Regentis Biomaterials

Investor Presentation

Overview

There is currently no approved, ready-to-use, off-the-shelf product in the United States market for cartilage repair.

Knee cartilage repair
large market with unmet need

U.S. market: 472,500+ procedures annually
Limitations: Microfracture (MFx) the current gold standard of care
- Short-term relief
- Often requires repeat surgical intervention

GelrinC®
Acellular, unique hydrogel for off-the-shelf knee cartilage repair

- Successful Pilot study
- CE Mark approved in Europe
- FDA pivotal (PMA) trial underway in the EU & the U.S.

Development & commercial milestones

- Pivotal trial enrollment completion (Est. Q4,25)
- EU commercialization efforts starting 2025
- PMA submission (Est. Q4,27)

Platform technology with multiple expansion opportunities

- Other cartilage injuries (ankle, wrist, elbow)
- Moderate osteoarthritis

IP Portfolio

- 34 global granted & issued patents + 4 pending
- Covering composition, surgical, and manufacturing features

Company at a Glance

Regenerative medicine company, developing GelrinC® for knee cartilage injuries.

Ready-to-use hydrogel technology, offering cost-effective, restorative tissue repair, sustained pain relief and improved function.

Phase II success, Approx. 100% greater KOOS (1) and VAS (2) improvement vs. microfracture.

Approved – CE mark in Europe

FDA pivotal trial, 41 of 80 patients already treated and follow up completed in the U.S. and Europe.

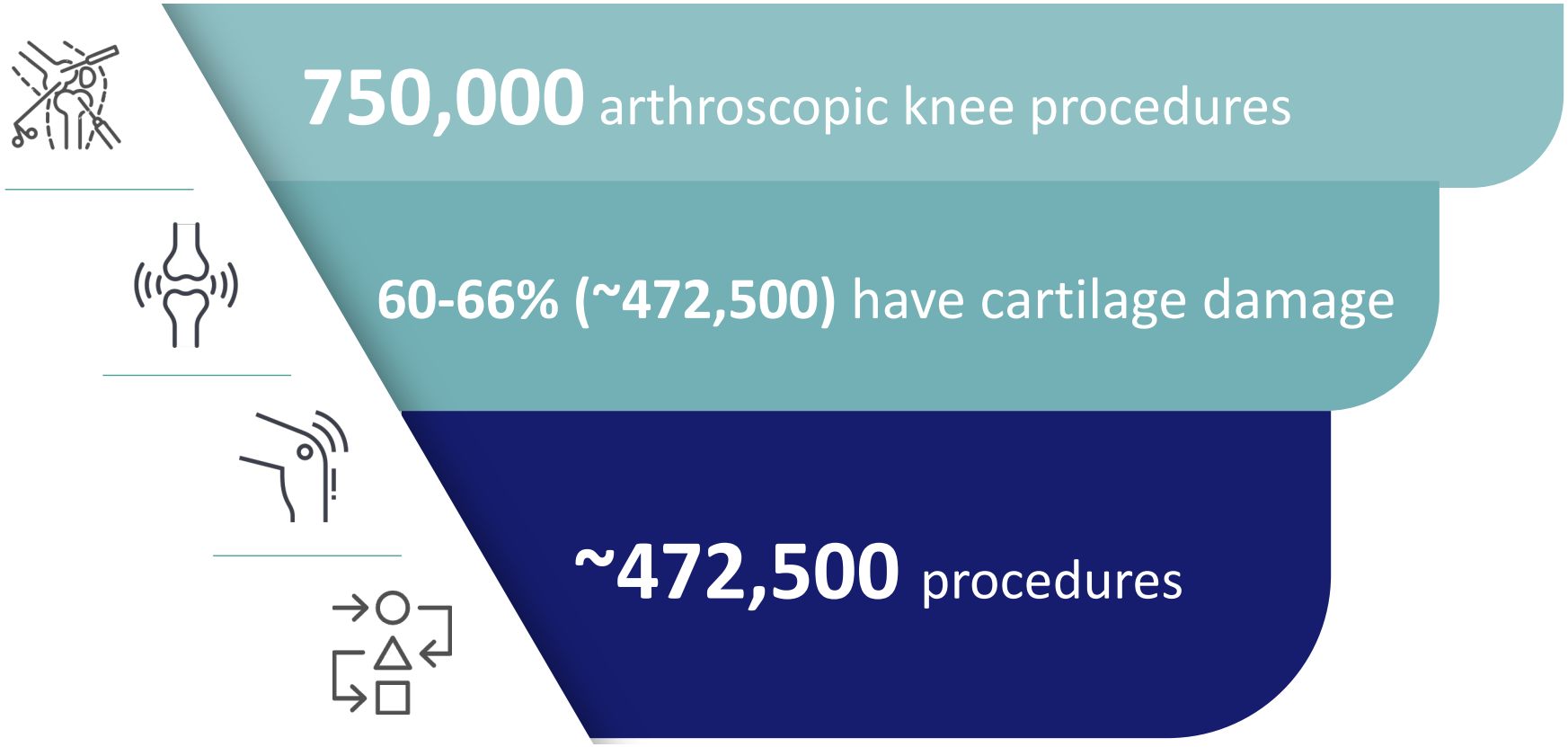
Unique, to our knowledge, there is currently no approved off-the-shelf product marketed in the U.S. for cartilage repair.

Broader potential, treats osteoarthritis and other cartilage injuries, supported by animal studies.

(1) KOOS Score: Measures knee pain, symptoms, function, and quality of life.

(2) VAS Score: Rates pain intensity on a 0–10 scale.

U.S. Addressable[(1)] Market



(1) Minimal market to further grow when Gelrin is introduced.

Advantages of GelrinC

(further supported by the Phase II-study)

- **Off-the-shelf** product for cartilage repair.
- **New class of acellular** solution leveraging:
  - Polyethylene glycol (PEG) hydrogel implant to drive new cartilage formation.
  - Denatured fibrinogen-controlled erosion enabling hyaline-like cartilage regeneration.
- **Liquid form** for optimal defect filling, **curing** into a **solid** form to remain in place.
- **Single, approx. 10-minute** surgical procedure.
- Implantable via open or **minimally-invasive** techniques.
- **Low-cost** manufacturing process with **scalability**.
- Designed for **restorative repair** of focal cartilage and osteochondral defects.

GelrinC vs Competition in Cartilage Repair

Off-the-shelf, immediate treatment

	Resorbable Hydrogel GelrinC	Cell-based Products (Maci of Vericel)	Bi-phasic plugs (AgiliC of Cartiheal)
	GelrinC	maci	
Type of Lesion	All Types – involving multiple areas of the cartilage	Limited - small, well-defined region of the cartilage	Limited - small, well-defined region of the cartilage
Procedures Required	Single, minimally invasive	Two surgeries : Biopsy + reimplantation, 8-12 weeks duration	Single Requires removal of Healthy Bone tissue; requires drilling
Accessibility	Off-the-shelf, immediate	8-12 weeks	Requires drilling
Surgery Time	Approx. 10 min(1)	2x (1-3 hours)	45 min
Long Term Clinical Data	++	+	+-
Recovery time	2 weeks	6 weeks	N/A
Cost	<$10,000	~$38,000 - ~$45,000 (est.)(2)	Unknown
Market Availability	CE marked (EU) / Pivotal trial (U.S.)	U.S. only	FDA approved (2022) and CE marked
Market Cap / Sales	N/A	$1.9B / $46.3M(3)	Acquired by Smith+Nephew(4)

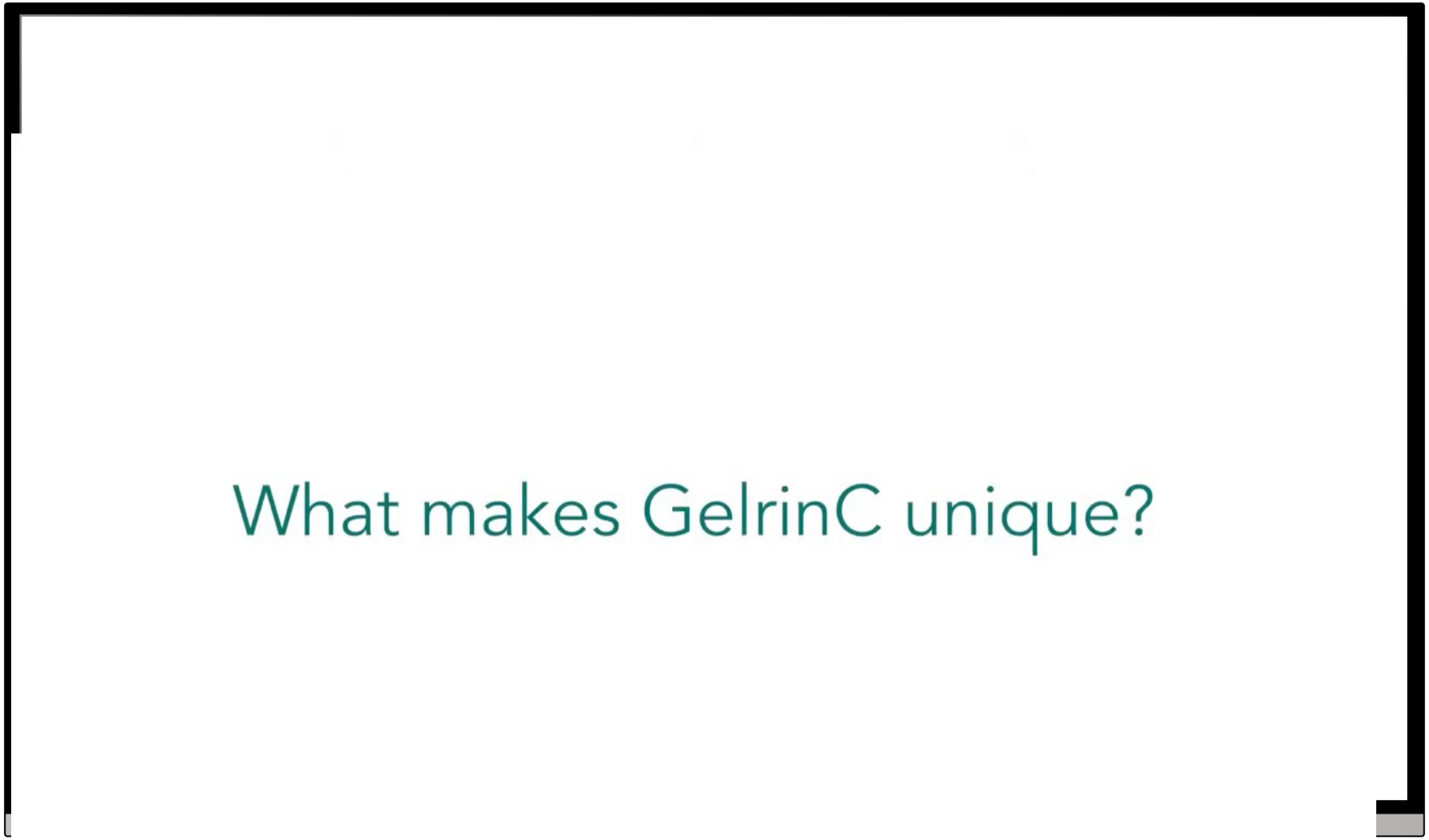
(1) Based on Company's internal measurements of surgery time.
(2) Bryn M, Vannabouathong C, AlBuhairan B, Bhandari M.Cost of matrix-induced autologous chondrocyte implantation in the United States.Arthroscopy. 2021;37(12):3499–3506.e1.
(3) Market Cap as of May 1, 2025. Net revenues of $46.3M for MACI in first quarter of Fiscal Year 2025 (https://investors.vcel.com/news-releases/news-release-details/vericel-reports-first-quarter-2025-financial-results-and-raises).
(4) https://www.smith-nephew.com/en/news/2024/01/10/20240110---sn-completes-acquisition-of-novel-cartilage-regeneration.

Testimonial: Dr. Brian Cole

Leading orthopaedic surgeon at Rush Hospital Center, Chicago

Testimonial: Jason M. Scopp, MD

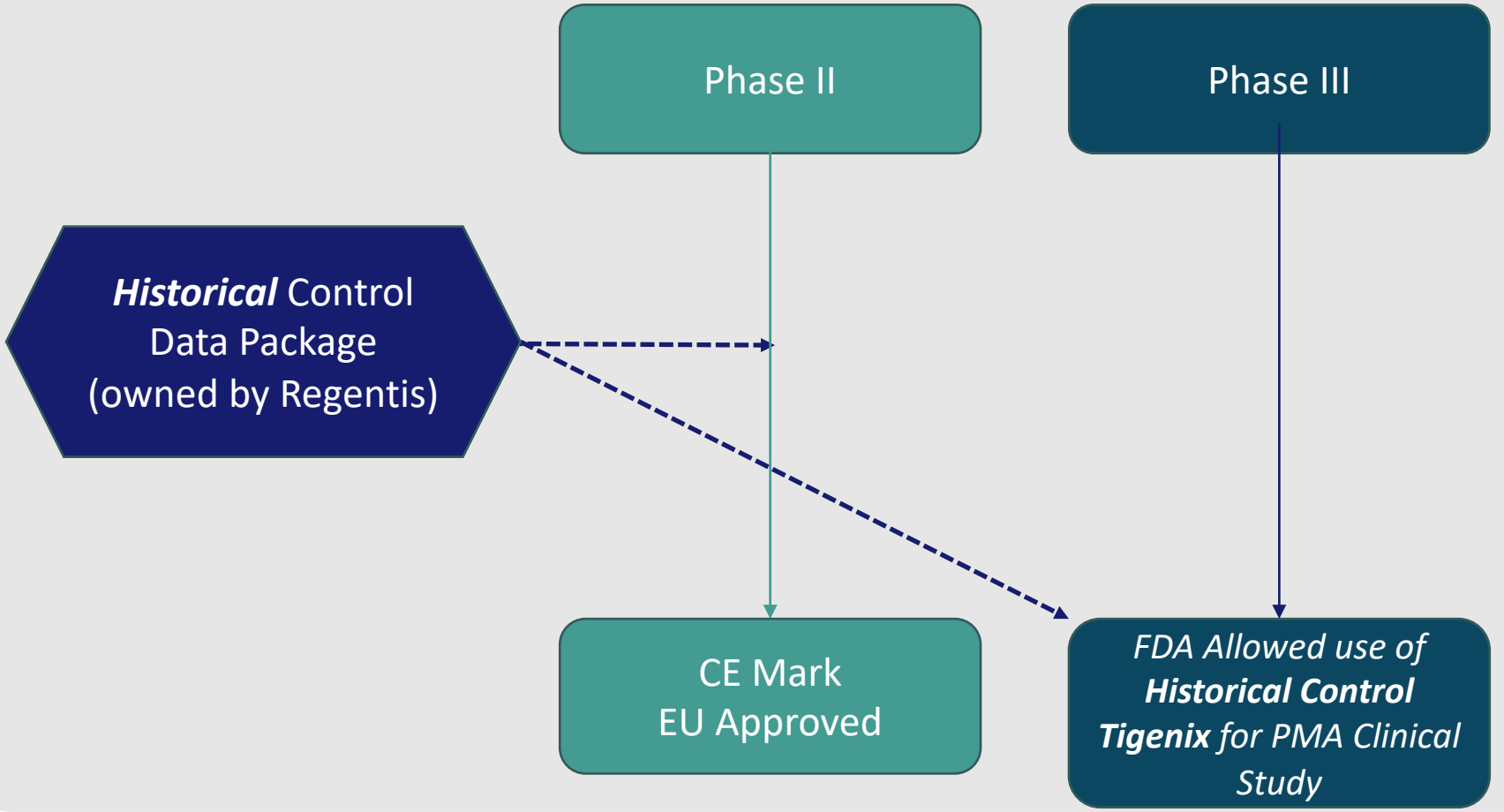
Orthopaedic surgeon – Director Peninsula Orthopaedic Associates, Maryland



Testimonial: Solomon Wilcots

Former NFL Defensive Back – Bengals, Vikings, Steelers, and TV Broadcaster

Unique, FDA approved IDE Clinical Protocol



Study Design Highlights

- 80 patients for submission
- 47 patients recruited and treated
- Balance to follow post-IPO
- FDA allowed the use of ***Historical Control*** in the unique single-arm protocol.

Clinical Phase II Pilot Study
Study Design and Results

Study Size	• 56 patients treated with GelrinC • Followed for up to 4 years in Northern Europe and Israel.
Primary Endpoints	Changes in KOOS overall and pain subscale scores at 24 months.
Efficacy	Primary endpoints – show superiority at 24 months - met; no serious adverse events observed.
European Approval	EU CE Mark obtained on the basis of Phase II study
Historical Control	Microfracture used as the 'gold standard' as common comparator in phase II pilot study and ongoing Phase III pivotal TiGenix trials.

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KOOS & VAS Results

Near- and long-term improvements superior to microfracture. KOOS scores ~100% greater pain reduction at 2 years.

KOOS Scores (Aprrox.)

GelrinC: 28 at 2 years, vs. Microfracture: 14.

MRI MOCART Scores

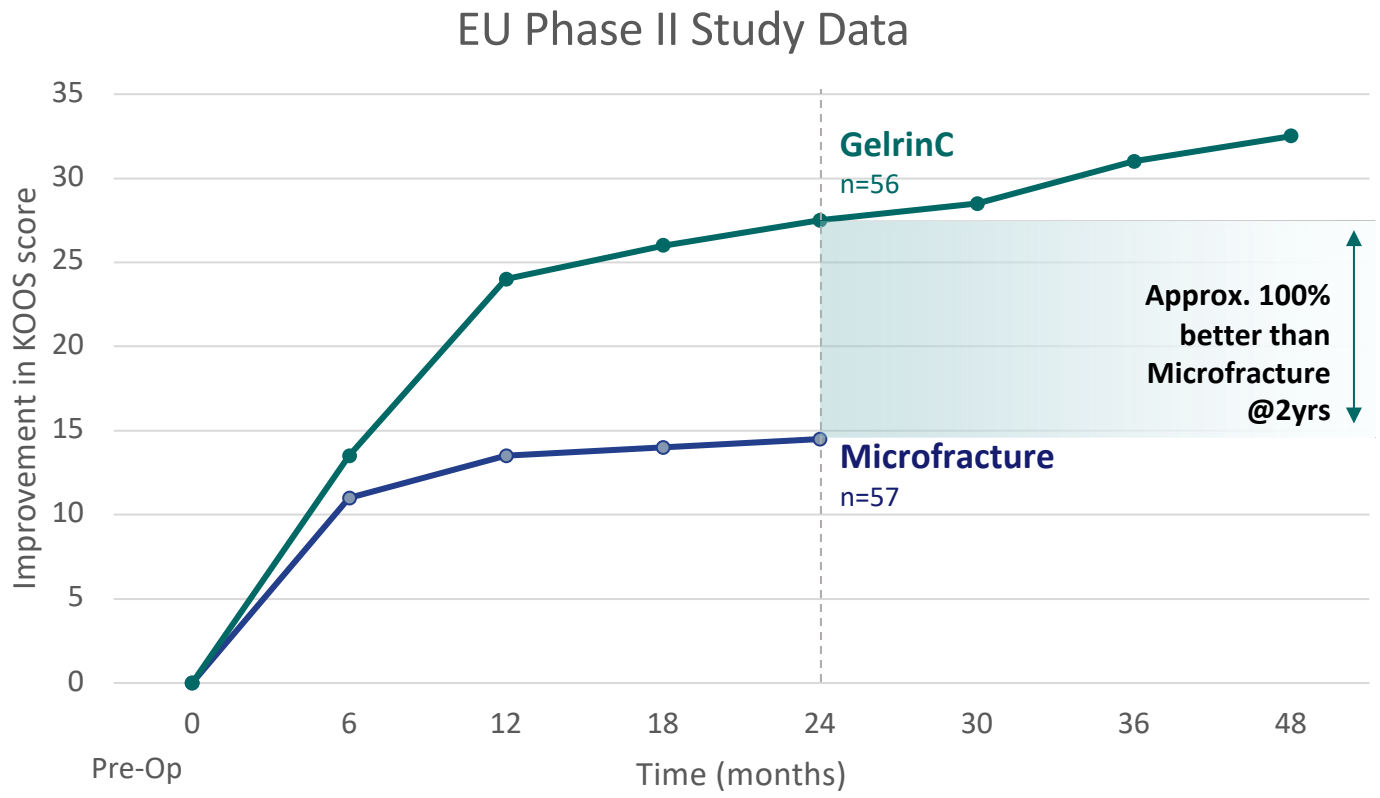
GelrinC scores reached 80+ within 24 months.

EU (Phase II) - Clinical Results

KOOS
Measurement – 4 Year Efficacy

Data demonstrated P<0.05[1] for 6-24 months compared to microfracture

- Safe - Low incidence of Adverse Events (equivalent to microfracture alone)
- Efficacy – Approx. 100% superiority improvement of Overall KOOS [2] score change over microfracture



(1) A P-value is a statistical measurement used to validate a hypothesis against observed data. A P-value measures the probability of obtaining the observed results, assuming that the null hypothesis is true. The lower the P-value, the greater the statistical significance of the observed difference. A P-value of P<0.05 is deemed statistically significant, as there is less than a 5% probability the results are random.

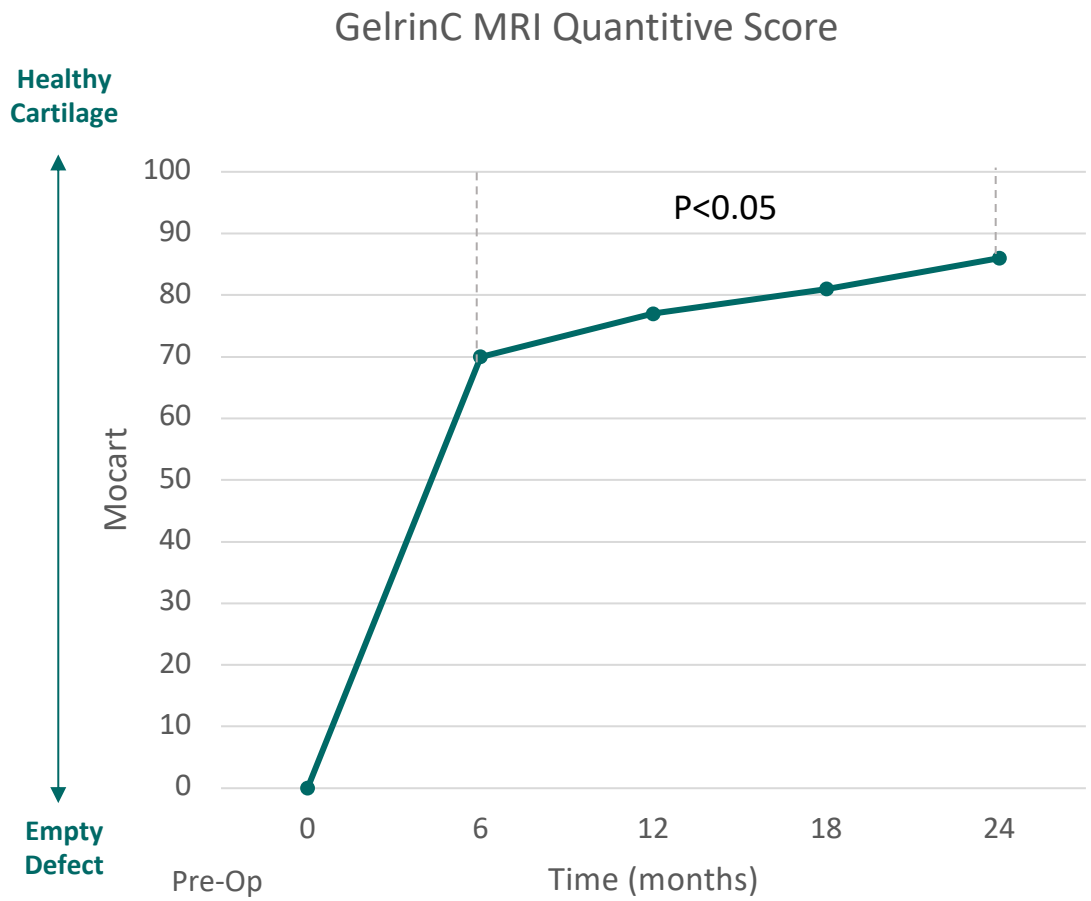
(2) The KOOS is a patient-reported outcome measurement instrument developed to assess the patient's opinion about their knee and associated problems. The KOOS evaluates both short-term and long-term consequences of knee injury and also consequences of primary osteoarthritis, or OA. It holds 42 items in five separately scored subscales: KOOS Pain, KOOS Symptoms, Function in daily living, or KOOS ADL, Function in Sport and Recreation, or KOOS Sport/Rec, and knee-related Quality of Life, or KOOS QOL (Roos and Lohmander 2003). The score above is presented in percentages.

EU (Phase II) - Clinical Results

MOCART Scores[1]

MOCART (Magnetic resonance Observation of Cartilage Repair Tissue) is a recognized nine-part assessment of cartilage repair based on MRI images
Data from GelrinC MRI results

P<0.05 in MOCART continues[2]



(1) The MOCART score is a 9-part and a 29-item scoring system, resulting in a final cartilage repair tissue score between 0 and 100 points; 0 points represents the worst imaginable score, while 100 points represent the best imaginable score. When patients measure pain, they sometimes fill out reports with subjective answers, and therefore we also use an MRI criteria (i.e., MOCART) to measure pain, which provides an objective pain score response calculation. A P-value is a statistical measurement used to validate a hypothesis against observed data.

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GelrinC Phase III (Pivotal) Trial Protocol Summary

Trial Scope	FDA-approved IDE trial in the U.S., Europe, and Israel.
Control Data	Microfracture historical data (TiGenix NV1) approved as control, reducing costs and variability.
Primary Endpoints	KOOS pain scores and Function in Daily Living (ADL) scores at 24 months.
Secondary Endpoints	Overall KOOS scores and MRI-based MOCART scores at 24 months.
Objectives	To achieve superiority over microfracture (MFx) at 24 months
Design	80 patients, 2-year follow-up for PMA submission.

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Progress

41 of 80 patients already recruited and treated with 24-month follow-up.

No serious adverse events observed.

Timelines

Recruitment by 2025; PMA submission by 2027.

Patient Match

First 40 patients closely match control group; high likelihood of efficacy in future readouts.

Gelrin Technology Platform Potential Additional Applications

May address osteoarthritis and other cartilage injuries in the ankle, wrist, and elbow, based on animal studies.

GelrinP

- A paste form of GelrinC, cured with UV light.
- Designed for treating injuries in smaller joints (ankle, wrist, elbow).

GelrinV

- A novel intra-articular injectable gel with pro-healing capabilities.
- Thermo-responsive and hydrophobic polymer.
- Injected as a liquid and turns into a thick gel at body temperature.
- Targeted for treating moderate osteoarthritis.

Comprehensive Intellectual Property Portfolio

35 **Granted & issued patents**
8: U.S. patents
26: Foreign patents(1)

3 **Pending patent applications**

Patents for Composition of Matter and treatment

- Claims protein-polymer conjugates of extracellular matrix proteins (e.g., fibrinogen) or serum proteins (e.g., albumin).
- Conjugates are covalently bound to synthetic polymers (e.g., polyethylene glycol, polaxamer).
- Covers applications for treating cartilage injuries, osteoarthritis, and scaffolds formed from these conjugates.

Patents for Delivery Device (Stelar)

- Unique device for effective administration of products to patients.
- Includes a UVA irradiation source for initiating scaffold crosslinking.

Scope of Granted Patents

- Covers GelrinC and GelrinP, including their uses and manufacturing processes.
- Provides supplementary protection for a specific administration device.

Additional Pending Patents

- Include protections for product improvements and manufacturing process advancements.

(1) 18 of the 26 Foreign patents being nationally validated in certain European extension/validation states

Board of Directors

(1) Please review Registration Statement which has been filed with the SEC for full bios
(2) Indicates an Independent Director and a member of Audit Committee and Compensation Committee

Ehud Geller, PhD, MBA

Executive Chairman

- Former President & CEO of Interpharm Laboratories and EVP of Teva Group
- Former head of the Israeli Pharmaceutical Manufacturers Association
- Board member of the Tel Aviv Stock Exchange
- National Industry award for contribution to biotech industry and management leadership
- Samuel Johnson Medal Columbia University
- Columbia University, Drexel Institute – Chemical Engineering (bio-chemical technology), MBA, PhD

Jeff Dykan, CPA

Director

- Served on Board of Directors since 2005, appointed by shareholder SCP Vitalife
- Chairman of ReWalk Robotics
- Director of Vitalife Partners Management LP since 2002
- Chairman and Chief Executive Officer of BitBand Inc. from 2001 to 2002
- Member of the American Institute of Certified Public Accountants from 1982 through 2021
- B.Sc. in accounting and management and an M.B.A. in computer applications, New York University

Pini Ben-Elazar

Director Nominee(1)(2)

- CEO of Mor Research Applications, Tech Transfer Office of Clalit Health Services in Israel since 2003
- Director of Ceretrieve, Enox, DreamMed Diabetes, Data2Life, NGS, APX ophthalmology, Zebra Medical Vision, and Galil Ofek
- MBA from Johnson& Wales University and B.Sc in Hospitality Management, Johnson & Wales University

Efraim Cohen Arazi

Director Nominee(1)

- Former CEO, Chairman and co-founder of Rainbow Medical
- Former VP operation at Amgen in California
- Former Senior VP operations at Immunex in Seattle
- Former Managing Director of Serono state of the art biotech facility in Switzerland
- M.Sc. in life sciences from the Hebrew university in Jerusale

Keith Valentine

Director (1)

- Served on Board of Directors since 2015
- President, Chief Executive Officer and as a director of SeaSpine 2015-2023
- President and Chief Operating Officer of NuVasive, Inc., from 2007 to 2015 and as President from 2004 to 2007
- Vice President of Marketing at ORATEC Interventions, Inc.
- B.B.A. in Management and Biomedical Sciences from Western Michigan University

Susan Alpert, PhD, MD

Director Nominee (1)(2)

- Principle of SFADC LLC (aka SFA Regulatory, LLC) since 2019
- Corporate Senior Vice President for Global Regulatory at Medtronic, Inc.
- Director of the Office of Device Evaluation from 1993-1999
- Undergraduate degree at Barnard College, Columbia University in New York City, master's degree and Ph.D. in Biomedical Sciences from New York University and medical degree from the University of Miami (Florida)

Successful track record of healthcare product development and life sciences operating expertise

The Only Restorative Solution for Cartilage Repair

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Knee cartilage repair

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Thank you