

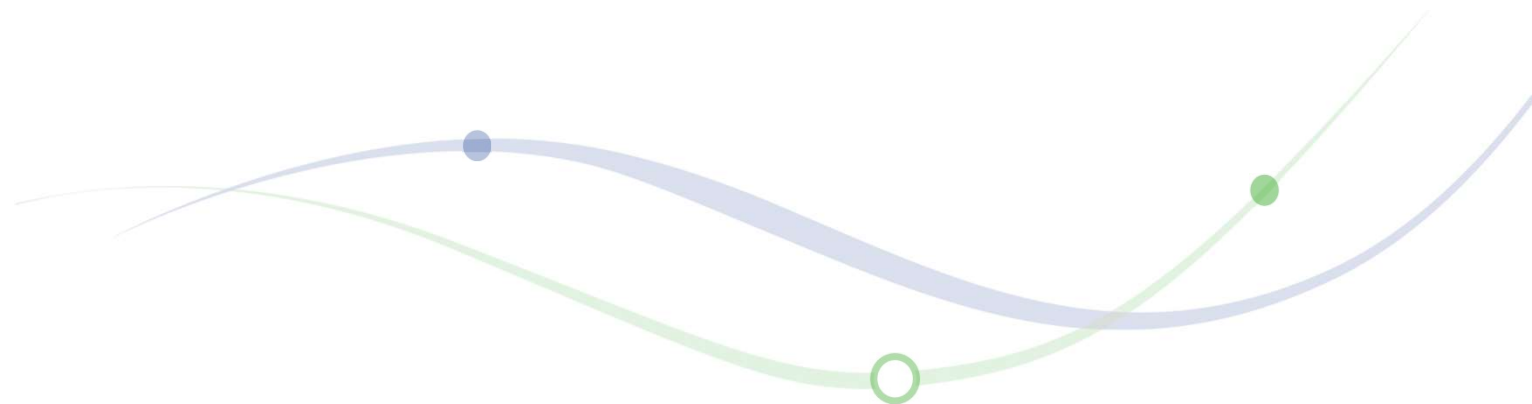
Vaccine Adjuvants for Global Health

Mark Alderson

May 2026

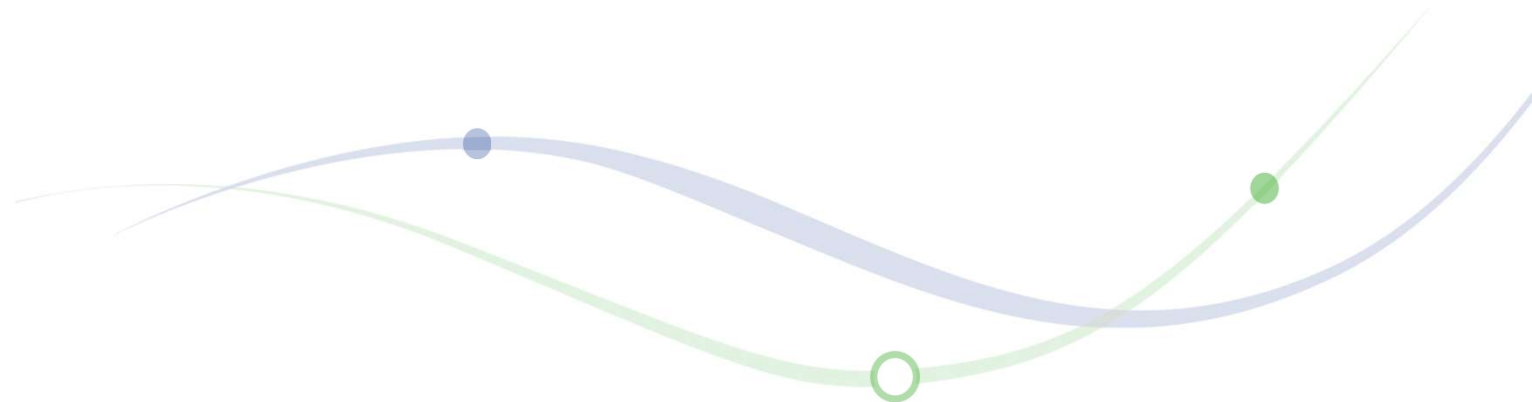
A decorative graphic consisting of two wavy lines, one blue and one green, that overlap and curve across the bottom half of the slide. There are two circular markers: a solid green circle on the blue line and an outlined green circle on the green line.

- 1. Background**
- 2. Some (personal) history**
- 3. Maxvax adjuvant program**



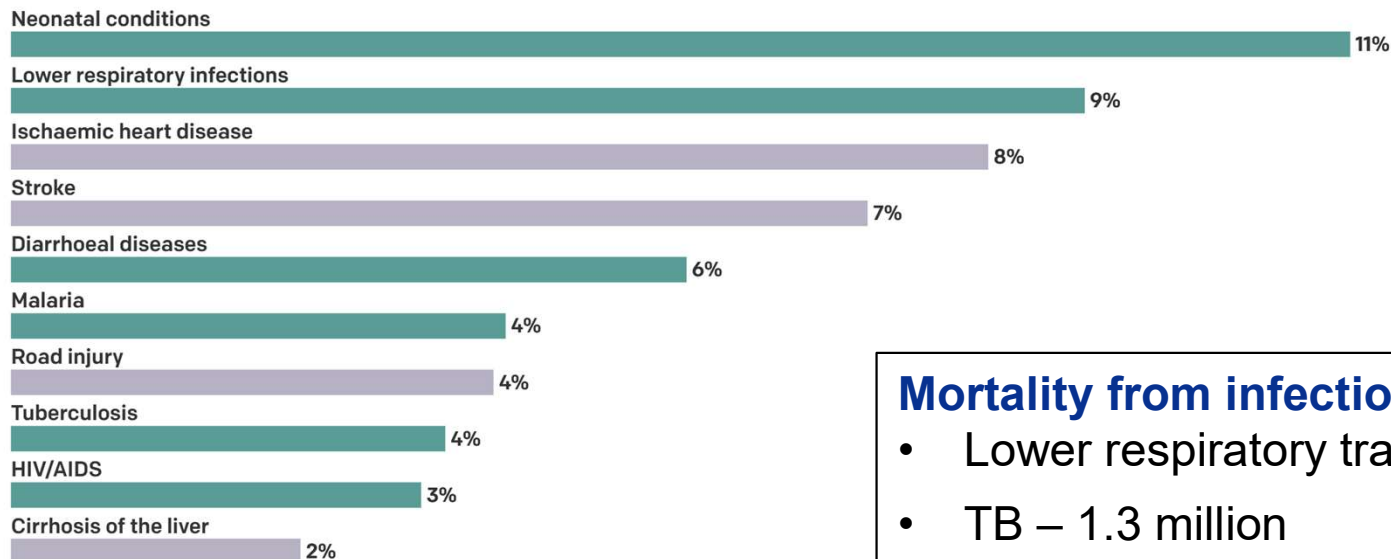
Impact of vaccines on Global Health

- Dramatic reduction in child mortality since the early 1900s
 - But infectious diseases remain the leading cause of childhood death worldwide
- Easy vaccines are done...
- More challenging (TB, HIV, malaria) require specialized adjuvants (or delivery systems) in order to promote protective immunity...



Leading causes of death by income group

Low income Lower-middle income Upper-middle income High income



Leading causes of death in 2019 by income group

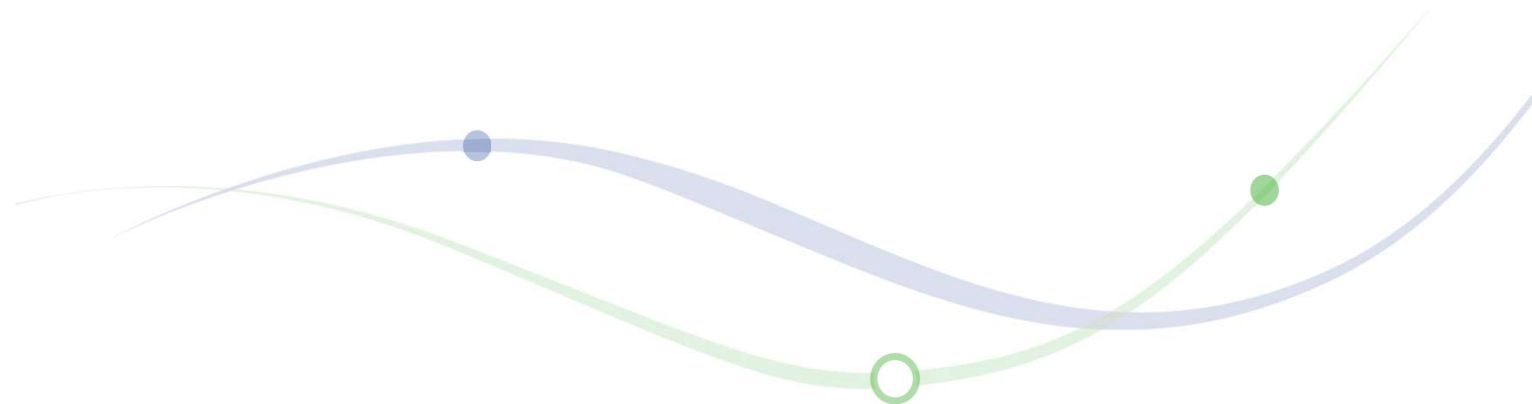
Mortality from infectious diseases (2023)

- Lower respiratory tract infections - 2.5 million
- TB – 1.3 million
- Malaria – 608,000

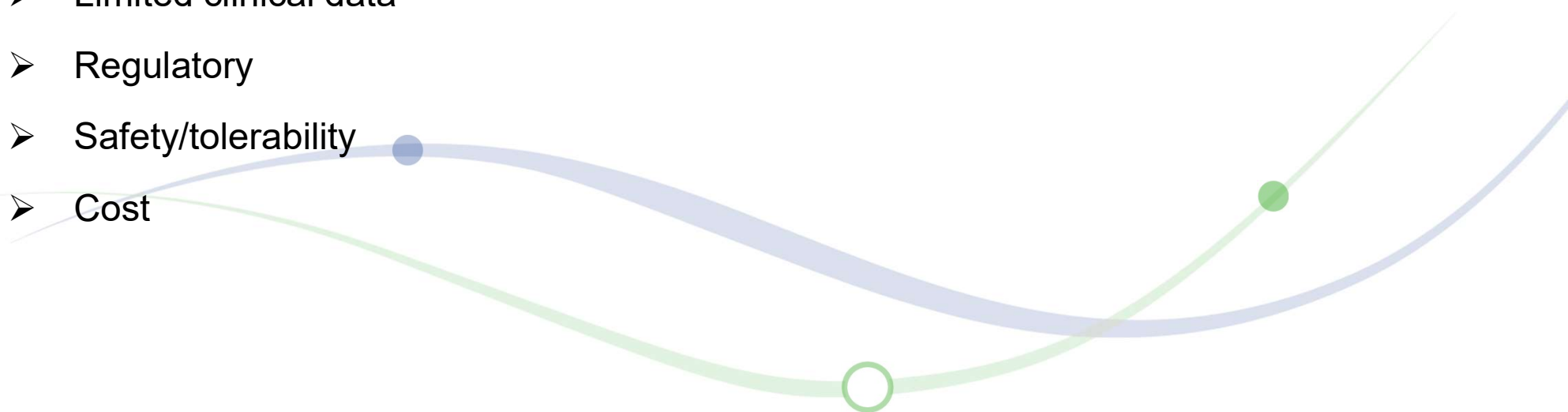
From One Data <https://data.one.org/analysis/health>

Why focus on novel adjuvants?

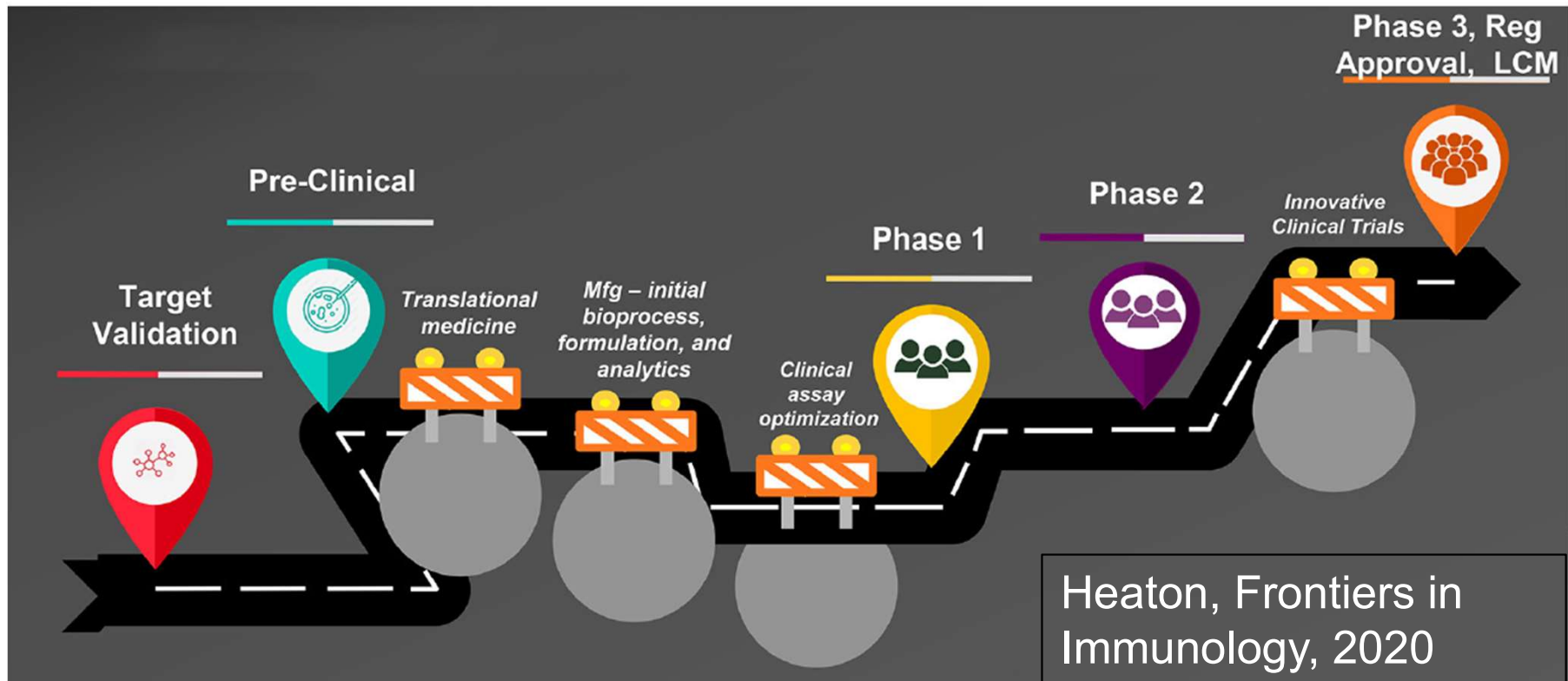
- Traditional adjuvants like aluminum salts are insufficient for eliciting protective immunity to certain pathogens such as malaria and tuberculosis (TB).
- Novel adjuvants are needed for individuals with suboptimal immunity such as older adults and immunocompromised individuals.
- Potential to reduce antigen dose or number of doses administered.



Challenges for developing novel adjuvants for global health

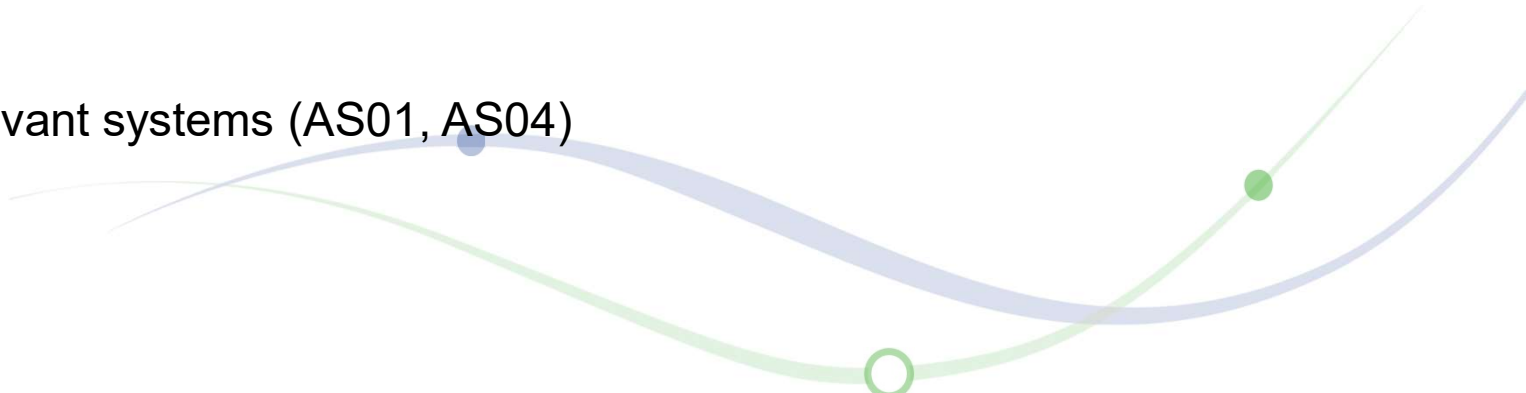
- Translation from preclinical to clinical (“mice lie and monkeys exaggerate”)
 - Manufacturing/supply
 - Availability (IP)
 - Limited clinical data
 - Regulatory
 - Safety/tolerability
 - Cost
- 
- A decorative graphic consisting of two wavy lines, one light blue and one light green, that overlap and curve across the bottom half of the slide. Three circles are placed on these lines: a solid blue circle on the blue line, a hollow green circle on the green line, and a solid green circle on the blue line.

Vaccine development is complex and challenging



Inclusion of a novel adjuvant adds another layer of complexity

Licensed adjuvants

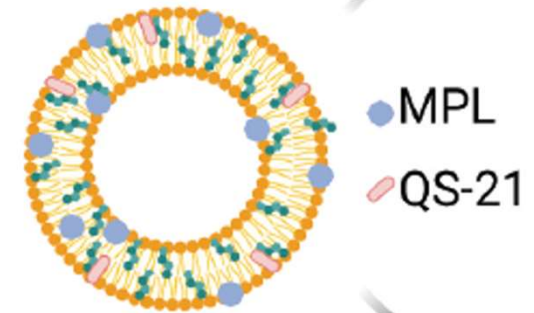
- Aluminum salts (alum)
 - Oil-in-water emulsions (MF59, AS03)
 - CpG oligonucleotides
 - MPL
 - TLR7/8 agonists
 - Saponins (Matrix M, QS-21)
 - Liposomes
 - Combination adjuvant systems (AS01, AS04)
- 

GSK's AS01 Adjuvant System



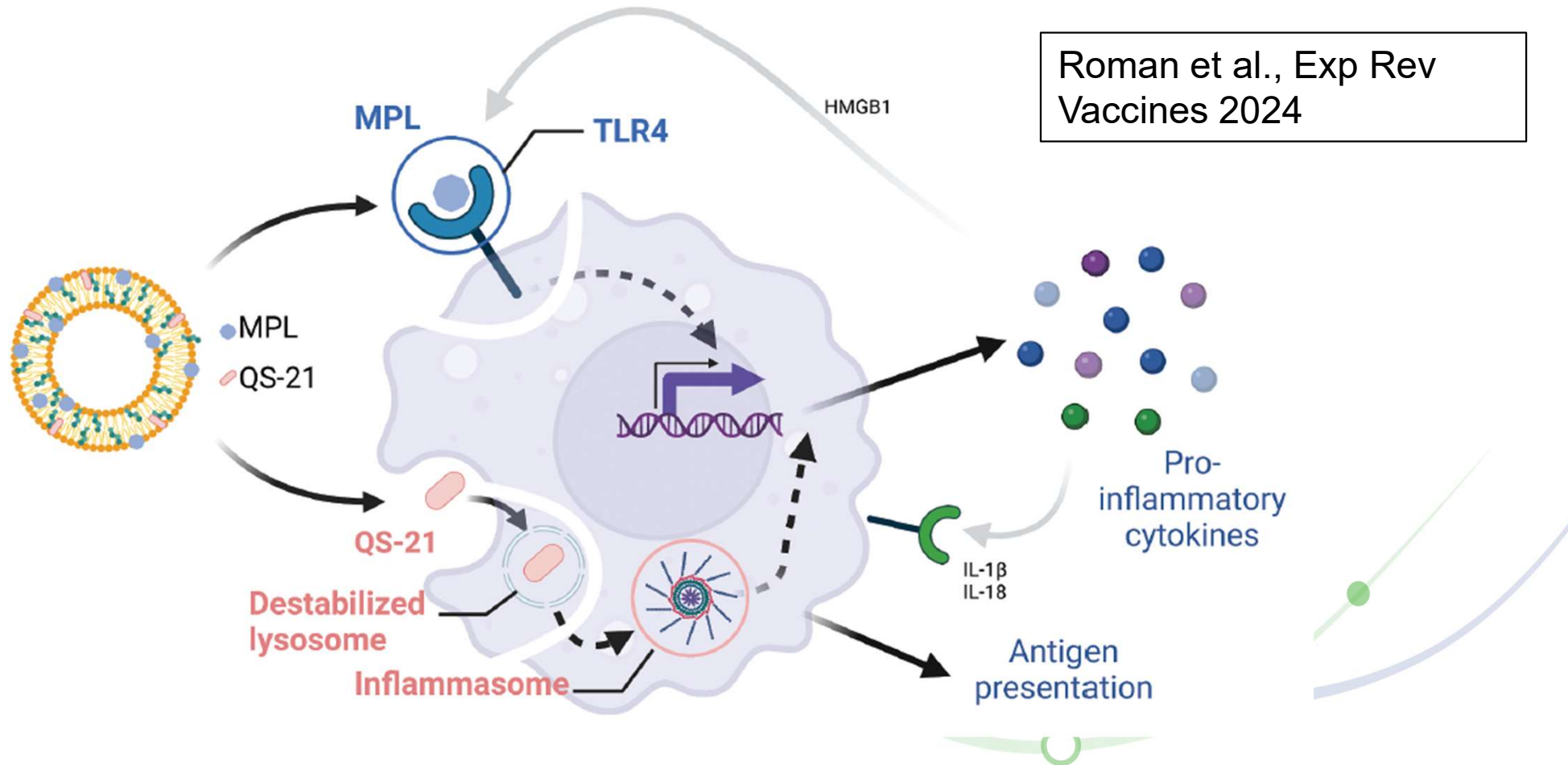
MPL (purified from *S. minnesota*) plus QS-21 (purified from the bark of *Quillaja saponaria* trees) in a liposomal formulation

- Shingles (Shingrix®) – AS01_B
- **Malaria (RTS,S - Mosquirix) – AS01_E**
- RSV (Arexvy®) – AS01_E
- **TB (M72 – in Phase 3) – AS01_E**

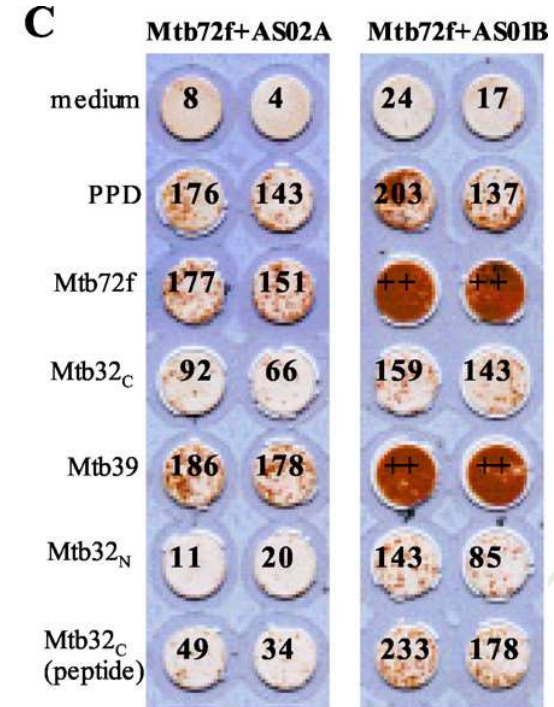
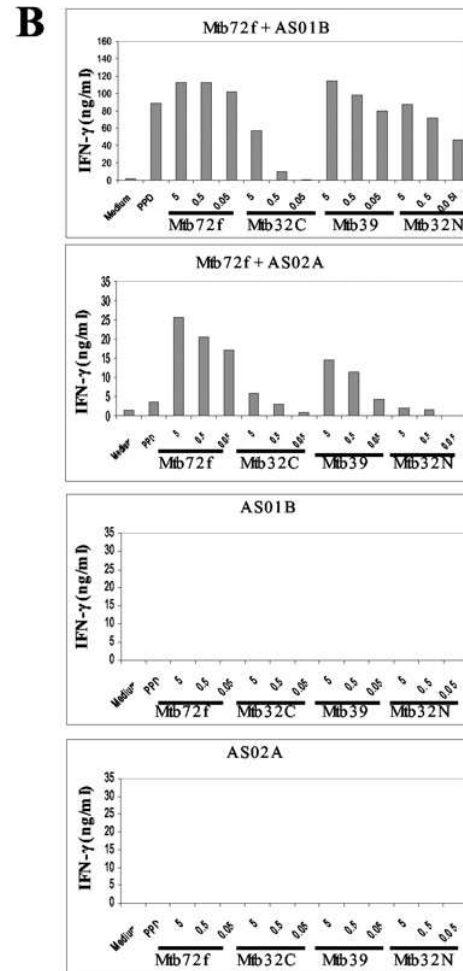
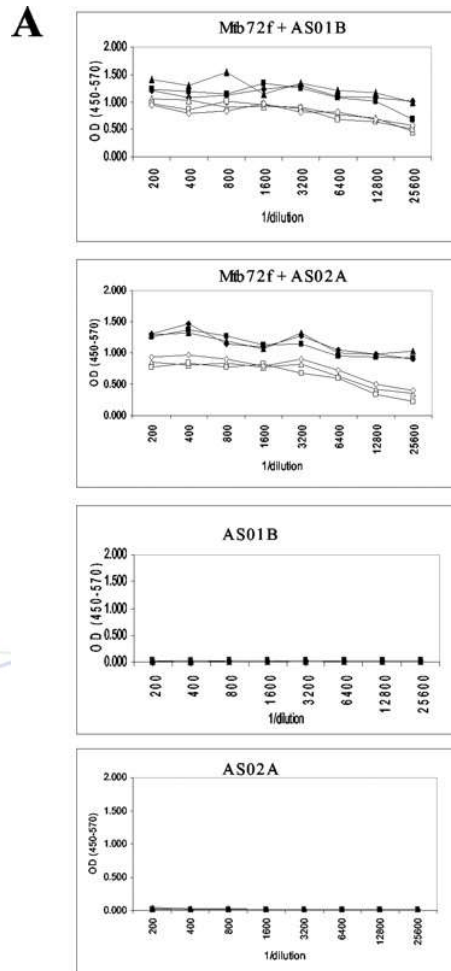


- MPL activates antigen-presenting cells expressing TLR4 and promotes antigen-specific antibodies and T cells with a Th1 bias
- QS-21 promotes antigen-specific antibodies and T cells, including CD8⁺ T cells in mice

GSK's AS01 Adjuvant System



M72 Preclinical adjuvant selection



Skeiky et al., J. Immunol 2004

M72/AS01_E Phase 2b data

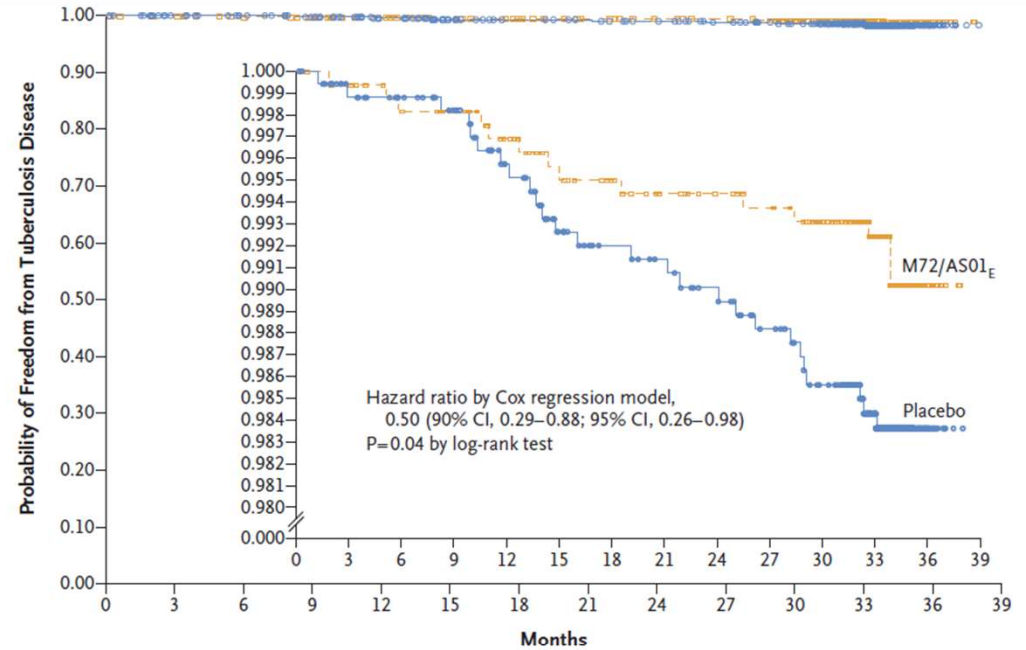


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Final Analysis of a Trial of M72/AS01_E Vaccine to Prevent Tuberculosis

D.R. Tait, M. Hatherill, O. Van Der Meeren, A.M. Ginsberg, E. Van Brakel, B. Salaun, T.J. Scriba, E.J. Akite, H.M. Ayles, A. Bollaerts, M.-A. Demoit  , A. Diacon, T.G. Evans, P. Gillard, E. Hellstr  m, J.C. Innes, M. Lempicki, M. Malahleha, N. Martinson, D. Mesia Vela, M. Muyoyeta, V. Nduba, T.G. Pascal, M. Tameris, F. Thienemann, R.J. Wilkinson, and F. Roman



No. at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36	39
M72/AS01 _E	1626	1621	1614	1609	1592	1580	1573	1566	1561	1557	1542	1468	12	
Placebo	1663	1650	1642	1632	1610	1586	1576	1571	1564	1553	1539	1460	19	

Figure 1. Kaplan–Meier Estimate of Definite Pulmonary Tuberculosis According to the First Case Definition.

Shown is the Kaplan–Meier estimate of the probability of freedom from tuberculosis disease according to the first case definition (bacteriologically confirmed pulmonary tuberculosis not associated with HIV infection, diagnosed before the initiation of treatment for tuberculosis). The analysis was conducted in the according-to-protocol efficacy cohort (3289 participants — 1626 in the M72/AS01_E group and 1663 in the placebo group). The time shown is the time from the beginning of follow-up (i.e., 30 days after dose 2). The inset shows the same data on an enlarged y axis.

M72/AS01_E Phase 3 trial



The Phase 3 Clinical Trial of the M72/AS01E tuberculosis (TB) Vaccine Candidate Has Reached Full Enrollment

April 16, 2025

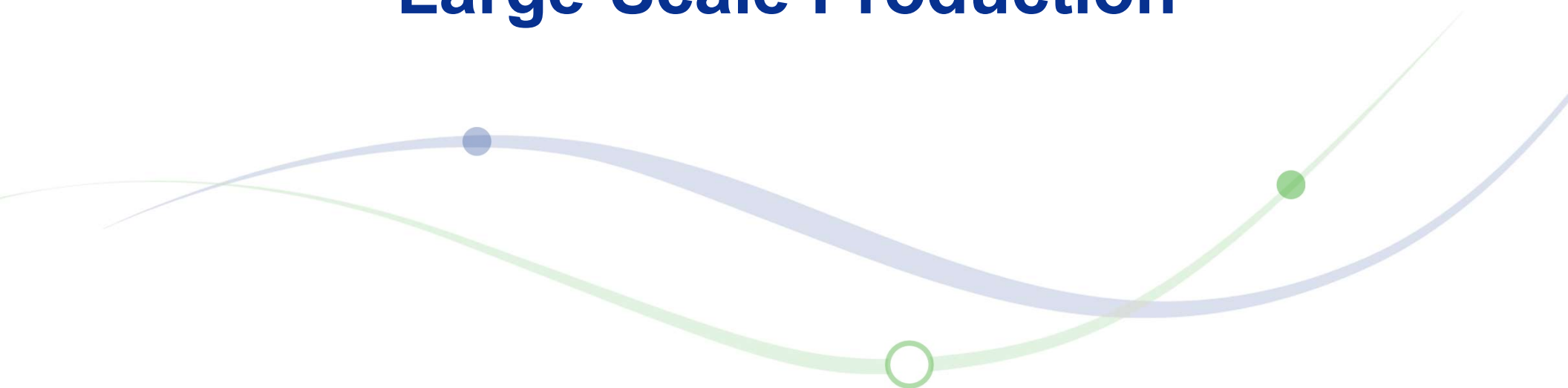
We're glad to announce that the Phase 3 clinical trial of the M72/AS01E tuberculosis (TB) vaccine candidate has reached full enrollment eleven months ahead of schedule— with approximately 20,000 participants enrolled.

With the M72 trial at full enrollment, we take another step closer to the critically important goal of a safe and effective tuberculosis vaccine. A TB vaccine that can help prevent adolescents and adults from the disease is urgently needed.

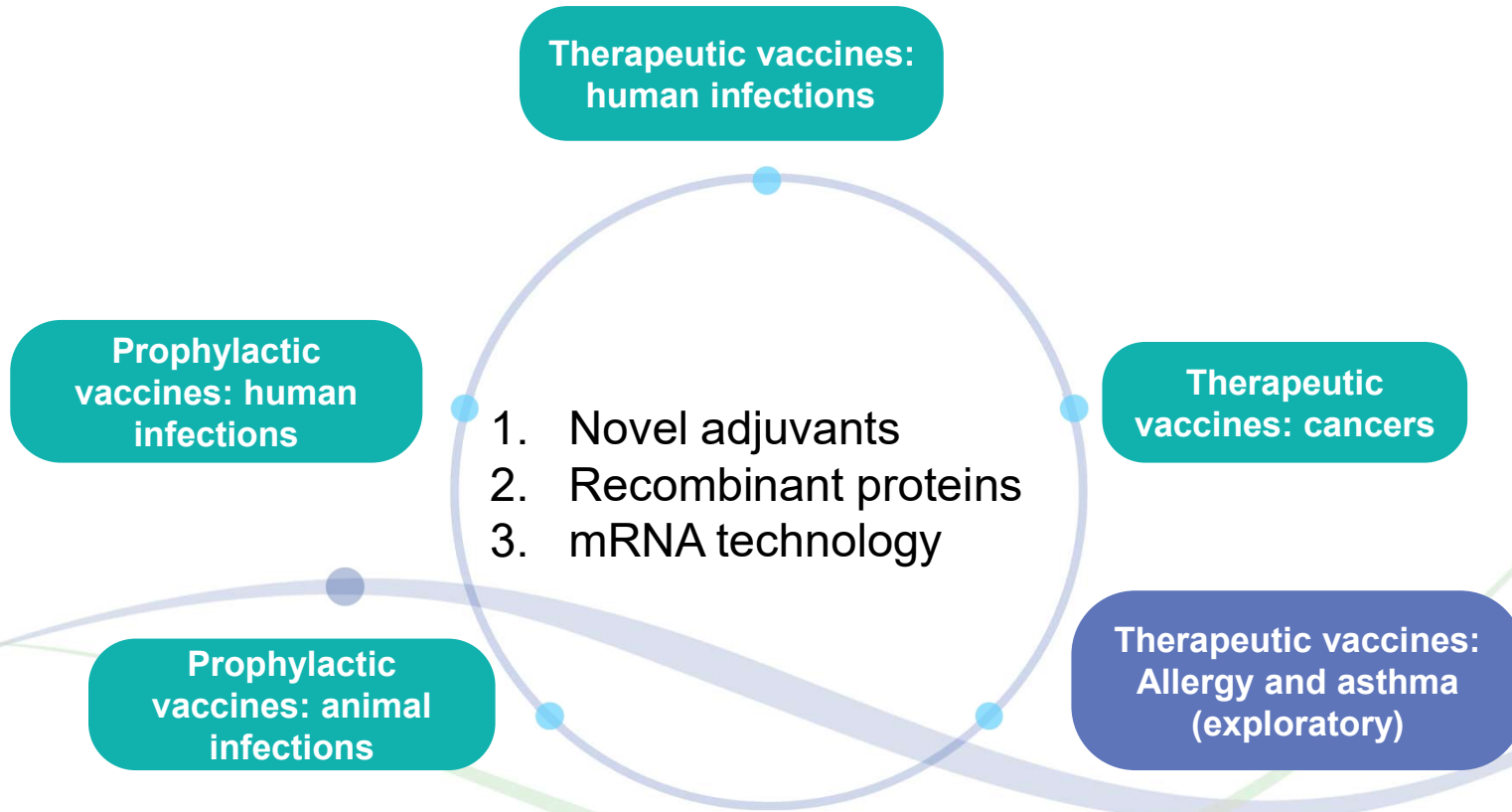
Patrice Matchaba, CEO of the Gates MRI

Fifty four trial sites have activated across five countries to assess the efficacy and safety of this M72/AS01E vaccine candidate.

Novel Adjuvant Development and Large-Scale Production



Maxvax technology platforms and product areas



>60 patents and patent applications

R&D and commercial manufacturing facility making adjuvants and vaccines



Chengdu

- ① Operational since 2020
- ② 70K SF, GMP
- ③ Manufacture of adjuvants and vaccines for Phase 1 and 2 studies



Manufacturing facilities in Shanghai

- ① Operational since 2023
- ② 120K SF, GMP
- ③ Manufacture of adjuvants and vaccines at commercial scale



- ① Ready by 2026 (under construction)
- ② 700K SF, GMP
- ③ Manufacture of adjuvants and vaccines at commercial scale

Goal of Maxvax's adjuvant program



Develop adjuvant systems that are scalable from a manufacturing perspective and are tailored to the protective immune response required but are well tolerated and affordable

- Vaccines for certain viral diseases (e.g. RSV), intracellular bacteria (e.g. tuberculosis) and parasites (e.g. malaria), and vaccines for cancers

Adjuvants may be key for optimal responses in older adults with declining immune systems:

- GSK's AS01 adjuvant system, used in shingles and RSV vaccines for older adults, has demonstrated excellent efficacy

Vaccine developers face many barriers for accessing adjuvants and formulations

- Knowledge and expertise
- Adjuvant raw materials and formulations, especially GMP-grade made at commercial scale
- Financial and time costs associated with assessing and accessing adjuvants

Maxvax's adjuvant program



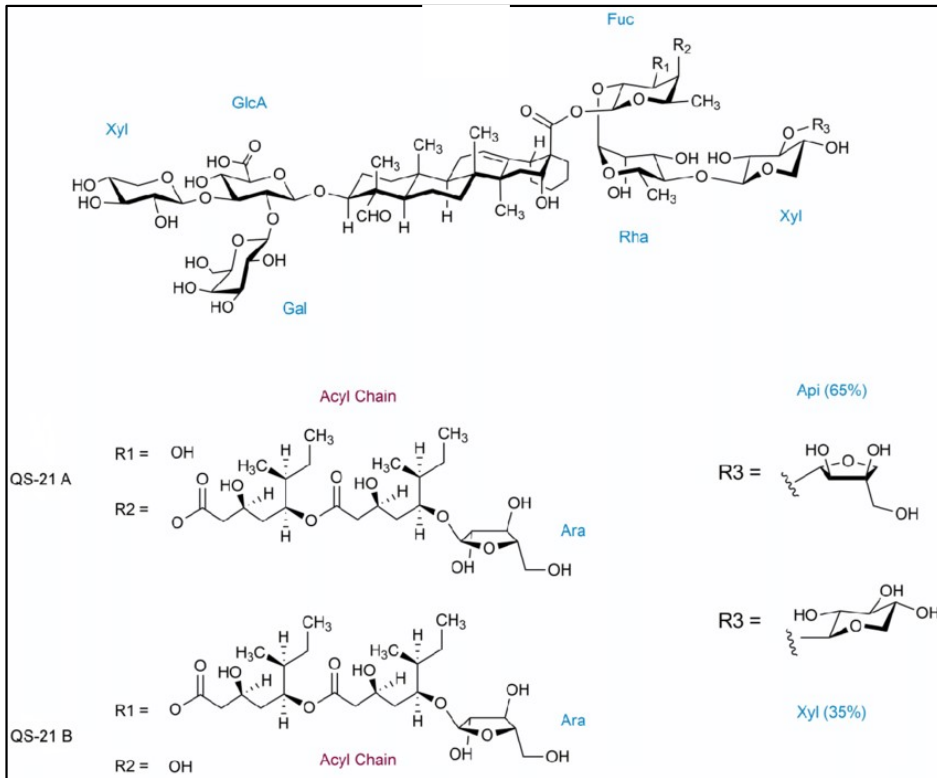
- **Adjuvant Molecules:** Designed and manufactured over twenty adjuvant molecules.
- **Delivery systems:** Developed three delivery systems: liposomes, oil-in-water emulsions, and aluminum hydroxide.
- **Adjuvant formulations:** Developed a dozen adjuvant formulations with different adjuvant properties for research use.
- **Scale-up and production under GMP:** Three adjuvant molecules, two lipids, two delivery systems, and five adjuvant formulations are currently produced in our pilot or commercial manufacturing plants under GMP compliance.
 - Scalable for global health applications
- **Application to in-house and partner's vaccine projects:**
 - One adjuvant at licensure stage (shingles)
 - One other adjuvant in Phase 3 (RSV)
 - Several in pre-clinical development.

Adjuvants and lipids made by Maxvax



Adjuvant Molecules	Manufacturing method	Batch size	Regulatory status	Quality
QS-21	Purified from plants	50 g (1M doses)	<ul style="list-style-type: none"> ➤ Reviewed by Chinese FDA during IND ➤ US pre-IND ➤ US DMF planned 	GMP
TLR-3 agonist	Synthetic	1 kg (2M doses)		
TLR-4 agonist		100 g (2M doses)		
DOTAP lipid		1 kg (20M doses)		
DOPC lipid		1 kg (1M doses)		
QS-21-like		5-10 g	None	
TLR7/8 agonist	5-10 g			
iNKT agonist	5-10 g			

QS-21 made under GMP compliance



QS-21 molecules

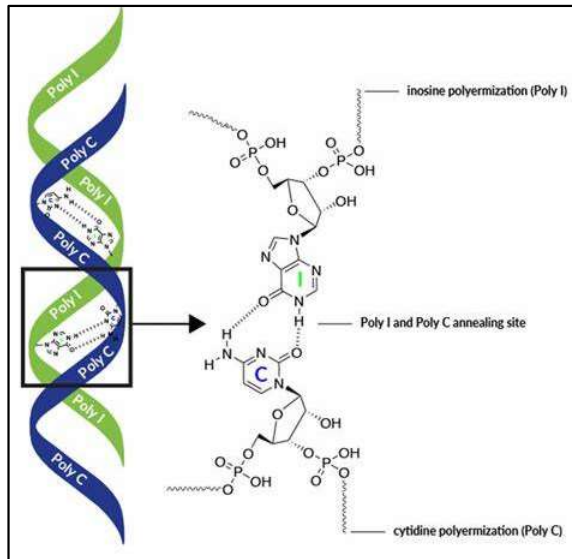
Background:

- QS-21 is a saponin component found in trees native to Chile (*Quillaja Saponaria*).
- QS-21 purified from the natural source is used in licensed vaccines against shingles, RSV, malaria etc.
- Purified QS-21 is a mixture of several structurally distinct molecules, making quality control difficult.

Maxvax's activities:

- Developed an industrial-scale process for isolating QS-21 from natural raw materials with a yield of 50 grams of QS-21 per batch.
- Purified QS-21 is used in MA103, MA105 and MA107 adjuvant systems. Vaccines containing MA103 and MA105 are both in Phase 3 clinical trials.
- Semi-synthetic QS-21 is under development.

Poly (I:C) made under GMP compliance



Molecular structure of poly (I:C)

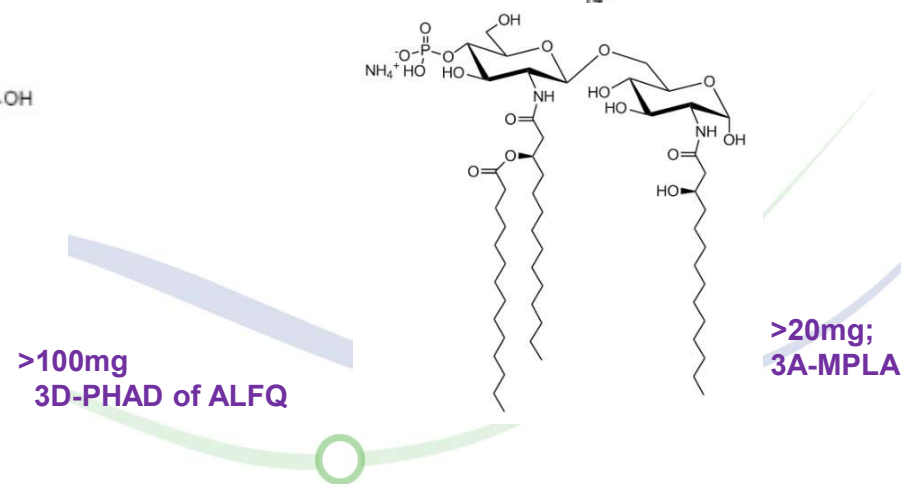
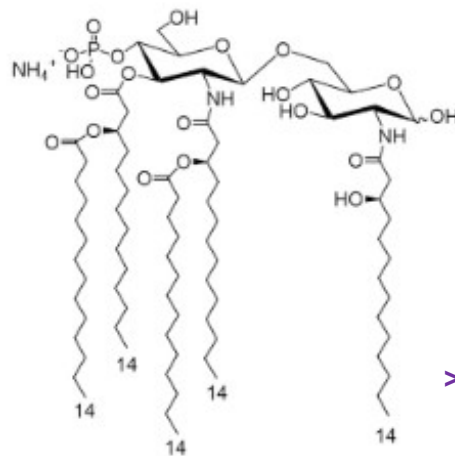
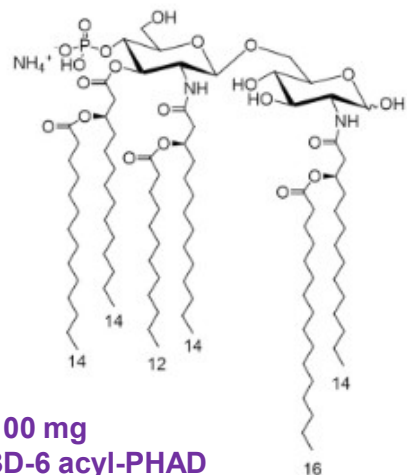
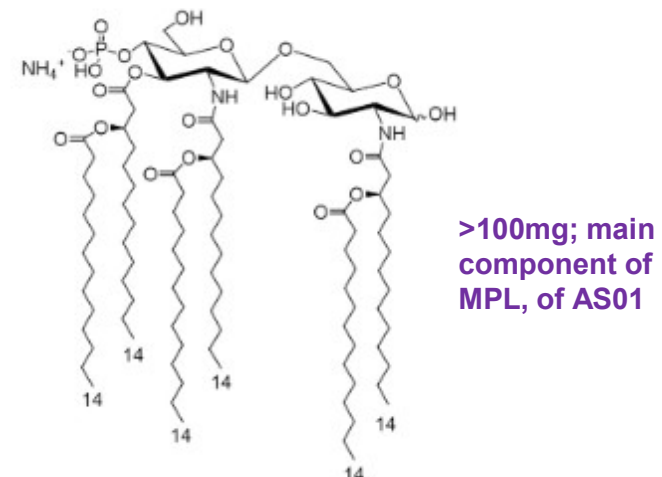
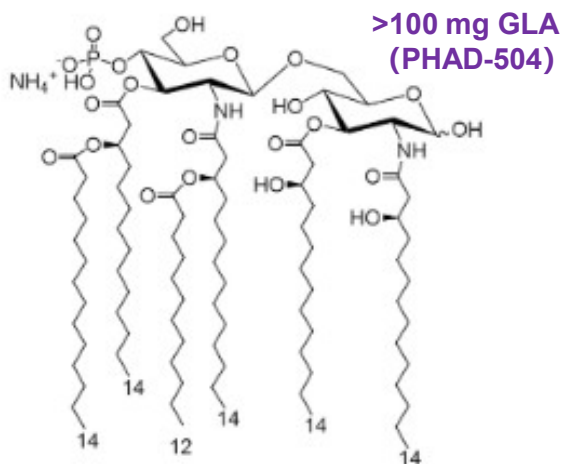
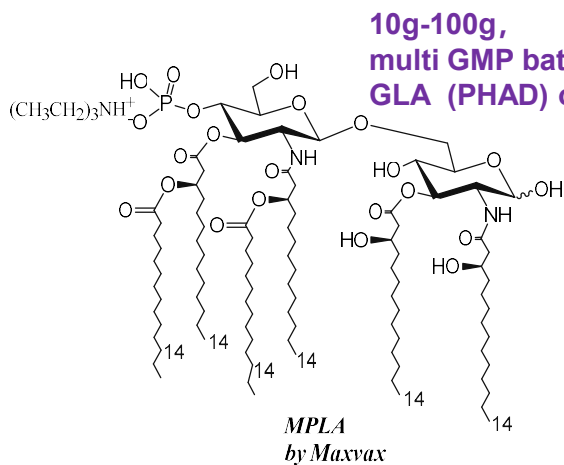
Background:

- Poly (I:C) is a TLR-3 ligand that stimulates Th1 responses to co-administered antigens.
- As a stand alone, poly (I:C) is a licensed drug for treating shingles and chronic hepatitis B in China.
- Poly (I:C) is being studied as a vaccine adjuvant and cancer immunotherapy.
- The molecular weight of poly (I:C) is related to its adjuvant activity.

Maxvax's project:

- Maxvax has made synthetic poly (I:C) at a kilogram scale with low endotoxin content and tightly controlled size distribution.
- Poly (I:C) is included in the MA105 adjuvant system that is a key component of our shingles vaccine candidate in Phase 3 studies in China.

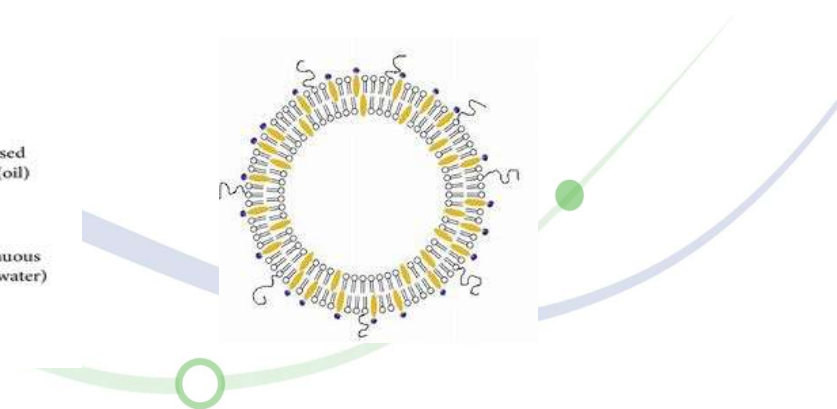
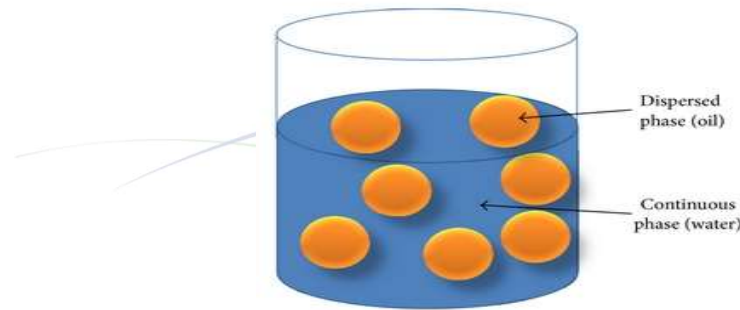
MPLs synthesized at Maxvax



Delivery systems made by Maxvax



Delivery system	Current Batch size (GMP, Commercial scale)	Number of vaccine doses per batch
Aluminum hydroxide	500 liter	2.50 million
Oil-in-water emulsion	120 liter	0.48 million
liposome	100 liter	0.40 million



Lead adjuvant systems and development status

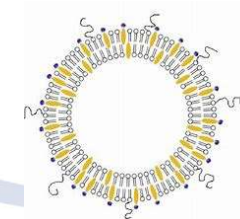
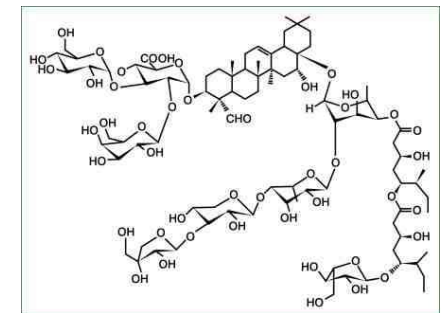
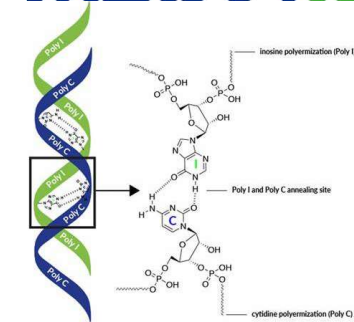


Adjuvant system	Immune response profile	Status
MA103	Antibody, CD4 ⁺ T cells	RSV adults (Phase 3)
MA105	Antibody, CD4 ⁺ , CD8 ⁺ T cells	Shingles (Phase 3/NDA) therapeutic HPV (Pre-IND)
MA107 (AS01-like)	Antibody, CD4 ⁺ T cells	Malaria, TB (preclinical)

MA105 adjuvant system

- Lead AS for shingles and therapeutic HPV vaccine candidates.
- Combines TLR-3 agonist poly (I:C) with the saponin QS-21 in a liposomal formulation
 - Compares to GSK's AS01 that has MPL and QS-21 in a liposomal formulation.
- Presented in PFS for simpler and more efficient administration.
- Goal is to promote similar immune responses to AS01 but with lower reactogenicity.
 - Recent Phase 2 and Phase 3 data with shingles vaccine candidate supports this notion.
 - Safety database ~13,000 subjects.

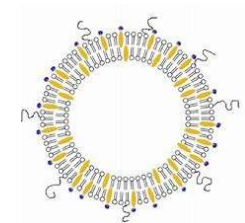
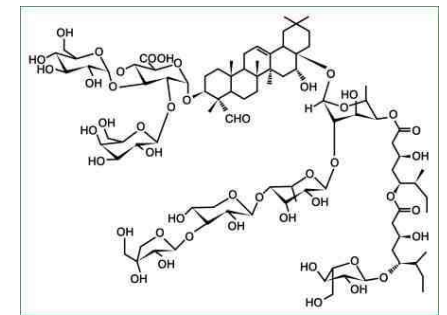
MAXVAX 物



MA103 adjuvant system



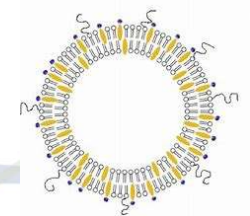
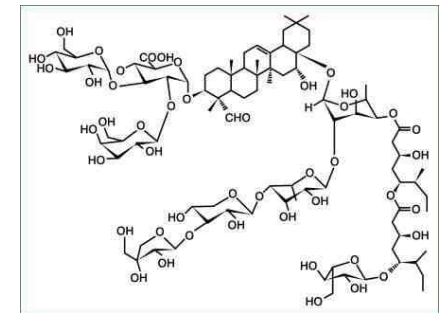
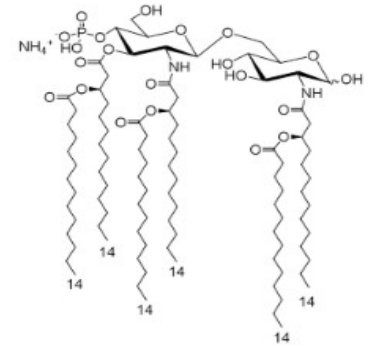
- Lead AS for RSV vaccine candidate for adults.
- Includes QS-21 in a liposomal formulation.
- Presented in PFS for simpler and more efficient administration.
- Goal is similar efficacy to the licensed protein vaccines from GSK and Pfizer.
- Currently in a Phase 3 efficacy study in China with 25,000 participants for prevention of RSV LRTI.



MA107 adjuvant system

- Lead AS for malaria and TB.
- Includes a synthetic TLR4 agonist and QS-21 in a liposomal formulation.
- Goal is similar adjuvant properties to AS01.
- Commercial-scale process under development. Will leverage existing experience in making QS-21 and liposomal adjuvants (MA103 and M105) at commercial scale.

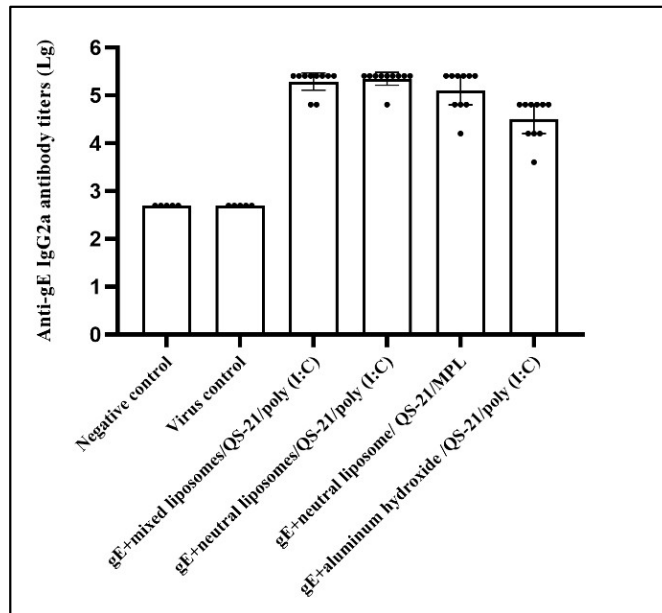
MAXVAX
迈科康生物



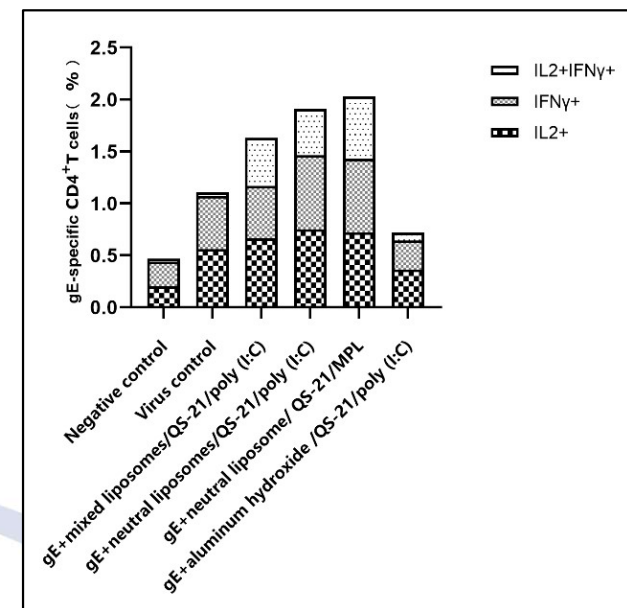
MA105 and MA107 induce strong antibody and cellular immune responses to VZV gE antigen in mice

- The data shows that either QS-21/poly (I:C) or QS-21/synthetic MPL induces strong serum IgG2a antibody titers and CD4⁺ T cells expressing IL-2/IFN- γ .

Serum IgG2a antibody titers



Percentage of CD4⁺ T-cells expressing IFN- γ & IL-2

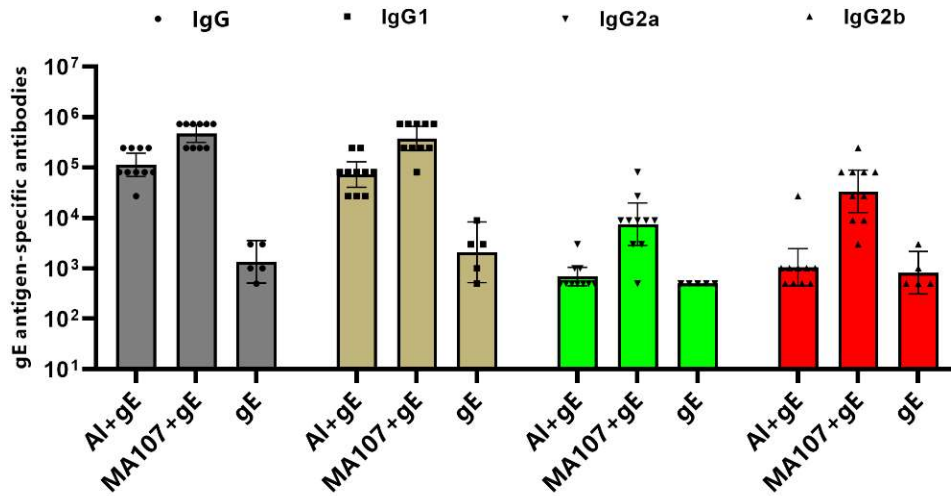


Notes :

- Dose of MPL was 5 μ g; dose of QS-21 was 40 μ g; antigen dose was 5 μ g.

Mouse study evaluating MA107 using VZV gE protein

14 days after the 3rd dose

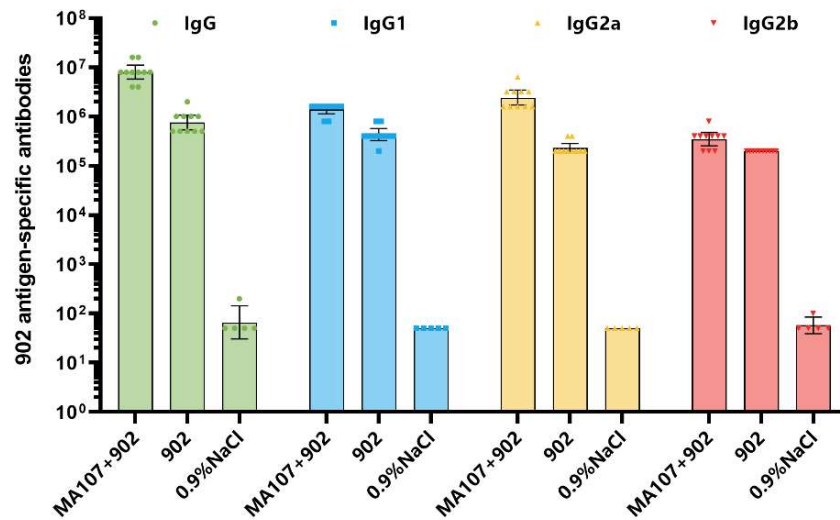


Study Group	IgG	IgG1	IgG2a	IgG2b
Al+gE	112622	72573	687	1054
MA107+gE	469763	377098	7524	33635
gE	1351	2096	500	822

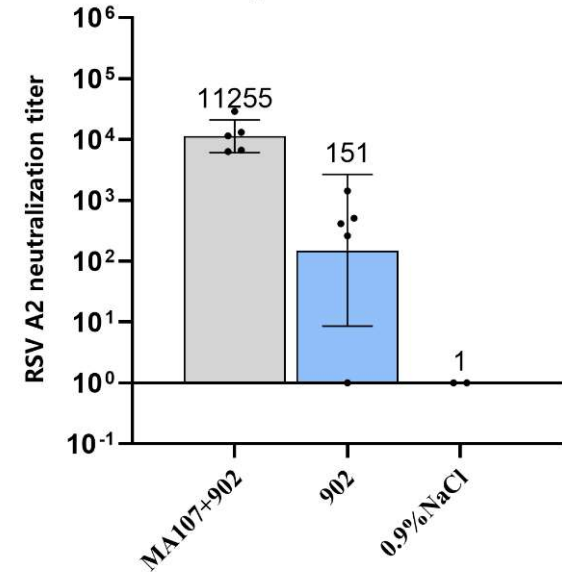
MA107 superior to aluminum hydroxide for IgG responses

Mouse study evaluating MA107 using RSV pre-F protein - antibody responses

10 days after the 3rd dose

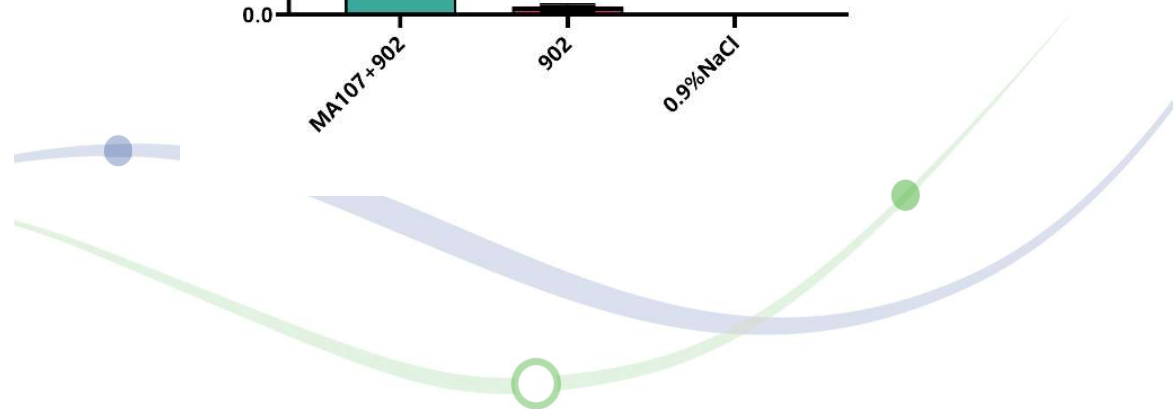
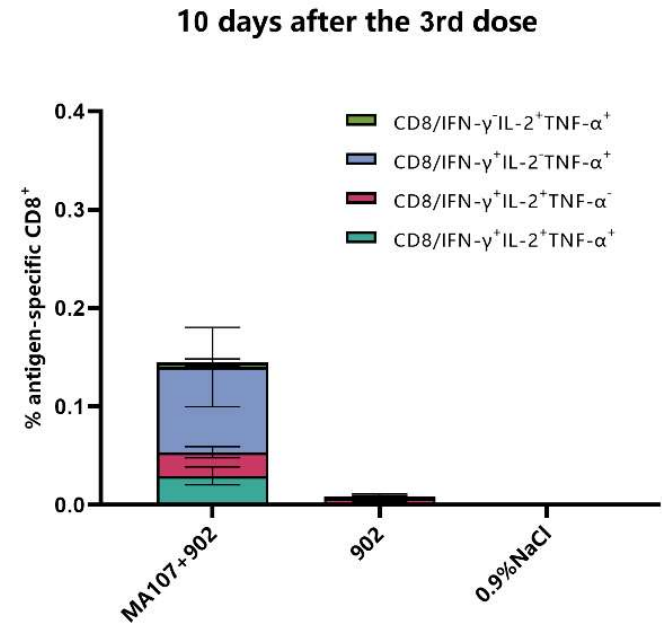
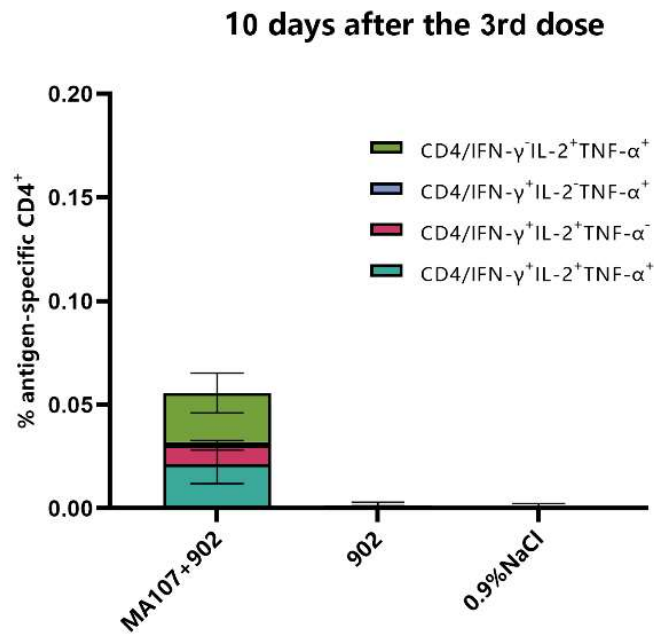


10 days after the 3rd dose



Study Group	IgG	IgG1	IgG2a	IgG2b
MA107+902	8000000	1392881	2425147	348220
902	757858	428709	229740	200000
0.9%NaCl	66	50	50	57

Mouse study evaluating MA107 using RSV pre-F protein - T-cell responses



Summary



- Novel and potent adjuvants are required to develop vaccines against challenging diseases such as malaria and TB where classical adjuvants have been unsuccessful.
- Multi-component adjuvant systems such as GSK's AS01 have been incorporated into a number of recently licensed vaccines (Malaria, shingles, RSV) and vaccines in late-stage development (TB).
- Maxvax is developing adjuvant systems that can be manufactured in high quantities and a low cost that are suitable for global health applications such as next generation malaria and TB vaccines.
- To date, more than 25,000 adults have received vaccines formulated with Maxvax adjuvant systems.



Thank you!

