 trial for mRNA Japanese Encephalitis vaccine</li> <li>Development of Rota vaccine based on collaboration with CDC<sup>2)</sup></li> </ul>	<ul> <li>Songdo R&amp;PD center ('25.12 completion, '26.02 occupancy)</li> <li>Securing PCV commercial production infrastructure with G2+ completion (May 31, 2025)</li> <li>Enhancing yield and upgrading to cGMP standards at Andong L-house using AI</li> </ul>	<ul> <li>Promoting local vaccine development and manufacturing localization based on a Public-Private partnership with the Thai government</li> </ul>	<ul> <li>2 Track strategy         <ul> <li>R&amp;D Capabilities : Securing Next Pandemic Platform such as mRNA</li> <li>Manufacturing Capability: Securing facilities and strengthening track record through IDT and Songdo R&amp;PD</li> </ul> </li> </ul>	<ul> <li>Expanding CGT based on IDT capabilities</li> <li>Specification of expansion target based on mRNA Platform</li> </ul>

#### SK bioscience

1) Pan Sarbeco : Pan-Sarbecovirus vaccine, broad protection against multiple sarbecoviruses

2) Centers for Disease Control and Prevention



#### **Appendix : Abbreviations and Terminology**

5'Cap	Plays a crucial role in enhancing intracellular stability and facilitating the initiation of translation
BSL-3	Biological Safety Level-3
CDC	Centers for Disease Control and Prevention
cGMP	Current Good Manufacturing Practices
CGT	Cell and Gene Therapy
Dtap	Diphtheria, Tetanus, and Pertussis
EMA	European Medicines Agency
FDA	Food and Drug Administration
HiB	Hemophilus influenzae type B
HPV	Human Papilloma Virus
IPD	Invasive Pneumococcal Disease
IPV	Inactivated Poliovirus Vaccine
JEV	Japanese Encephalitis Virus
Lassa	Lassa Fever
LNP	Lipid nano particle
mRNA	Messenger RNA
NIP	National Immunization Program
Pan Sarbeco	A vaccine providing broad protection against multiple sarbecoviruses
PCV	Pneumococcal Conjugate Vaccine
Poly A 3'	A long chain of adenine nucleotides
PMDA	Pharmaceuticals and Medical Devices Agency
SKYShield	SK bioscience's global vaccine Hub establishment project
SKYVAX	SK bioscience's in-house vaccine portfolio
UTR	Untranslated Region



# Q&A





## MISSION WE PROMOTE HUMAN HEALTH, FROM PREVENTION TO CURE

**GLOBAL INNOVATIVE PARTNER** OF VACCINE AND BIOTECH

