SPI Pharma™

An ABF Ingredients Company

Innovative Adjuvants for Advancing Global Health

ABFI · AB biotek Health · AB ENZYMES · ABITEC · Fytexia · only · PGP International · SPI Pharma

About SPI Pharma

SPI Pharma™
An ABF Ingredients Company

At SPI Pharma, we don't just make ingredients — we help deliver better health. From molecule to meaning, we transform science into real-world impact.

What We Make

Drug delivery systems · Functional excipients · Antacid actives · Vaccine adjuvants

Markets We Serve

Pharmaceutical · Nutraceutical · OTC · Consumer Health · Animal Health · Biologics

What We Do

We supply the ingredients and formulation expertise that help bring innovative therapies, vaccines, and healthcare solutions to every life

Our Promise

Quality, safety, and service — delivering confidence, consistency, and trust at every step

ABFI: Backed by a Family of Six Specialty Ingredients Businesses

Operating principle: Devolved autonomy to the Businesses

- Operational decisions made at each business level
- Strong and autonomous management teams
- Lean ABFI central functions
- Investments in capabilities

Poll Question 1

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Which vaccine applications are you most interested in exploring with new adjuvants?

- Established infectious-disease vaccines
- Emerging or pandemic pathogens
- Therapeutic vaccines
- Pediatric or maternal vaccines

Adjuvants Shape the Strength and Quality of Vaccine Responses

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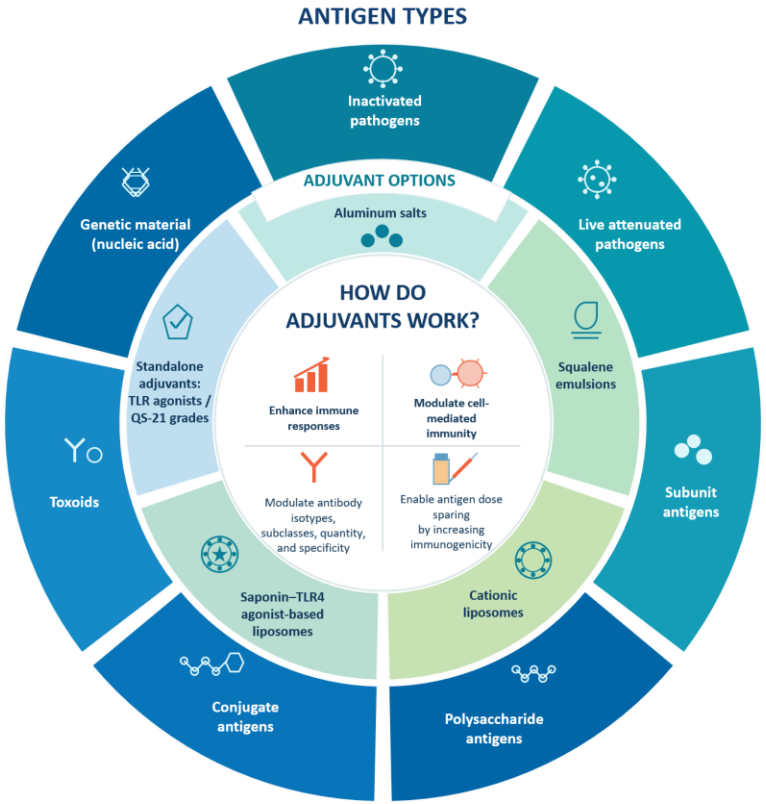

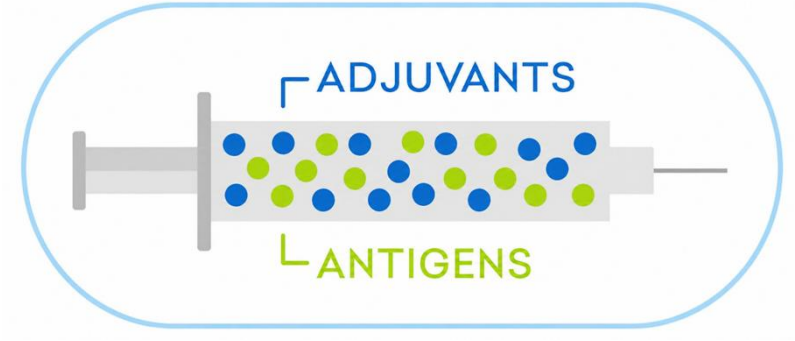

TOGETHER, THEY CREATE THE RIGHT IMMUNE RESPONSE

Antigens provide the immune target. Adjuvants enhance and direct the response—supporting stronger immunity, tailored cellular and antibody responses, and potential antigen dose sparing.

The Key Challenges for Vaccine Developers

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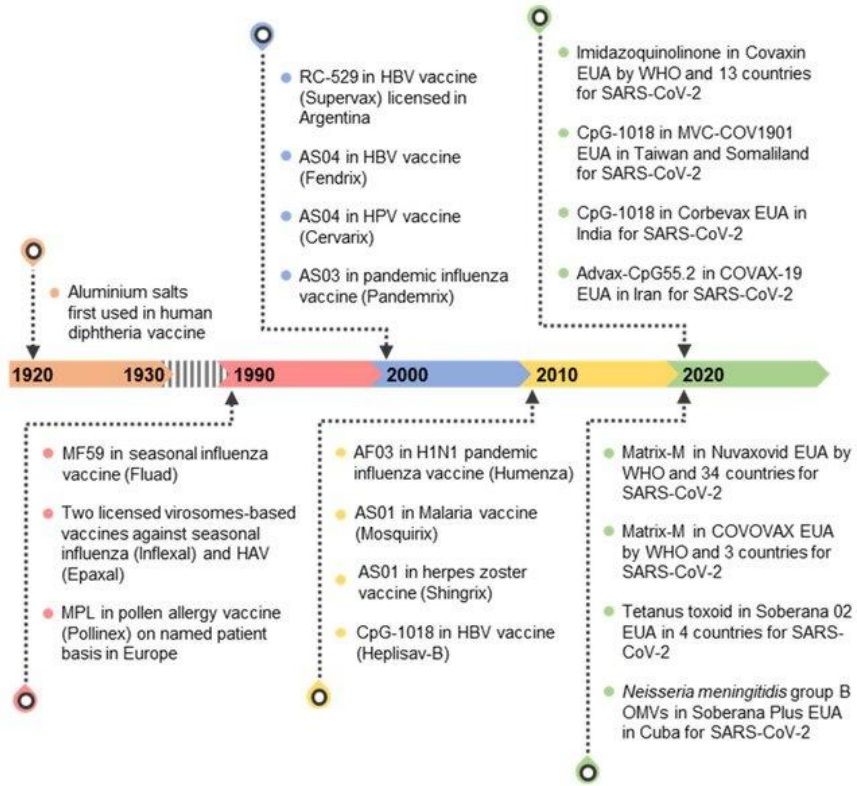
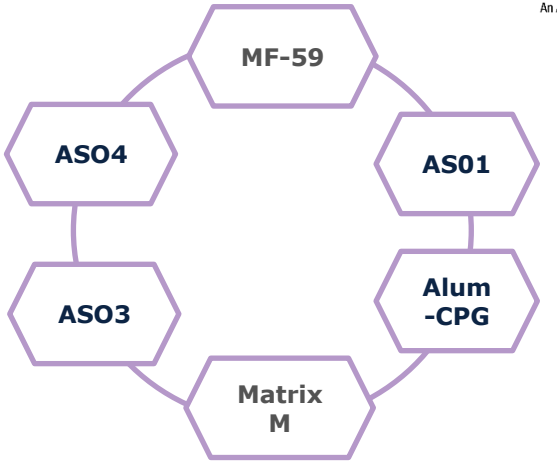


Figure 1. A timeline of adjuvant development and vaccine licensing.
https://www.researchgate.net/publication/358666400/figure/fig1/AS:1143128139533296@1745459102728/A-timeline-of-adjuvant-development-and-vaccine-licensing-The-year-the-adjuvant-was-used_W640.jpg



CURRENT CHALLENGES

- Limited Availability
- High Costs
- Distribution Challenges

Our Commitment to Advancing Vaccine Adjuvants

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2023

Expanded saponin capabilities

Q-Vant Biosciences became SPI Pharma's commercial arm for saponin-based adjuvant technologies.

2024

Established the Inimmune partnership

SPI Pharma partnered with Inimmune to commercialize and license its novel adjuvants and adjuvant systems.

2025

Invested in alum manufacturing

SPI Pharma invested $10 million to expand and upgrade its alum adjuvant manufacturing capabilities.

Q-VANT BIOSCIENCES™

Inimmune

Building on 20 years of vaccine-adjuvant expertise, SPI Pharma continues to invest in innovative technologies that address emerging global health needs.

Partnerships Power an Innovative Adjuvant Toolbox

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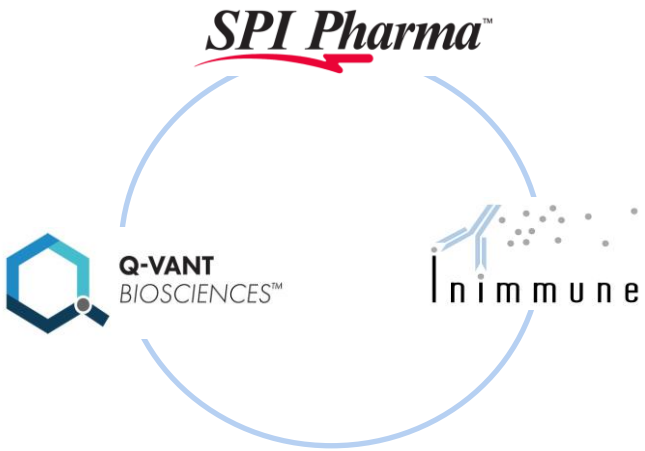
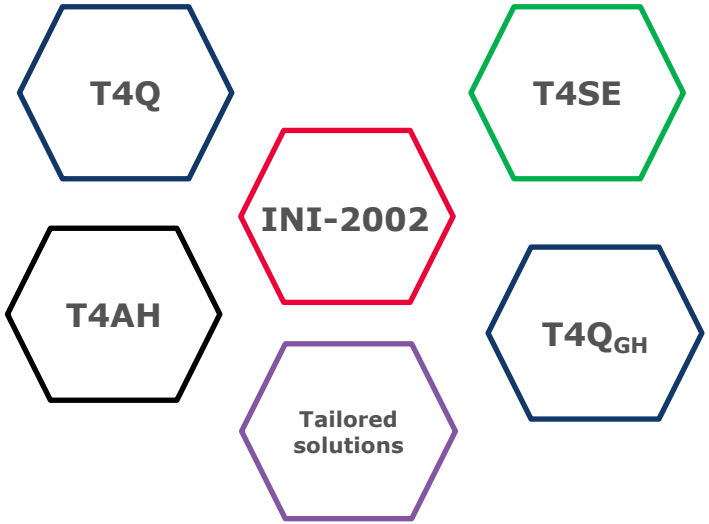
Combining complementary expertise to deliver accessible, application-ready adjuvant systems.





Together, we create differentiated adjuvant systems—and make them more accessible to vaccine developers.

Vaccine Adjuvant Technology Portfolio

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Alum Salts	Valens™ 1.5 Valens™ 2.0 Valens™ 3.0

Proven technology with an established safety profile

Liposomal Adjuvants	T4Q T4Q GH

Enhanced humoral and cellular immune responses

Alum-Based Adjuvant System	T4AH

Advanced alum-based immune enhancement

Saponin Adjuvants	VAC Saponin Valens™ QS-21 XP QS-21 90 QS-21 GH

Potent immune stimulation for challenging antigens

Emulsion Adjuvants	T4SE T4E-VET

Balanced efficacy and cost-effectiveness

Synthetic TLR4 Agonist	INI-2002

Thermostable and versatile immune potentiator

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Valens™ Alum Hydroxide

Why Aluminum Hydroxide?

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Decades of Proven Safety

Established safety record in licensed vaccines across multiple indications.

Combinable with Other Adjuvants

Can be combined with TLR4 agonists to achieve a balanced Th1/Th2 immune response.

Well-Characterized Profile

Familiar regulatory and manufacturing profile; often used in early-stage clinical trials.

Wide Antigen Compatibility

Compatible with a wide range of antigens for diverse vaccine applications.

Valens™ AH: Aluminum Hydroxide Adjuvants for Human Vaccines

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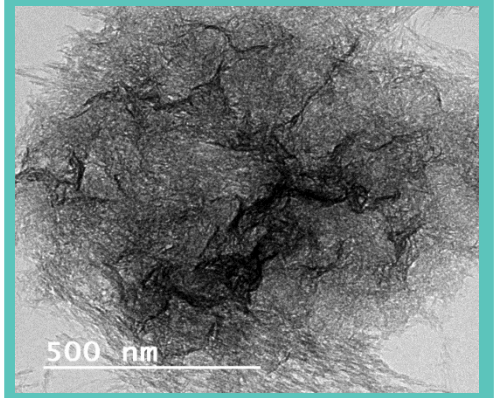
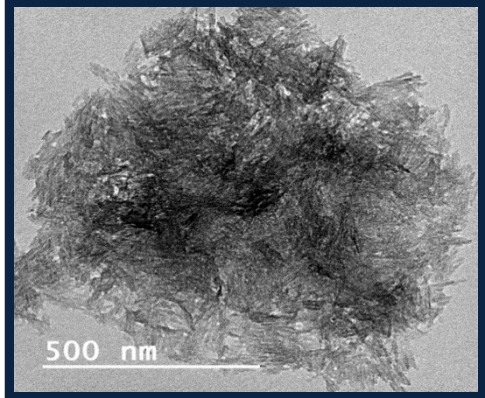
TEM: Morphology

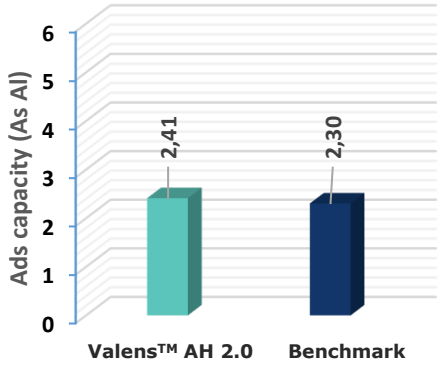
Valens™ AH 2.0



Benchmark



Protein Adsorption



Structural Equivalence

The TEM analysis confirms that Valens™ AH 2.0 is **structurally equivalent** to the benchmark, validating product consistency and quality.

High purity, low bioburden aluminium hydroxide

Available with different adsorption grades and concentration :

1.5%, 2.0% and 3.0% (%Al_2O_3)

Ph.Eur compliant and Manufactured according to cGMP

Available Valens™ Grades

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Four grades available to meet diverse formulation needs.

Characteristic	Valens™ AH 2.0 HA	Valens™ AH 2.0	Valens™ AH 3.0	Valens™ AH 1.5
Assay Al_2O_3 %	1.9–2.1%	1.9–2.1%	2.9–3.1%	1.4–1.6%
Protein Binding (Adsorption Capacity) mg BSA adsorbed/mg of Al_2O_3	3,5 - 4,0	2,5	2,5	2,5
Particle Size	5 µm	25 µm	25 µm	25 µm
Product Status	GMP targeted to 2027 Engineering lot by Q4/26	**Available**	**Available**	**Available**

Valens AH 2.0 represents the first human vaccine-grade offering within the Valens™ portfolio, launched in 2025.

Q-VANT BIOSCIENCES™

Secure and Large-Scale Supply of Saponins Adjuvant for Global Vaccine Development

Sustainable Supply

Our technology allows us to obtain QS-21 from any quillaja plant material including biomass, leaves, plantlets, cell culture.

Robust process that meets **cGMP requirements.**

Excipat Certified

Streamlined, continuous manufacturing at the source

July 2026:

- GMP adjuvants for veterinary vaccines
- GMP fractionation of QS-21 and other saponin for human use.

QS-21 Product Offering

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Valens™ QS-21 XP

›95% QS-21 Content

QS-21 with high purity standards.

Valens™ QS-21 90

≥90% QS-21 Content

Cost-effective alternative to premium grade.

Valens™ QS-21 GH

65-80% QS-21 Content

Acessible option designed to maximize affordability and access.

Affordability

QSapTM Technology: Supply for Global Health

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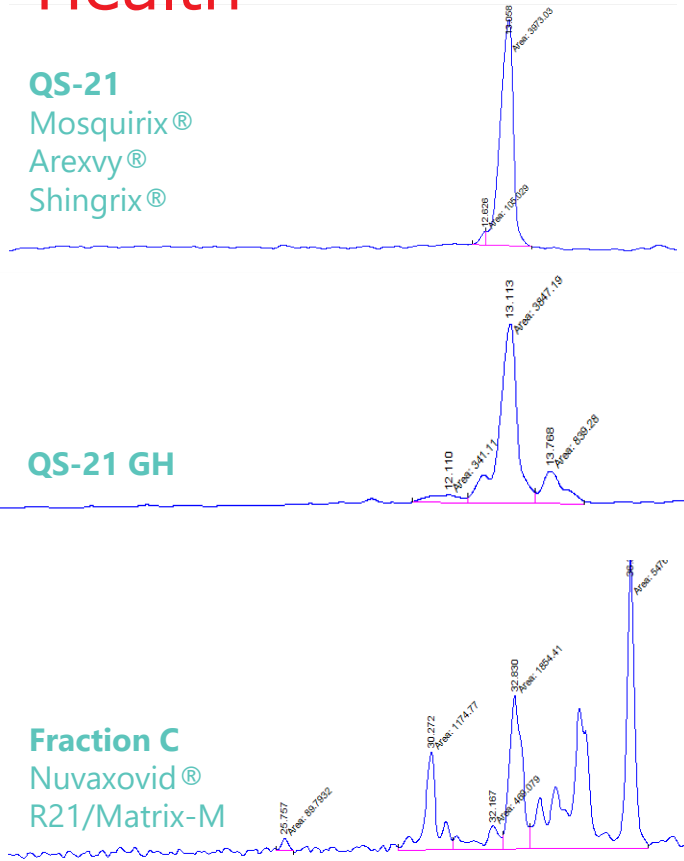

- **Sustainable:** No bark extraction required
- **Affordable:** QS-21 GH for global health
- **Open Access**
- **GMP-ready**
- **Compatible:** Works with TLR4-based adjuvants
- **Potent:** Drives strong humoral and cellular immunity

Reliable, scalable, cost-effective QS-21 supply

Poll Question 2

- **What would make you consider replacing an established adjuvant with a newer technology?**
  - Significantly improved immune response
  - Better safety / tolerability
  - Better dose sparing
  - Better stability
  - Lower adjuvant cost

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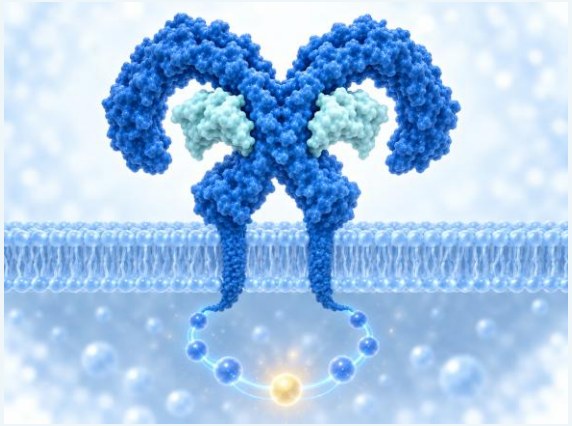
Innovative Next Generation Adjuvant Systems

Affordable | Accessible | Available

The Inimmune Difference

End-to-end adjuvant innovation from immune-target design to development readiness



Innate immune innovation with global reach

Designing immune responses—not simply adding an adjuvant

- Inimmune combines innate-immune biology, medicinal chemistry, formulation science and translational development to create adjuvants with purposeful immune profiles.
- 20+ Years experience in the design and development of vaccine adjuvants.

01
DESIGN
Medicinal chemistry and molecular design

02
FORMULATE
Liposomes, emulsions and alum systems

03
PROFILE
Innate signaling and immune profiling

04
TRANSLATE
Process development, CMC and clinical readiness

Designing adjuvants to deliver the immune response each vaccine needs

TLR4: A Validated Adjuvant Target

MPL provides clinical proof that TLR4 agonism can strengthen and shape vaccine-induced immunity.

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A PROVEN BIOLOGICAL PATHWAY

MPL engages innate immunity and translates antigen recognition into a purposeful adaptive response.

MPL | THE PROOF POINT

MPL

Monophosphoryl lipid A

- Detoxified lipid A derivative
- Signals through TLR4
- Used within AS04 and AS01

CLINICAL VALIDATION ACROSS LICENSED VACCINES

AS04

MPL + aluminum salt

Cervarix®
Fendrix®

Established alum-containing adjuvant system

AS01

MPL + QS-21 in liposomes

Shingrix® • Arexvy®
Mosquirix™

Established liposome-based adjuvant system

Building on Validated TLR4 Biology

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The opportunity is to broaden access—not to change the clinically established target.

VALIDATED FOUNDATION

TLR4

AGONISM

MPL demonstrates that targeted TLR4 activation can strengthen and shape vaccine-induced immunity.

CLINICALLY ESTABLISHED

BUILD ON THE TARGET

EXPAND ACCESS

NEXT-GENERATION OPPORTUNITY

Accessible TLR4 agonist alternatives

1. Broader availability
2. Scalable, consistent manufacturing
3. Formulation flexibility
4. Practical global deployment

Evolution of TLR4 Agonists

From established MPL to structurally defined, thermostable synthetic DAPs

Inimmune

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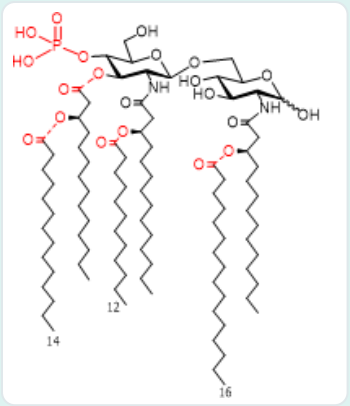
ESTABLISHED BENCHMARK

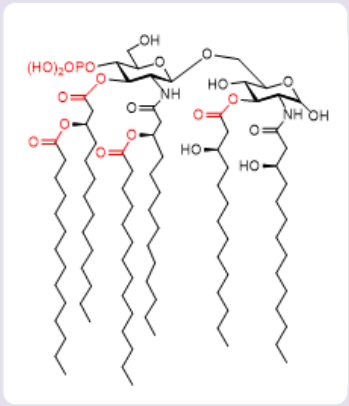


MPL® adjuvant

Heterogeneous mixture of lipid A congeners

BIOLOGICALLY DERIVED

GENERATION 1

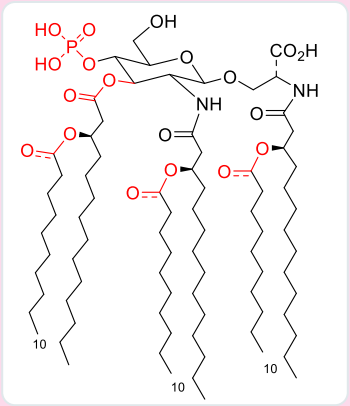


GLA or PHAD

Structurally defined synthetic disaccharide

SYNTHETIC

GENERATIONS 2/3



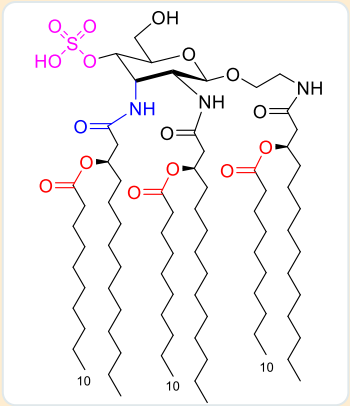
AGPs

Amino Glucosoamine Phosphates

Simplified synthetic monosaccharide

SIMPLIFIED

GENERATION 4



DAPs

Diamino Allose Phosphates

Structurally defined, synthetic and thermostable

NEXT GENERATION

Patent protection through 2038

INI-2002: Next Generation Synthetic TLR4 Agonist

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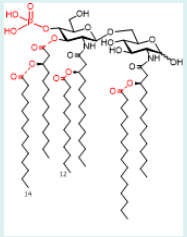
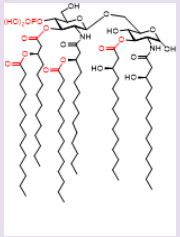
A simplified, structurally defined and thermostable scaffold that builds on validated TLR4 biology.



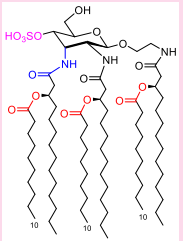
MPL® adjuvant

Biologically derived benchmark



GLA or PHAD

Defined synthetic disaccharide



INI-2002 (DAP)

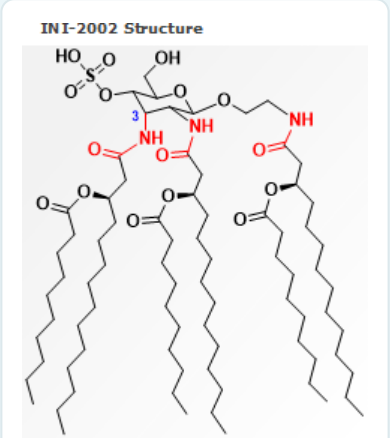
Defined synthetic monosaccharide

ATTRIBUTE	MPL® ADJUVANT	GLA or PHAD	INI-2002 (DAP)
Material type	Biologically derived mixture	Structurally defined synthetic molecule	Structurally defined synthetic molecule
Core scaffold	Disaccharide	Disaccharide	Monosaccharide
Preparation	Detoxified lipid A derivative	Synthesis (~36 steps)	Shorter synthesis (~24 steps)
Key distinction	Heterogeneous lipid A congeners	Defined synthetic disaccharide	Simplified, thermostable synthetic scaffold
Functional groups	4-Phosphate and 3-ester linkages	4-Phosphate and 3-ester linkages	4-Sulfate and 3-amide linkages

INI-2002: Fully Synthetic TLR4 Agonist

Designed for consistent, scalable vaccine-adjuvant manufacturing

DESIGNED, NOT EXTRACTED



INI-2002

Diamino allose phosphate TLR4 agonist

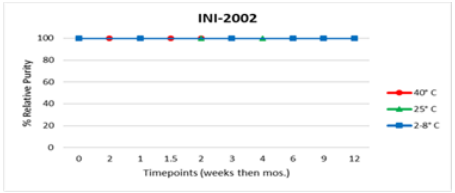
FULLY SYNTHETIC • CONSISTENT • SCALABLE

Why INI-2002?

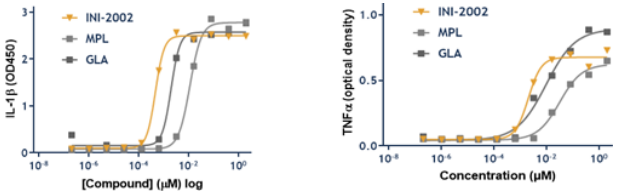
1. **Defined by design**
   A fully synthetic, structurally defined molecule—not an extracted mixture.
2. **Stability supports flexibility**
   Thermal stability may support broader storage, handling and distribution options.
3. **Benchmarked innate immune activity**
   Comparable cytokine-response profiles to MPL and GLA in human PBMC testing.

SUPPORTING EVIDENCE

Stable Across Temperatures



Comparable to Benchmark TLR4 Agonists



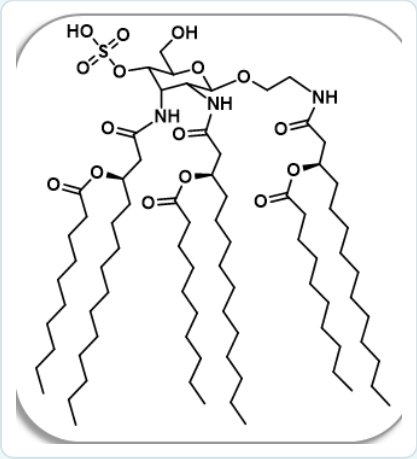
INI-2002: A Versatile Adjuvant Platform

One synthetic TLR4 agonist enables multiple formulation and delivery systems.

COMMON ACTIVE COMPONENT

INI-2002

Fully synthetic TLR4 agonist



CONSISTENT • STABLE • SCALABLE

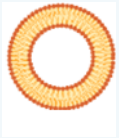
TUNABLE IMMUNE PROFILE

Th1

Th2

FORMULATION

DELIVERY SYSTEMS

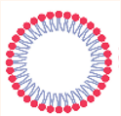


LIPOSOME

QS-21 / QS-21 GH

Two QS-21 sourcing options

T4Q **T4Q$_{GH}$**

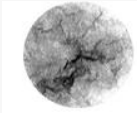


SQUALENE EMULSION

Oil-in-water emulsion

Flexible emulsion-based formulation

T4SE



ALUMINUM HYDROXIDE

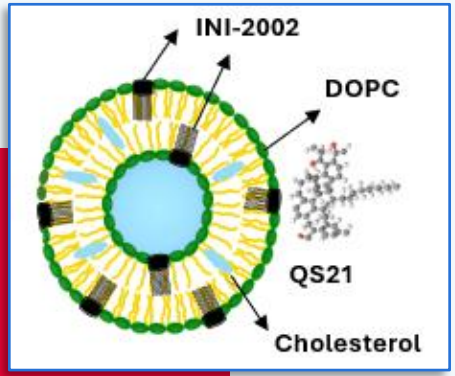
Valens™

Alum-adsorbed formulation

T4AH

T4Q: A High-Performance Adjuvant System for Next Generation Vaccines

T4Q Liposomal System



Why T4Q?

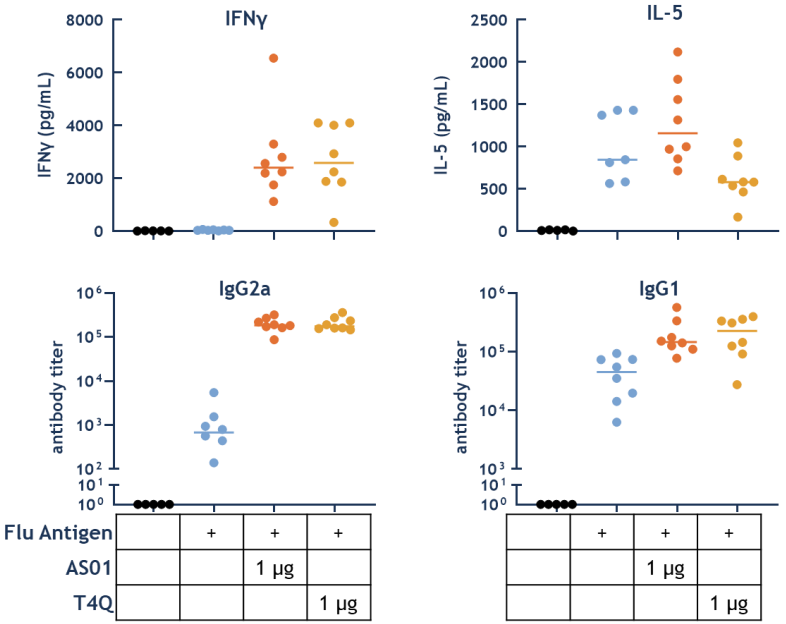
- **Fully synthetic TLR4 agonist (INI-2002) + QS-21**
- **Synergistic, Th1-biased immunity**
- **Human vaccine applications**
- **cGMP manufactured • Licensing-ready**
- **Thermostable**

Potent • Synergistic • Licensing-Ready Adjuvant System

T4Q Stable, Drives Strong Immune Responses

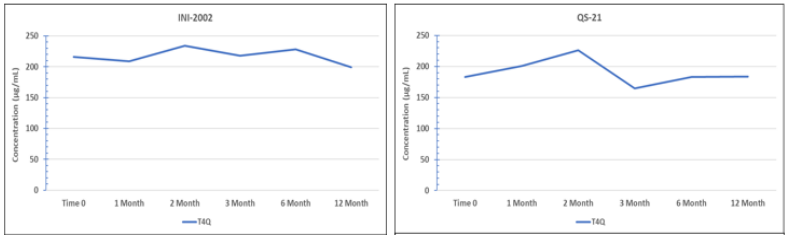
Demonstrates performance comparable to ASO1®

Strong Th1-Biased Immune Response

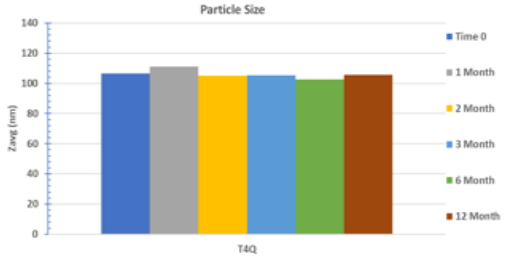


- Th1-biased response comparable to AS01®
- Enhances both cellular (IFNγ) and humoral responses
- Minimal Th2 shift

Chemical Stability



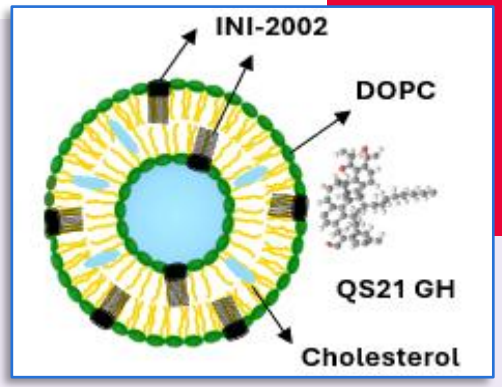
Colloidal Stability



- Robust chemical stability at 2–8°C
- Stable colloidal properties
- Lyophilized for flexible storage and handling

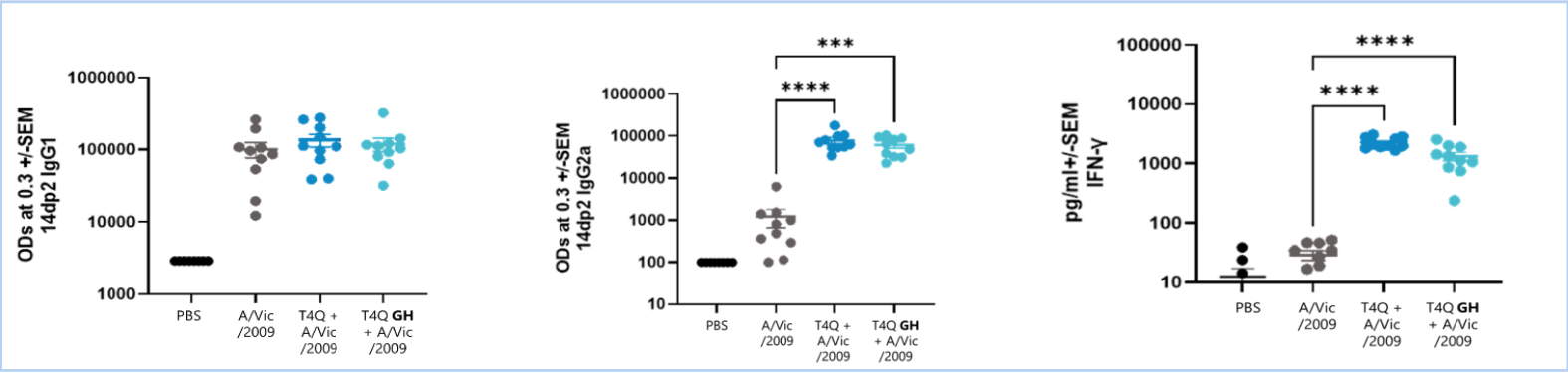
$T4Q_{GH}$: A Next-Generation Synergistic Adjuvant System

$T4Q_{GH}$ Liposomal System



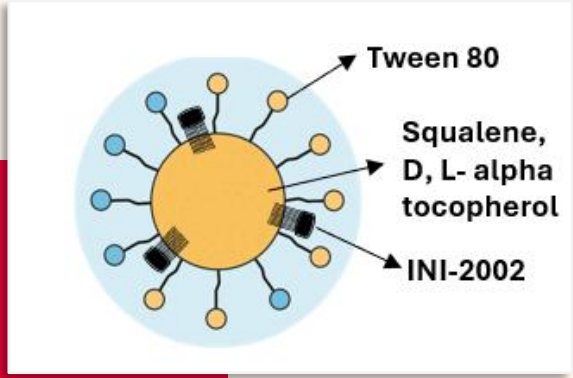
Why $T4Q_{GH}$?

- **Cost-optimized for global health**
- **Synergistic, Th1-biased immunity**
- **Ready for human applications**
- **Comparable to T4Q and AS01®**



T4SE: A TLR4-Emulsion Synergistic Adjuvant System

T4SE Emulsion System



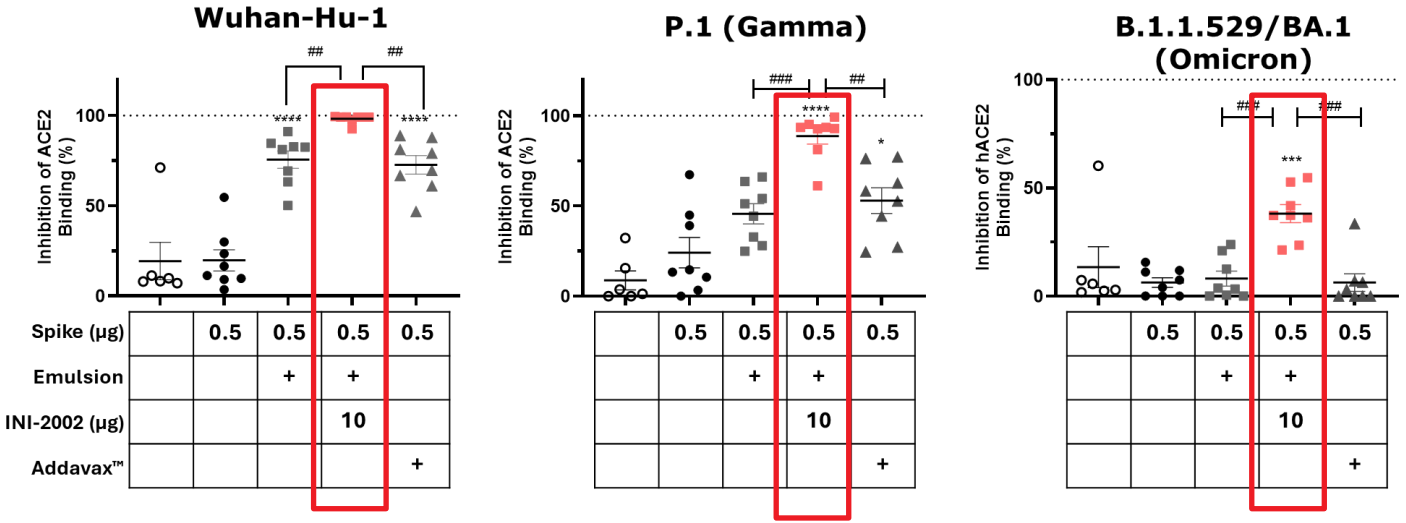
Why T4SE?

- **Synergistic activation of innate and adaptive immunity**
- **Drives strong, broad immune responses**
- **Human and veterinary vaccine applications**
- **Scalable, cGMP-ready manufacturing *(engineering lot Q1, 2027)***
- **RUO samples available. Licensing ready**

Well-established emulsion platform with enhanced TLR4 activation.

T4SE: Squalene-Based Emulsion Formulation

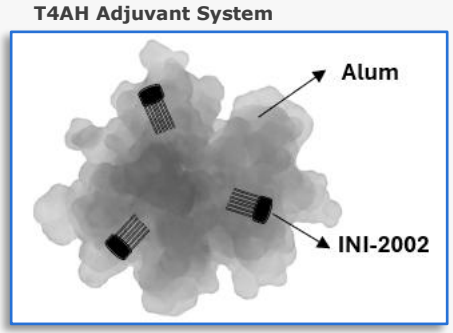
- T4SE is an oil-in-water emulsion containing INI-2002 and Squalene



Data generated at the University of Montana and adapted from Lathrop, Stephanie K., et al. "Vaccination with ancestral SARS-CoV-2 spike adjuvanted with TLR agonists provides cross-protection against XBB. 1." npj Viruses 2.1 (2024): 28.

Delivers broad cross-protection against evolving strains, helping vaccines stay one step ahead as the virus changes.

T4AH: A TLR4-Alum Synergistic Adjuvant System



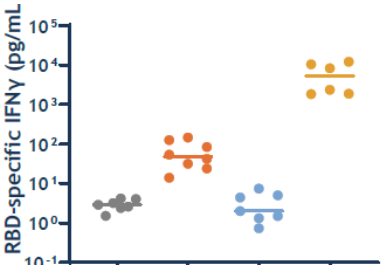
Why T4AH?

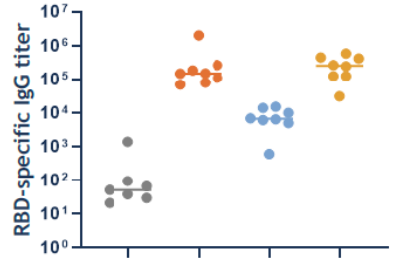
- **Synthetic INI-2002 adsorbed on alum**
- **Synergistic activation of innate and adaptive immunity**
- **Extends alum with TLR4-driven cellular immunity**
- **Human and veterinary vaccine applications**
- **Scalable, cGMP-ready manufacturing**
- **Strong IP protection**

Potent • Synergistic • Licensing-Ready Adjuvant System

T4AH Drives Cellular Immunity with Robust Stability

Enhanced Immune Response

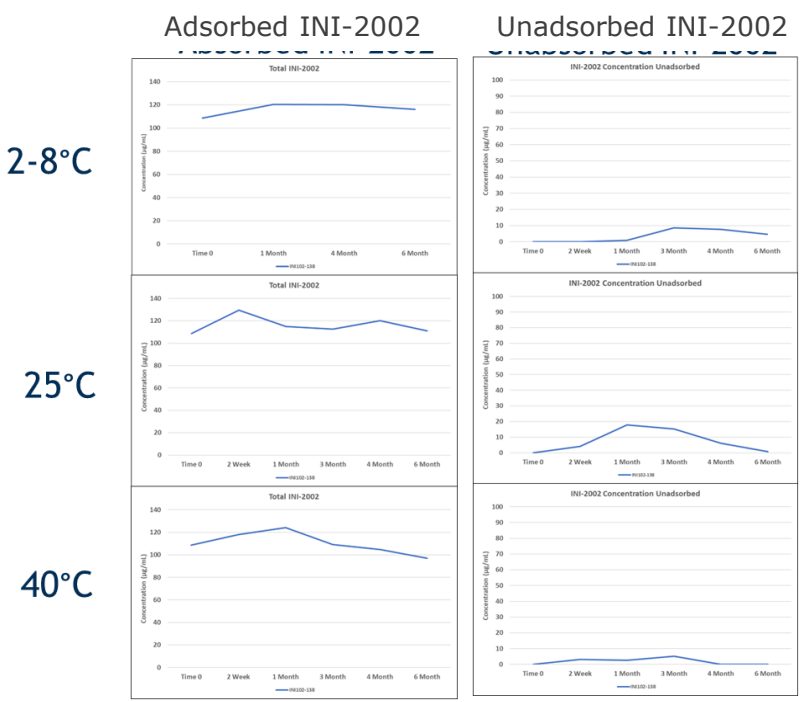




SARS-CoV-2 antigen	+	+	+	+
INI-2002		+		+
Aluminum Hydroxide			+	+

- Drives strong Th1 response.
- Enables T cell response to weak antigens.

Data generated by University of Montana (CTM).



- Stable adsorption across temperatures
- Minimal free (unadsorbed) INI-2002
- Supports long-term storage (~ 24 months)

References

- **INI-2002**
  Diamino Allose Phosphates: Novel, Potent, and Highly Stable Toll-like Receptor 4 Agonists, J. Med. Chem. 66 (20): 13900–13917 (**2023**) .

- **INI-2002 in emulsion**
  Vaccination with ancestral SARS-CoV-2 spike adjuvanted with TLR agonists provides cross-protection against XBB.1, npj Viruses 2, 28 (**2024**).

- **INI-2002 adsorbed on alum**
  Co-Delivery of Novel Synthetic TLR4 and TLR7/8 Ligands Adsorbed to Aluminum Salts Promotes Th1-Mediated Immunity against Poorly Immunogenic SARS-CoV-2 RBD. Vaccines (Basel), Dec 23;12(1):21 (**2024**).

Poll Question 3

SPI Pharma™
An ABF Ingredients Company

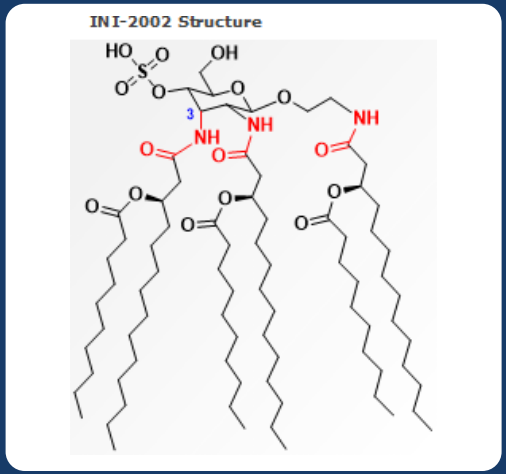
- **What is currently the biggest challenge when selecting an adjuvant for your vaccine program?**

  - Access / licensing restrictions
  - Safety / tolerability
  - Stability / formulation
  - Manufacturing scalability
  - Cost
  - Regulatory requirements
  - We don't currently have an adjuvant challenge.

INI-2002 | Fully Synthetic TLR4 Agonist

A stable, scalable and formulation-flexible adjuvant active for next-generation vaccines

DESIGNED, NOT EXTRACTED



INI-2002

Diamino allose phosphate

FULLY SYNTHETIC • STRUCTURALLY DEFINED

Why INI-2002?

Validated biology—engineered for practical development

01

Validated TLR4 target

Builds on a clinically established innate-immune pathway and is benchmarked against MPL and GLA.

02

Synthetic consistency

A defined molecular structure designed to avoid the variability associated with biologically extracted mixtures.

03

Stable and scalable

Thermal stability and synthetic manufacture support consistent supply and practical vaccine development.

04

Flexible formulation

Available as a standalone TLR4 agonist and compatible with liposomal, emulsion and aluminum-based approaches.

cGMP MANUFACTURED | THERMALLY STABLE | HUMAN PBMC BENCHMARKED

AVAILABLE FOR STANDALONE EVALUATION, CUSTOM FORMULATION AND INTEGRATION INTO TAILORED ADJUVANT SYSTEMS

Integrated Adjuvant Systems

INI-2002 combines with established formulation technologies to support distinct vaccine needs.

COMMON IMMUNE ACTIVATOR	FORMULATION COMPONENTS	TAILORED SYSTEMS
INI-2002 Fully synthetic TLR4 agonist Defined by design Stable and scalable Available standalone	**LIPOSOME + QS-21 / QS-21GH** Sustainable saponin option	T4Q T4Q GH
	SQUALENE EMULSION Oil-in-water emulsion platform	T4SE
	ALUMINUM HYDROXIDE Valens™ aluminum hydroxide	T4AH

ONE SYNTHETIC IMMUNE ACTIVATOR + PROVEN FORMULATION TECHNOLOGIES = TAILORED ADJUVANT SYSTEMS

Tailored Adjuvant Systems

DECISION ATTRIBUTE	T4Q HUMAN	T4Q GH HUMAN	T4SE HUMAN	T4AH HUMAN
Formulation	Liposome (QS-21)	Liposome (QS-21 GH)	Squalene emulsion	Aluminum hydroxide
Immune profile	Th1	Th1	Broad Th1	Th1 / Th17
Best-fit application	Advanced human vaccines	Scalable human vaccines	Broad-access and global vaccines	Established, scalable vaccines
Intended advantage	Designed for high potency	Balanced potency and cost	Broad immune-response potential	Supports cellular immunity
Development stage	cGMP manufactured	cGMP manufacturing ready	Engineering-stage development	Engineering lot
Indicative target cost per dose (USD)	**> $3.50**	**< $1.50**	**< $0.50**	**< $0.50**

Four formulation options span high-potency, cost-balanced, broad-access and advanced development phase.

Advancing Adjuvant Systems Toward Clinical Readiness

T4Q • NEAR TERM

Complete GLP toxicology

Study is nearing completion. Finalize reporting, review findings and confirm implications for continued development.

TOXICOLOGY DATA MILESTONE

T4SE • MANUFACTURING

Advance the engineering lot

Finalize the manufacturing plan, initiate the engineering campaign and establish the release and stability program.

MANUFACTURING READINESS

SELECTED SYSTEM • CLINICAL

Prepare for clinical entry

Target potential clinical-trial initiation as early as Q1 2028, subject to data, regulatory and partner alignment.

TARGET: AS EARLY AS Q1 2028

Let's identify the right adjuvant system for your antigen and development stage.

Our Promise

01

Tailored Adjuvant Systems

To design and deliver tailored adjuvant systems for human and veterinary applications

02

Safe, Affordable & Effective

To provide safe, affordable, effective adjuvant systems available for licensing

03

Trusted Partner

To be the trusted partner and deliver solutions and products on time and in full

Take the next step **with us**

Innovation | Partnership | Global Health

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