HA-Alg Injectable Hydrogel

Translational Development, Regulatory Status, and Commercialization Readiness Report

MORE INFO

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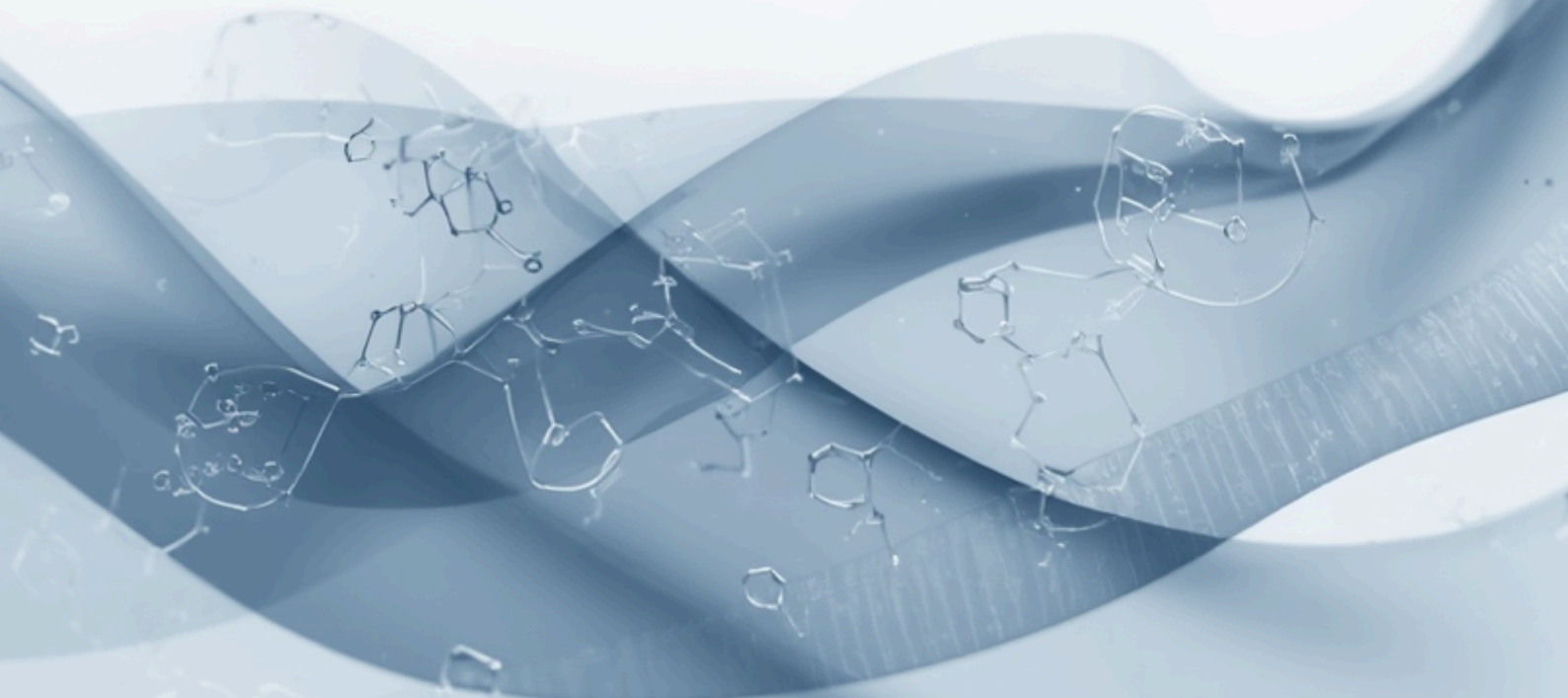
1. Executive Overview

The HA-Alg hydrogel is a proprietary injectable biomaterial developed at the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand. The product is based on a hyaluronic acid–alginate (HA-Alg) formulation and is designed as a cell-free viscoelastic injectable hydrogel for the management of pain associated with knee osteoarthritis (OA).

Originally conceived as a cell carrier for cartilage tissue engineering, the HA-Alg platform has undergone extensive formulation refinement and translational optimization, resulting in a stand-alone injectable product that provides mechanical cushioning, viscoelastic support, and favorable interaction with native synovial fluid. The current product strategy prioritizes safety, manufacturability, and regulatory alignment with existing intra-articular hyaluronic acid products.

The HA-Alg hydrogel has reached pilot-scale manufacturing readiness, is protected by a US patent (Pending), and has successfully completed a comprehensive suite of ISO 10993 biocompatibility tests at a GLP-accredited facility. While globally aligned with medical device classification as a synovial fluid supplementation medium, the product has been classified as a drug by the Thai FDA, creating a unique regulatory landscape that is being actively addressed through alternative manufacturing and market-entry strategies.

With a strong safety profile, scalable production capability, and a clear development roadmap toward clinical validation, HA-Alg hydrogel represents a near-market injectable biomaterial platform with applications in human osteoarthritis management, research use, and veterinary orthopedics.



2. Product and Technology Description

2.1 Composition and Design Rationale

The HA-Alg hydrogel is composed of hyaluronic acid and alginate polymers formulated to create a sterile, injectable viscoelastic gel. The formulation is optimized to balance injectability, mechanical integrity, and in situ interaction with joint environments. The product is intended for intra-articular injection, particularly in large load-bearing joints such as the knee, where endogenous synovial fluid viscosity is reduced due to degenerative disease.

2.2 Mechanism of Action

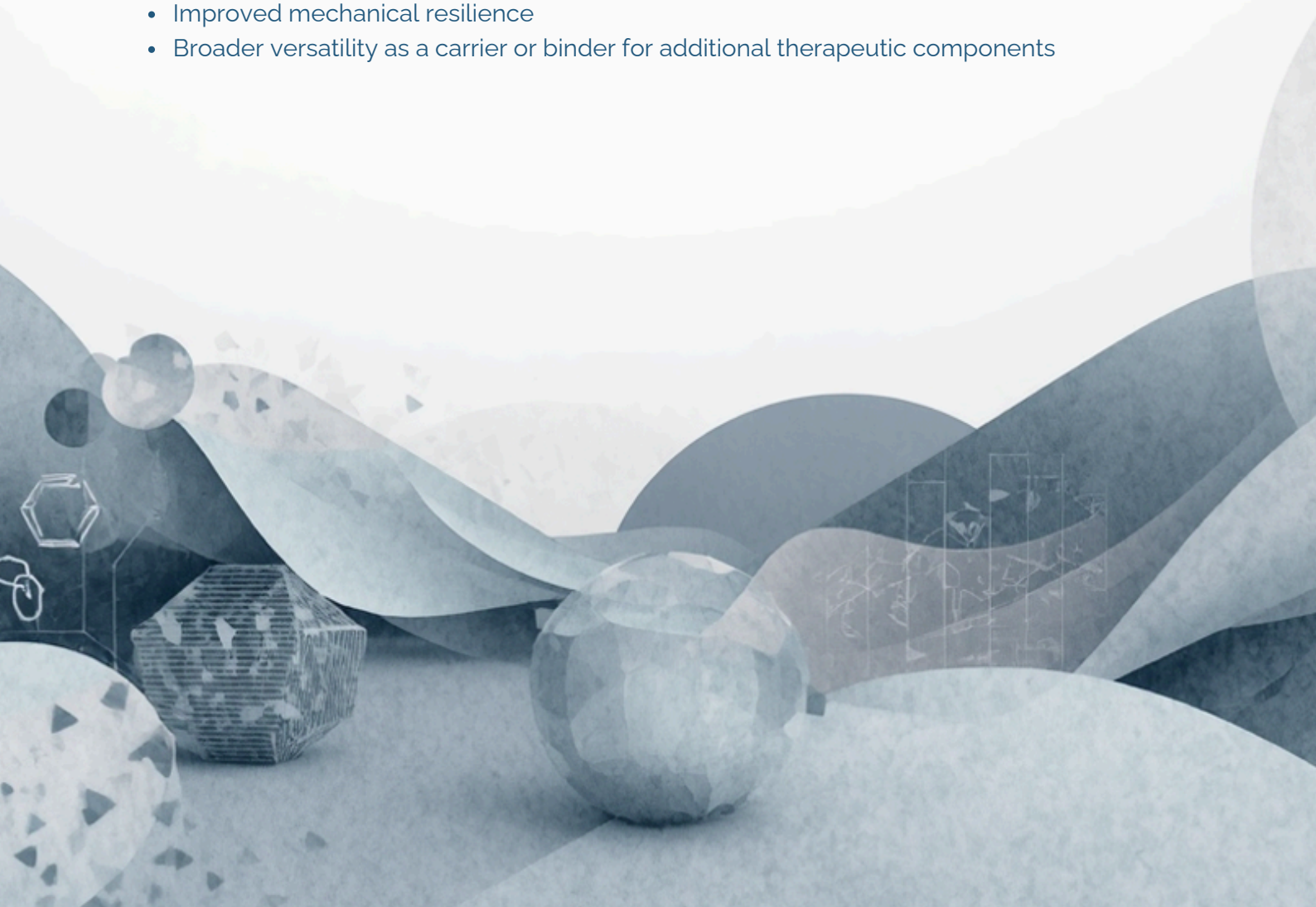
The HA-Alg hydrogel functions primarily through:

- Restoration of viscoelastic properties within the joint space
- Mechanical cushioning and load distribution
- Interaction with native synovial fluid, including induction of gelation even when diluted up to 10-fold
- Compressive testing demonstrates a higher compressive modulus compared with a commercial competitor, supporting its mechanical performance claims.

2.3 Differentiation from Conventional HA Products

Unlike conventional hyaluronic acid solutions, the HA-Alg hydrogel exhibits:

- Enhanced gel stability
- Improved mechanical resilience
- Broader versatility as a carrier or binder for additional therapeutic components



3. Development and Manufacturing Status

3.1 Funding and Institutional Support

Program Management Unit for Competitiveness (PMUC) funding since 2021

- Phase 1: USD ~89,000
- Phase 2: USD ~150,000

3.2 Manufacturing Capability

- Pilot-scale production established at CU SCI PRODUCTS & SERVICES
- Secondary production facility at EngineLife, Faculty of Engineering, Chulalongkorn University
- Small-scale batches (≈250 mL) produced for testing and validation

Established protocols for:

- Process control
- Terminal sterilization
- Packaging development
- Shelf-life evaluation

Future manufacturing strategy focuses on pre-filled syringe production, requiring filling-line capability and ISO-compliant facilities.

4. Regulatory Landscape and Strategy

4.1 Global Classification

Under the Global Medical Device Nomenclature (GMDN), the HA-Alg hydrogel aligns with:

Synovial fluid supplementation medium (GMDN code 44757)

Defined as a sterile viscoelastic solution intended for intra-articular injection to cushion joints affected by degenerative disease

4.2 Thai FDA Classification Challenge

Despite international alignment as a medical device, the Thai FDA has officially classified HA-Alg hydrogel as a drug. This classification significantly impacts:

- Manufacturing requirements (GMP pharmaceutical plants)
- Clinical development pathways
- Time and cost to market

4.3 Proposed Regulatory Mitigation Strategy

- Utilize OEM manufacturing services in Asian countries with ISO 13485-certified facilities
- Manufacture HA and alginate solutions as pre-filled injectable products
- Pursue non-IVD medical device pathways outside Thailand while maintaining parallel domestic regulatory discussions

5. Biocompatibility and Safety Evaluation

5.1 ISO 10993 Testing Program

Biocompatibility testing was conducted at Bioneeds India Private Limited, a GLP-accredited preclinical facility. All tests were completed successfully.

Test	Standard	Result
Cytotoxicity	ISO 10993-5	Pass
Skin Sensitization	ISO 10993-10	Pass
Intracutaneous Reactivity	ISO 10993-23	Pass
Acute Systemic Toxicity	ISO 10993-11	Pass
Subacute Systemic Toxicity	ISO 10993-11	Pass
Material-Mediated Pyrogenicity	ISO 10993-11 / USP	Pass
Genotoxicity (Ames)	ISO 10993-3 / 33	Pass
Genotoxicity (Chromosomal Aberration)	ISO 10993-3 / 33	Pass
Intramuscular Implantation (13 weeks)	ISO 10993-6	Pass

5.2 Benchmarking Against a Commercially Available product

The HA-Alg hydrogel demonstrates equivalent biocompatibility performance to a Commercially Available product, a marketed intra-articular HA product.

6. Stage-Gate Development Timeline

6.1 R&D Phase (2007–2021)

- Chondrocyte isolation and MSC differentiation studies
- Lab-grown cartilage development
- Initial hydrogel formulation

6.2 Patent and Publication Phase (2021–2023)

- Provisional patent filing (2021)
- Peer-reviewed publication (European Polymer Journal, 2022)
- PCT filing (2023)
- US Patent (2025) : Publication no. US 2025/0002659 A1 (Pending)

6.3 Manufacturing Development (2023–Present)

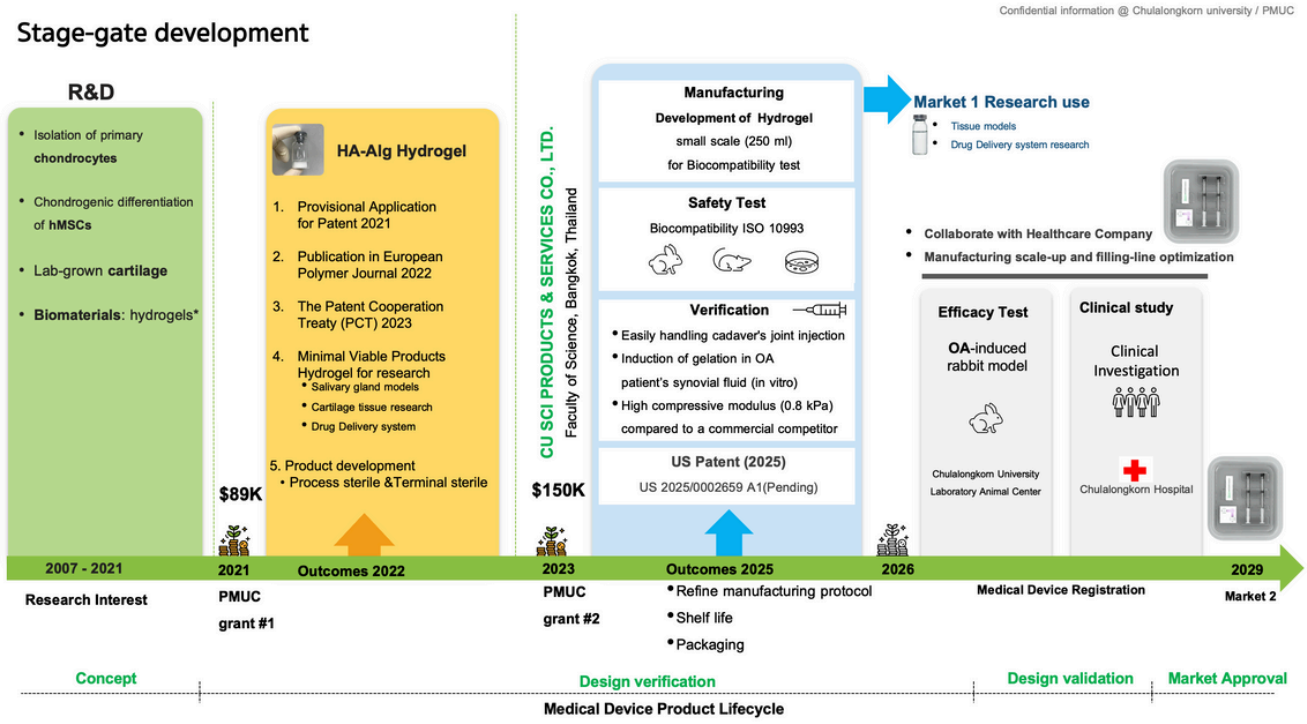
- Process optimization
- Sterilization validation
- Pilot-scale production

6.4 Current Phase: Safety and Handling Validation

- ISO 10993 biocompatibility completion
- Cadaveric handling validation
- Orthopedic specialist evaluation

6.5 Future Milestones

- Efficacy Testing (2025–2026): OA-induced rabbit model
- Clinical Investigation (2027): Human studies in collaboration with Maha Chakri Sirindhorn Clinical Research Center (Chula CRC)
- Target Market Entry: 2029



7. Technical Capabilities and Applications

7.1 Core Capabilities

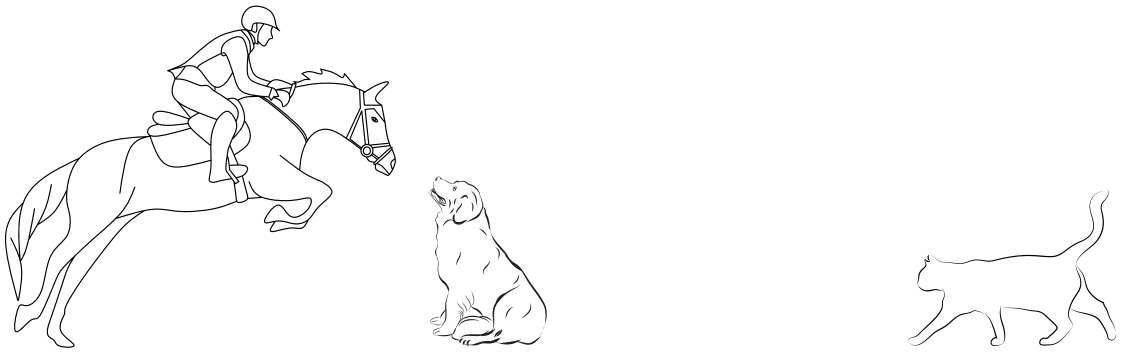
- Tunable viscoelastic properties
- Injectable and mechanically stable
- Compatible with biological additives

7.2 Potential Applications

- Knee osteoarthritis pain management
- Controlled release of therapeutic agents
- Cartilage tissue engineering scaffold
- Binder for demineralized bone matrix
- Adipose tissue support

8. Veterinary and Adjacent Markets

The Faculty of Veterinary Science, Chulalongkorn University, has expressed interest in applying HA-Alg hydrogel for equine osteoarthritis, where joint replacement options are limited. Veterinary applications present a parallel and potentially faster market entry pathway.



9. Development Gaps and Partnership Needs

Key areas requiring strategic collaboration include:

- Regulatory strategy across Asian markets
- CRO support for preclinical and clinical studies
- Manufacturing scale-up and filling-line optimization
- Market access and commercialization expertise

Conclusion

The HA-Alg hydrogel has achieved a high level of technical and regulatory readiness, supported by comprehensive safety data, pilot-scale manufacturing, and intellectual property protection. The primary remaining milestones involve site-specific efficacy validation and regulatory navigation, particularly in light of divergent classification frameworks.

Strategic partnerships with experienced healthcare companies, CROs, and manufacturers will be critical to accelerating the transition from a validated translational asset to a market-ready injectable therapy