COMPANY UPDATE

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Innovation Team

Keunhee Seo, Ph.D.
Team Leader
keunhee.seo@samsung.com

Suhan Shin
Research Associate
shn.shin@samsung.com

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Kolon TissueGene (950160)

2026 US Phase III results: A key inflection point

- Kolon TissueGene's TG-C, a gene therapy for osteoarthritis, is currently being evaluated in two US Phase III clinical trials, both scheduled for completion in 2026. Given that TG-C already obtained regulatory approval in Korea, the risk of failure in the ongoing US studies is considered relatively low.
- If TG-C ultimately demonstrates both durable pain relief and cartilage regeneration, its commercial potential could be materially reassessed.

(§The Korean version of this report was published on Nov 21, 2025)

WHAT'S THE STORY?

US Phase III trials focused on reproducibility: Two US Phase III studies of TG-C (TGF-β gene therapy) are underway, with the first expected to reach primary completion in Mar 2026 and top-line data anticipated in Jun 2026. An interim update may be presented at the Osteoarthritis Research Society International (OARSI) conference in April. Top-line results from the second Phase III study are expected in Oct 2026. TG-C's competitive positioning was reinforced by its inclusion among 13 development-stage candidates in a recent review article (Biomedicines, 2025) covering pipeline drugs targeting structural improvement in osteoarthritis. Despite an increasingly crowded landscape, the large unmet need in osteoarthritis points to meaningful commercial upside. If TG-C meets the criteria for a disease-modifying osteoarthritis drug (DMOAD), it could clearly differentiate itself at launch. The company plans to file for US approval in 1Q27, pursuing either a direct-to-market or distribution-partner model in the US, alongside an out-licensing strategy for other regions.

(Continued on the next page)

AT A GLANCE

Not rated

Target price	n/a
Current price	**KRW72,900**
Market Cap	KRW6.1t/USD4.2b
Shares (float)	83,221,265 (33.8%)
52-week high/low	KRW87,300/KRW28,500
Avg daily trading value (60-day)	KRW39.9b/ USD27.2m

ONE-YEAR PERFORMANCE

	1M	6M	12M
Kolon TissueGene (%)	-10.2	74.2	154.9
Vs Kosdaq (%pts)	-11.4	46.8	92.7

SAMSUNG vs THE STREET

No of estimates	1
Target price	150,000
Recommendation	4.0

※ Rating: 4 < → BUY, 3 = HOLD, 2 > → SELL

SUMMARY FINANCIAL DATA

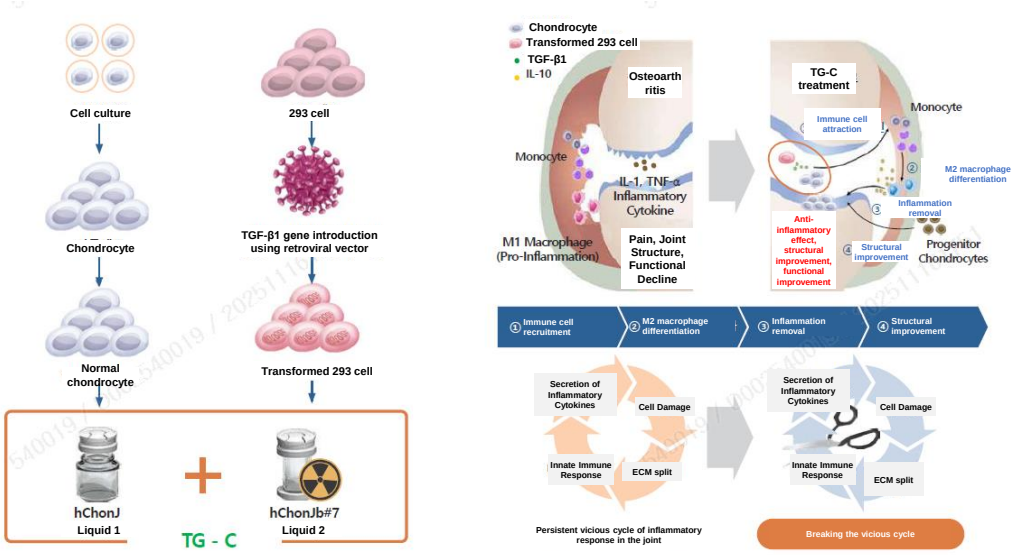
(KRWb)	2021	2022	2023	2024
Revenue	4	9	4	5
Operating profit	(47)	(16)	(21)	(22)
Net profit	(47)	(11)	(17)	(34)
EPS (adj) (KRW)	(773)	(168)	(241)	(440)
EPS (adj) growth (%)	nm	nm	nm	nm
EBITDA margin (%)	(1,132.9)	(154.8)	(515.2)	(417.6)
ROE (%)	(109.2)	(17.1)	(16.7)	(25.9)
P/E (adj) (x)	n/a	n/a	n/a	n/a
P/B (x)	26.9	6.7	5.7	12.7
EV/EBITDA (x)	(10.7)	(38.3)	(33.3)	(89.4)
Dividend yield (%)	0.0	0.0	0.0	0.0

Source: Company data, Samsung Securities

Chemistry, manufacturing, and controls preparation underway: Kolon TissueGene has advanced its commercialization readiness by signing a manufacturing agreement with Lonza, securing chemistry, manufacturing, and controls capabilities to support regulatory approval and initial commercial supply. Preparations for a biologics license application are expected to begin from 2026. In parallel, the company is pursuing a diversified manufacturing strategy through Kolon Biotech's facilities in the US and Singapore.

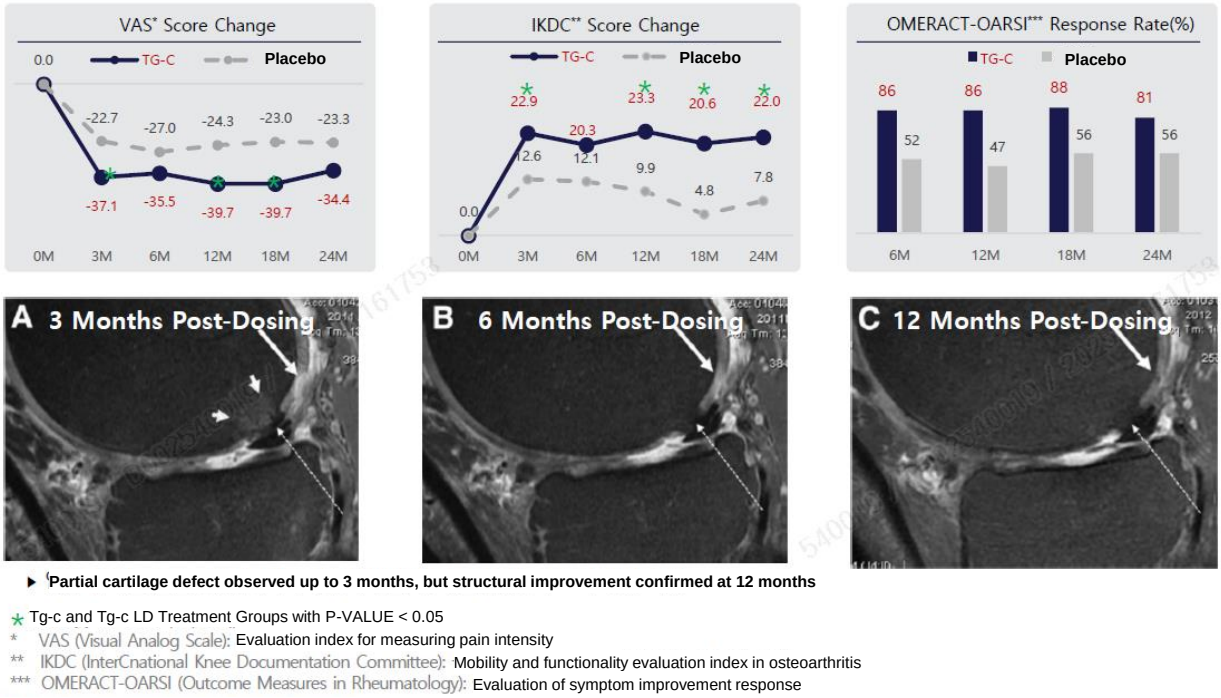
Key points to watch: TG-C previously completed Phase III trials and obtained regulatory approval in Korea; accordingly, the current US Phase III studies are designed primarily to confirm reproducibility rather than to establish new efficacy. As such, clinical risk is viewed as limited, provided patient selection remains sufficiently homogeneous. Conventional osteoarthritis treatments have largely focused on symptomatic pain relief. If TG-C demonstrates both sustained analgesic benefit and structural cartilage regeneration, annual pricing could exceed USD10,000. The company raised KRW122.5b via convertible bonds in Sep 2025, with proceeds expected to fund clinical development and commercialization activities.

TG-C: Structure and mechanism of action



Source: Kolon TissueGene, Samsung Securities

TG-C: US Phase II results



▶ (Partial cartilage defect observed up to 3 months, but structural improvement confirmed at 12 months

* Tg-c and Tg-c LD Treatment Groups with P-VALUE < 0.05
* VAS (Visual Analog Scale): Evaluation index for measuring pain intensity
** IKDC (InterCnational Knee Documentation Committee): Mobility and functionality evaluation index in osteoarthritis
*** OMERACT-OARSI (Outcome Measures in Rheumatology): Evaluation of symptom improvement response

Source: Kolon TissueGene, Samsung Securities

TG-C: Phase III comparison

Country		US	Korea
Clinical structure		Approximately 80 sites	12 sites
Number of patients		1,020	159
K&L grade		Grade 2 or 3	Grade 3
Treatment group		TG-CLD: 78, Placebo: 81	TG-C: 680, Placebo: 340
Observation period		24 months	
Endpoints	Primary endpoint	VAS, WOMAC Total[1]	IKDC, VAS
	Secondary endpoint	MRI, SF-12[3], HAQ-DI[4]	WOMAC, KOOS[5], MRI, X-ray (JSW), biomarkers
	Other endpoints	X-ray (JSW[2]), liquid biomarker, IKDS, *etc*	-
Claim range		Primary endpoint, secondary endpoint	Primary endpoint

Note: [1]Western Ontario and McMaster Universities Osteoarthritis Index, a subjective evaluation of pain, joint stiffness, and functionality in arthritis patients;
[2]Joint space width = indicator for evaluating joint structural improvement;
[3]The Short Form (12) Health Survey, patient-reported survey of patient health;
[4]Health Assessment Questionnaire Disability Index;
[5]Knee injury and osteoarthritis evaluation
Source: Kolon TissueGene, Samsung Securities

TG-C: Marketing authorization and commercialization timeline

Period	Content
Dec 2021	Resumption of FDA Phase III patient enrollment
Jul 2024	Completion of 1,066 patient enrollments / start of 2-year follow-up
Oct 2024	Contract with Lonza for CMC preparation for marketing authorization
3Q26E	Confirmation of CSR for TG-C 15302 study (531 patients)
4Q26E	Confirmation of CSR for TG-C 12301 study (535 patients)
Feb 2027E	Completion of CMC package for marketing authorization
Mar 2027E	Submission of FDA BLA for marketing authorization
2H28E	Commencement of commercial sales

Source: Kolon TissueGene, Samsung Securities

DMOAD candidate development comparison

Substance	Developer (country)	Mechanism	Clinical result summary	Structural improvement	Pain improvement	FDA trial (completion basis)
TG-C	Kolon TissueGene (Korea)	Gene therapy (TGF-β)	Significant improvement in both pain and function	△	✓	Phase III (ongoing)
Lorecivivint	Biosplice Therapeutics (US)	Wnt/β-catenin inhibitor	Single joint pain, structural improvement uncertain	△	X	Phase III
Sprifermin	TrialSpark (US)	FGF-18 analog	Significant increase in cartilage thickness, no pain improvement	✓	X	Phase II
Cindunistat	Pfizer (US)	iNOS inhibitor	No effect on structural or pain improvement	X	X	Phase II
UBX0101	Unity Biotechnology (US)	Senolytic agent	No structural/pain improvement	X	X	Phase II
TPX-100	Ortho Trophix (US)	MEPE-like peptide	Pain improvement present, structural improvement limited	X	✓	Phase II
GLPG1972	Galapagos (Belgium)	ADAMTS-5 inhibitor	No effect, headache increase	X	X	Phase II
Lutikizumab	AbbVie (US)	IL-1α/β inhibitor	No effect, side effects present	X	X	Phase II
SAR113945	Sanofi (France)	NF-κB inhibitor	No effect	X	X	Phase IIa
MIV-711	Medivir (Sweden)	Cathepsin K inhibitor	Structural improvement, pain only partially in subgroups	✓	△	Phase II
LNA043	Novartis (Switzerland)	ANGPTL3 analog	Inhibition of cartilage loss, no pain improvement	✓	X	Phase II (ongoing)

Note: Trials conducted from 2010 to 2024;
△ indicates partial fulfilment of criterion
Source: Kolon TissueGene, *Advances and Challenges in the Pursuit of Disease-Modifying Osteoarthritis Drugs: A Review of 2010-2024 Clinical Trials*, Samsung Securities

Comparison of non-DMOAD treatments

Substance	Developer (country)	Mechanism	Clinical result summary	Structural improvement	Pain improvement	Clinical status
Non-DMOAD candidates						
Tanezumab	Pfizer, Eli Lilly (US)	Anti-NGF	Increased osteoarthritis at high doses, safety issues raised	n/a	✓	Authorization rejected
Fulranumab	Amgen (US), Takeda (Japan)	n/a	Some improvement reported (initial data)	n/a	△	Development discontinued (Phase II complete)
Fasinumab	Regeneron (US), Teva (Israel)	n/a	Difficulty in commercialization due to structural damage side effects	n/a	△	Phase III discontinued
Expansion of indications for obesity treatment medications						
Wegovy	Novo Nordisk (Denmark)	Weight loss-driven pain relief	Pain relief observed in obese patients (muscle mass loss)	n/a	✓	Phase III complete
Current status of stem cell field development						
JointStem	Naturecell (Korea)	Anti-inflammatory, regeneration (autologous fat[1])	Insufficient clinical significance in pain/structure improvement	△	△	Authorization rejected in Korea (FDA 2b/3a)
OSCA	Kangstem Biotech (Korea)	Anti-inflammatory, regeneration (allogeneic umbilical cord blood[2])	Phase I results (12 patients), pain/structure improvement observed	△	△	Korea Phase IIa

Note: [1]Autologous fat-derived stem cells cultured for treatment, mass-production difficulties exist;
[2] Allogeneic cells based on umbilical cord blood allow mass-production;
△ indicates partial fulfilment of criterion
Source: Kolon TissueGene, Clinical Trials.gov, MFDS, company data, Samsung Securities

Income statement

Year-end Dec 31 (KRWb)	2020	2021	2022	2023	2024
Sales	**4**	**4**	**9**	**4**	**5**
Cost of goods sold	3	4	2	3	4
Gross profit	**0**	**0**	**8**	**0**	**1**
Gross margin (%)	10.6	10.9	81.3	11.1	11.7
SG&A expenses	42	47	24	21	23
Operating profit	**(42)**	**(47)**	**(16)**	**(21)**	**(22)**
Operating margin (%)	(1,168.7)	(1,171.7)	(172.4)	(553.3)	(433.6)
Non-operating gains (losses)	**(0)**	**(0)**	**6**	**4**	**(12)**
Financial profit	1	0	1	2	1
Financial costs	1	0	0	0	14
Equity-method gains (losses)	0	0	0	0	0
Other	(0)	0	6	2	1
Pre-tax profit	**(42)**	**(47)**	**(10)**	**(17)**	**(34)**
Taxes	0	0	1	0	(0)
Effective tax rate (%)	(0.3)	(0.5)	(13.4)	(1.5)	0.3
Profit from continuing operations	(42)	(47)	(11)	(17)	(34)
Profit from discontinued operations	0	0	0	0	0
Net profit	**(42)**	**(47)**	**(11)**	**(17)**	**(34)**
Net margin (%)	(1,175.2)	(1,183.3)	(117.8)	(464.8)	(666.2)
Net profit (controlling interests)	(42)	(47)	(11)	(17)	(34)
Net profit (non-controlling interests)	0	0	0	0	0
EBITDA	(40)	(45)	(15)	(19)	(21)
EBITDA margin (%)	(1,122.5)	(1,132.9)	(154.8)	(515.2)	(417.6)
EPS (parent-based) (KRW)	(684)	(773)	(168)	(241)	(440)
EPS (consolidated) (KRW)	(684)	(773)	(168)	(241)	(440)
Adjusted EPS (KRW)*	(684)	(773)	(168)	(241)	(440)

Balance sheet

Year-end Dec 31 (KRWb)	2020	2021	2022	2023	2024
Current assets	**63**	**43**	**63**	**32**	**7**
Cash & equivalents	19	39	42	27	1
Accounts receivable	1	0	0	0	0
Inventories	0	0	0	0	0
Other current assets	44	4	21	4	6
Fixed assets	**10**	**18**	**47**	**103**	**215**
Investment assets	0	0	0	0	0
Tangible assets	3	3	2	2	2
Intangible assets	0	6	31	88	200
Other long-term assets	7	9	13	13	13
Total assets	**73**	**61**	**110**	**135**	**222**
Current liabilities	**15**	**16**	**12**	**14**	**71**
Accounts payable	0	0	0	0	0
Short-term debt	5	0	0	0	0
Other current liabilities	9	16	12	14	71
Long-term liabilities	**10**	**7**	**7**	**6**	**5**
Bonds & long-term debt	3	0	0	0	0
Other long-term liabilities	7	7	7	6	5
Total liabilities	**25**	**23**	**18**	**20**	**76**
Owners of parent equity	**48**	**39**	**91**	**115**	**146**
Capital stock	0	0	0	0	0
Capital surplus	279	340	424	470	587
Retained earnings	(231)	(301)	(332)	(355)	(442)
Other	(0)	(0)	(0)	(0)	0
Non-controlling interests' equity	**0**	**0**	**0**	**0**	**0**
Total equity	**48**	**39**	**91**	**115**	**146**
Net debt	(41)	(32)	(51)	(21)	46

Cash flow statement

Year-end Dec 31 (KRWb)	2020	2021	2022	2023	2024
Cash flow from operations	**(38)**	**(40)**	**(27)**	**(24)**	**(20)**
Net profit	(42)	(47)	(11)	(17)	(34)
Non-cash profit and expenses	2	2	(3)	(1)	13
Depreciation	2	1	2	1	1
Amortization	0	0	0	0	0
Other	0	1	(4)	(3)	12
Changes in A/L from operating activities	1	5	(12)	(8)	(1)
Cash flow from investments	**19**	**33**	**(40)**	**(29)**	**(77)**
Change in tangible assets	(1)	(1)	(0)	(0)	(0)
Change in financial assets	22	38	(16)	17	0
Other	(2)	(4)	(23)	(45)	(77)
Cash flow from financing	**(7)**	**25**	**67**	**38**	**69**
Change in debt	(7)	(8)	(0)	(1)	41
Change in equity	(18)	60	85	46	117
Dividends	0	0	0	0	0
Other	18	(28)	(18)	(8)	(88)
Change in cash	(26)	18	0	(15)	(28)
Cash at beginning of year	46	19	42	43	29
Cash at end of year	20	37	42	28	1
Gross cash flow	**(40)**	**(45)**	**(14)**	**(19)**	**(21)**
Free cash flow	**(39)**	**(41)**	**(27)**	**(24)**	**(21)**

Financial ratios

Year-end Dec 31	2020	2021	2022	2023	2024
Growth (%)					
Sales	17.2	12.6	136.2	(60.8)	36.9
Operating profit	nm	nm	nm	nm	nm
Net profit	nm	nm	nm	nm	nm
Adjusted EPS**	nm	nm	nm	nm	nm
Per-share data (KRW)					
EPS (parent-based)	(684)	(773)	(168)	(241)	(440)
EPS (consolidated)	(684)	(773)	(168)	(241)	(440)
Adjusted EPS**	(684)	(773)	(168)	(241)	(440)
BVPS	787	597	1,328	1,581	1,834
DPS (common)	0	0	0	0	0
Valuations (x)					
P/E***	n/a	n/a	n/a	n/a	n/a
P/B***	26.9	6.7	5.7	12.7	12.7
EV/EBITDA	(10.7)	(38.3)	(33.3)	(89.4)	(89.4)
Ratios (%)					
ROE	(59.6)	(109.2)	(17.1)	(16.7)	(25.9)
ROA	(42.4)	(70.6)	(13.0)	(14.1)	(18.9)
ROIC	(468.3)	(654.6)	(77.4)	(30.8)	(15.3)
Payout ratio	0.0	0.0	0.0	0.0	0.0
Dividend yield (common)	0.0	0.0	0.0	0.0	0.0
Net debt to equity	(84.9)	(82.2)	(56.0)	(18.2)	31.7
Interest coverage (x)	(49.8)	(100.6)	(43.9)	(71.7)	(244.8)

Note: *Excluding one-off items
**Fully diluted, excluding one-off items
***From companies subject to equity-method valuation

Source: Company data, Samsung Securities

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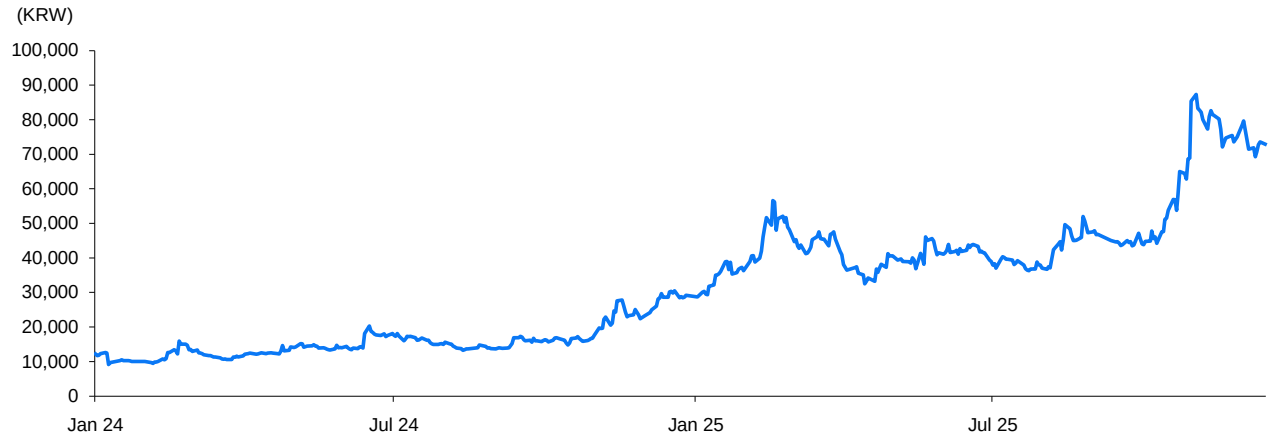

Rating changes over past two years (adjusted share prices)

Date	2026/1/13
Recommendation	Not Rated
Target price (KRW)	n/a
Gap* (average)	
(max or min)**	

Note: * [(average, maximum, or minimum share price over duration of target price minus target price) / target price] x 100%
** Maximum/minimum share price if new target is higher/lower than market close on the business day prior to target price change

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Percentage of ratings in 12 months prior to 2025.12.31

BUY(85.8%)·HOLD(14.2%)·SELL(0%)

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Yang District, Beijing, China
Tel: 86-10-6522-1855 (extension 7891)
Fax: 86-10-6522-1855 (extension 7889)

TOKYO

Samsung Securities Tokyo Representative Office
#106-8532 19F, Roppongi T-Cube 3-1-1,
Roppongi Minato-ku Tokyo, Japan
Tel: 81-3-6333-2952
Fax: 81-3-6333-2953

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