Valneva and LimmaTech Enter into a Strategic Partnership to Accelerate the Development of the World's Most Clinically Advanced Tetravalent Shigella Vaccine Candidate ("S4V")

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valneva

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This presentation presents information about investigational vaccine candidates that have not been approved for use and have not been determined by any regulatory authority to be safe or effective.

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Opportunity to develop first-in-class vaccine for a life-threatening disease

Expected to provide near-term R&D upside for investors with appealing risk-benefit profile

Aligned with Our Vision

- Addresses significant unmet medical need; Shigellosis is devastating for infants and children in LMICs[1]
- An important public health goal, considering potential for herd immunity protection from all-cause diarrhea
- Rising antimicrobial-resistant enteric bacteria

Aligned with Our Mission

- Differentiated asset with potential for first-in-class vaccine solution
- Augments clinical stage pipeline – anticipated Phase 3 initiation post potential Lyme approvals (2027)
- Potential “Plug-and play” with existing vaccine portfolio (Travel, Military, LMIC)

Aligned with Our Corp. Strategy

- Expected to provide near-term R&D upside for investors
- Aligns with mid-term R&D capital allocation strategy and guidance
- Risk-mitigating, staggered development plan: multiple catalysts and decision points

1 Low- and middle-income countries

Strategic Partnership with LimmaTech Biologics (“LMTB”)

Valneva gains exclusive worldwide rights to world’s most clinically advanced tetravalent Shigella program (“S4V”)

LMTB

- Clinical-stage biotech company with decades of expertise in vaccine technology and disease-specific vaccine development approaches
- Backed by specialist healthcare investors
- Expanding a pipeline focused on innovative vaccine candidates against antimicrobial-resistant pathogens
- Multi-valent bioconjugate vaccine against E. coli developed with Janssen and acquired by Sanofi; now in Phase 3
- Long-term partnerships with Pharma and NGOs

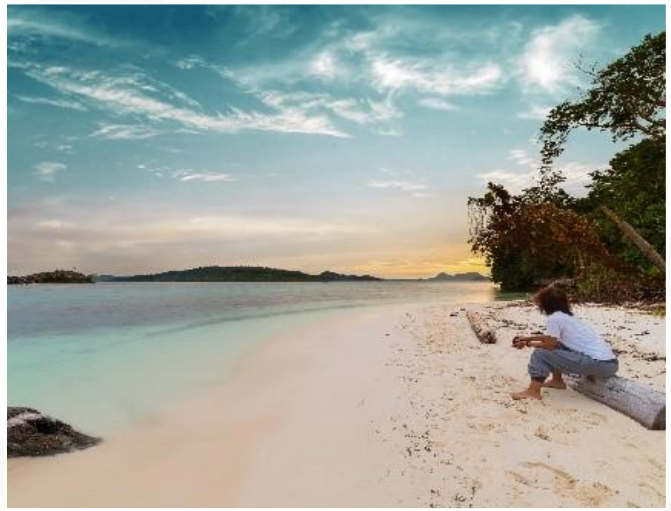
Vaccine candidate “S4V”

- World’s most clinically advanced tetravalent Shigellosis vaccine candidate
- Tetravalent bioconjugate vaccine for prevention of disease caused by Shigella bacteria (O-antigens of *S. flexneri* 2a, 3a, 6 and *S. sonnei)*
- Developed following positive proof-of-concept clinical data with monovalent vaccine candidate, which demonstrated promising efficacy in challenge model
- LMTB reported positive Phase 1/2 clinical data on S4V, including robust immunogenicity against all strains; favorable safety and tolerability[1]

1 https://lmtbio.com/wp-content/uploads/2024/02/20240221_LimmaTech_Shigella-Interim-Data-PR_Final.pdf

Shigellosis: Significant Unmet Medical Need[1]

No approved *Shigella* vaccine is currently available



- Second-leading cause of fatal diarrheal disease worldwide
- Estimated to cause up to 165 million cases and 600,000 deaths each year, particularly among children in LMICs[2]
- Caused by species of *Shigella* bacteria
- Highly contagious; person-to-person (directly or by contaminated materials), food- and water-borne transmissions are common
- Illness typically begins 1–2 days after exposure with symptoms lasting 5–7 days. Symptoms include diarrhea, fever and stomach cramps between others. Long term consequences can develop in children (linear growth faltering, stunting) and adults (arthritis).
- Considering the potential for herd immunity and protection from all-cause diarrhea, the development of a Shigella vaccine is an important goal for public health - priority for the World Health Organization (WHO)
- Shigella is a rising antimicrobial-resistant (AMR) enteric bacteria – hence a vaccine may indirectly impact the emergence of AMR

1. *Shigellosis* | CDC Yellow Book 2024; **2.** Low-and-middle-income countries

Potential first-in class vaccine, estimated >$500 million global market[1]

Committed to providing equitable access to novel vaccines[2]

Product	▪ 4-valent Shigella bio-conjugate vaccine (*S. flexneri* 2a, 3a, 6 and *S. sonnei* O-antigens)
Indication	▪ Prevention of Shigellosis caused by vaccine strains ▪ Shigellosis defined as severe or moderate diarrhea or dysentery
Storage	▪ 2-8 °C; expected shelf life >24 months
Administration	▪ Intramuscular injection ▪ One or two doses, depending on the target population

	Travelers/Military	**LMIC**
Population	▪ Travelers to endemic areas	▪ Children <5 years of age living in endemic areas
Registration	▪ Leverage Phase 2 CHIM results for immuno-bridging to remaining *S. flexneri* serotypes 3a and 6 ▪ Focus on FDA and EMA accelerated approval pathway (18+ years at launch, down to age 1)	▪ Sublicense to Global Health Partner(s) to make products available to non-profit/public sector purchasers ▪ Consider applicability for private LMIC markets either directly or via partners ▪ WHO Pre-qualification

1 Valneva assessment, 2. Supporting Valneva´s ESG objectives

Risk-mitigating and staggered development plan

Multiple catalysts and decision points for envisaged development strategy

Risk-mitigated clinical strategy allows for efficient capital allocation in line with mid-term guidance

Anticipated Clinical Development		Accountable Party[1]	Anticipated start	Objective	Anticipated read-out
Phase 2	CHIM[2] – Adults (*S. sonnei)*	LMTB	H2/2024	Dose confirmation, efficacy read-out	H2/2025
	Pediatric (Global Health)	LMTB	H2/2024	Dose confirmation, immunogencity	H2/2025
	CHIM – Adults (*S. flexneri* 2a)	VLA	H2/2025	Efficacy read-out	H2/2026
Phase 3	CHIM – Adults	VLA	H2/2027	Efficacy read-out	H2/2029
	Field efficacy Pediatric	VLA	H2/2027	Efficacy read-out	H2/2029
	Additional pivotal	VLA	H1/2028	Safety/Immunogenicity/lot-to lot etc.	H2/2029
First approval			H2/2029		H2/2030

1 Accountable for conduct and payment; 2. Controlled human infection model

Strategic Partnership with LMTB on Shigella candidate S4V

Key terms

- **VLA receives global exclusive license to develop, manufacture and commercialize "S4V"** (4 valent (flexneri 2a, 3a, 6 and sonnei O-antigens) bio-conjugate vaccine for the prevention of a disease caused by Shigella)
- **LMTB to receive upfront, is eligible for future milestone and royalty payments**
  - €10 million upfront payment
  - Future development, regulatory and sales-based milestone payments totaling up to €40 million
  - Low double-digit royalty on net sales in the travel segment
  - Additional payments and single-digit royalties based on commercialization in LMICs
- **Parties to collaborate through Phase 2**
  - LMTB to conduct first Phase 2 "human challenge" study (CHIM trial (*S. sonnei*)) and pediatric immunogenicity study in LMICs
  - Valneva to initiate second Phase 2 "human challenge" study (CHIM trial)(*S. flexneri* 2a)
  - LMTB to conduct technology transfer and transfer of IND[1] to Valneva once all Phase 2 studies are fully enrolled
- **Valneva to lead and manage all future development activities**

1 Investigational New Drug Application

Valneva's Commercial and R&D Portfolio

Further extending a unique, differentiated portfolio

	Program	Vaccine Design	Pre-Clinical	Phase 1	Phase 2	Phase 3	Commercial
Commercial Products	**IXIARO®**	Only U.S./ EU approved vaccine against Japanese encephalitis					
	DUKORAL®	Established Cholera (ETEC[1]) vaccine approved in >30 countries					
	IXCHIQ®	World's first and only approved chikungunya vaccine (U.S., Europe, Canada); Review ongoing in UK and Brazil					
Clinical Programs	**VLA15:** Lyme disease	Most clinically advanced Lyme vaccine program worldwide					
	VLA1553: Chikungunya	Phase 3 adolescent study (Brazil) and Phase 2 pediatric study support potential label expansion					
	S4V: Shigellosis	Phase 2 CHIM[2] and pediatric studies to begin H2 2024					
	VLA1601: Zika	Potential for first/best-in-class					
Key Pre-Clinical Activities	**VLA2112:** EBV						
	Various Enteric diseases						

1 ETEC indication in some markets only; 2 Controlled human infection model

Thank you
Merci
Danke
Tack

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