Regentis Biomaterials

NYSE: RGNT

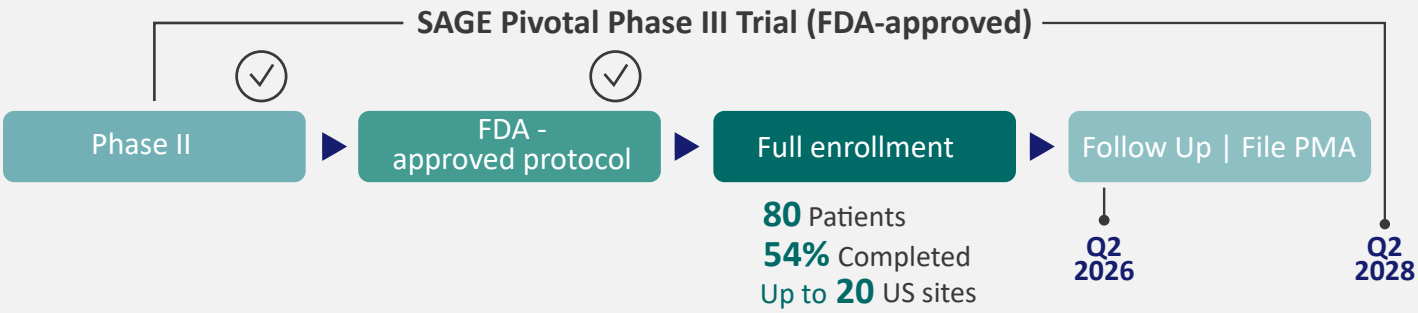
Pioneering a restorative, off-the-shelf solution for durable cartilage regeneration

Regentis Biomaterials is a regenerative medicine company developing GelrinC®, a ready-to-use, off-the-shelf hydrogel implant for focal knee cartilage injuries. The technology targets a large, under-served market and is supported by strong clinical data, CE Mark marketing approval in Europe, and an FDA-approved IDE for a pivotal clinical program in the U.S. and Europe.

GelrinC® – lead product candidate

GelrinC® is a ready-to-use, acellular hydrogel programmed implant already applied with approximately 100 patients across the U.S. and Europe and is currently being evaluated in an FDA-approved pivotal/Phase III clinical trial. GelrinC has received CE Mark marketing approval in Europe. Clinical and imaging data demonstrate the resulting formation of healthy, hyaline-like cartilage repair tissue, supporting durable structural repair and sustained functional improvement.

GelrinC® Development Momentum Defies Market Volatility



- Regentis demonstrated strong clinical performance of GelrinC® in Phase II clinical studies in patients with knee focal cartilage defects.
- The SAGE pivotal/ Phase III trial is ongoing, with 54% of patients already enrolled and completed followed up and the balance underway.
- FDA provided clear guidance to proceed with an IDE-approved pivotal/ Phase III trial, with PMA submission planned upon completion of enrolment of 80 patients - the SAGE study.
- European commercialization efforts are underway.

Upon successful conclusion, GelrinC® will represent a first-in-class technology with broader applications across cartilage repair indications, addressing a large and underserved orthopedic market with readily available, clinically effective, and durable solutions with highly favorable economic characteristics.

Competitive Arena vs. other approved products

- Current standard-of-care cartilage repair solutions are limited by procedural complexity, long recovery times, restricted lesion applicability, and high cost.
- Cell-based therapies require multiple surgical interventions and prolonged treatment courses.
- Permanent Implant- approaches involve traumatic invasive procedures and removal of healthy tissue.
- These limitations highlight a significant unmet need for an off-the-shelf, minimally invasive, durable, and economically attractive cartilage repair solution.

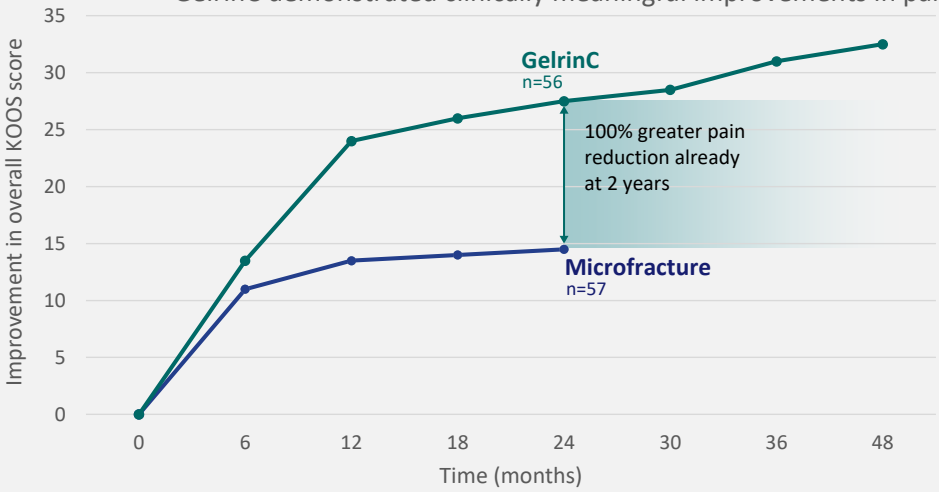
	Off-the-shelf, immediate treatment Resorbable Hydrogel GelrinC	Cell-based Products (Maci of Vericel)	Pre-formed Bi-phasic plugs (AgiliC of Cartiheal)
	GelrinC	maci	
Type of Lesion	All Types – involving multiple areas of the cartilage	Limited - small, well-defined region of the cartilage	Limited - small, 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 (S=est.)[2]	Unknown
Market Availability	CE marked (EU) / Pivotal trial (U.S.)	U.S. only	FDA approved (2022) and CE marked
Market Cap / Sales	NA	$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. Arthrosoopy. 2021;37(12):3499-3506.e1.
[3] Market cap as of May 1, 2025. Net revenues of $46.3M for MACI first quarter of Fiscal Year 2025 (https://investors.vcel.com/news-releases/news-release-details/vericel-reports-second-quarter-2024-financial-results)
[4] https://www.smith-nephew.com/en/news/2024/01/10/20240110---sn-completes-acquisition-of-novel-cartilage-regeneration

Efficacy

EU Phase II Study Data - GelrinC vs Microfracture

GelrinC demonstrated clinically meaningful improvements in pain and function (KOOS score)



GelrinC® has demonstrated clinically meaningful structural and functional improvements much beyond the current standard of care, with the potential to deliver durable cartilage repair, which is being further evaluated in the ongoing FDA-approved pivotal Phase III trial.

Safety

- 3 large animals trials
- Completed Phase II trial
- Phase III in progress
- >100 patients treated >5 years FU

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