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THE NEXT WAVE OF CELL AND GENE THERAPIES (CGTS):

Strategies to drive accessibility and commercial success

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Introduction

The cell and gene therapy (CGT) field is advancing rapidly. An ongoing parade of standout innovations is now poised to transform patient care and enable unprecedented outcomes, including more potential cures for previously untreatable conditions. There are many reasons for optimism about the current state of these transformative medicines, which have regulatory momentum and stable investment on their side.

CGT approvals are at an all-time high. In 2024, the Food and Drug Administration (FDA) greenlit a record-breaking nine CGT products, including stem cell therapies, bioengineered human tissues and allogenic therapies with exceptional safety and efficacy profiles.[1] Gene therapies targeting rare diseases are increasingly leveraging the FDA's Accelerated Approval pathway so that they can reach patients with unmet needs faster,[2] while the FDA is expanding another project to allow validated delivery systems (such as adeno-associated virus vectors) to be reused across indications without additional preclinical work.[3]

Even amid an overall decline in biopharma venture funding year over year, CGT investment remains on a growth trajectory. Investments in CGTs reached $15.2 billion in early 2025, marking a 30% increase since 2023.[4] Many of the world's largest pharmaceutical companies are taking part in this wave, with AbbVie, Bristol Myers Squibb, Novartis, Roche and Vertex Pharmaceuticals among the large-cap companies investing in the development or commercialization of CGTs. In the face of economic uncertainties, many investors are seeking less risk, leading them to gravitate toward products whose development is relatively advanced. This is favorable for CGTs, since many of these therapies — which have been in clinical development for some time — are about to be ready to hit the market.

But if these new therapies are to realize their full potential to improve people's lives, additional hurdles must be overcome — including patient access, provider education and logistical issues. By definition, every autologous therapy (which uses the patient's own cells) is unique, but even allogenic therapies (with off-the-shelf potential) require highly specialized manufacturing, complex batch-level quality controls, and careful handling during shipment and administration.

"There's so much novelty and innovation that it's hard to even identify overarching trends in the development of CGTs," said Kevin Chinn, vice president and head of cell and gene services at Cencora. "Every time a new cell or gene therapy is approved, it's the very first to do what it does. Every single one of these drugs is a snowflake, which makes commercialization resource-intensive."

That CGTs are enormously diverse — in terms of how and where they are administered, which diseases and populations they target, and what safety and regulatory concerns they raise — only adds to the challenge. Not all sites of care are equipped to store, handle and manage CGTs, which creates an access barrier. These therapies are often costly, with complex reimbursements and payer-specific requirements. Even identifying the patients eligible for a particular treatment can be complicated, involving multiple genetic and biological factors. To date, CGT patient populations have been small, but they're expected to increase as these treatments move into the mainstream. When they do, sites of care will need to prepare themselves to overcome all these barriers at scale.

As more and more CGTs receive market authorization, it will be increasingly important for their developers to deliver effective support to patients, providers and other stakeholders across the treatment ecosystem. They will need to streamline the administration of these treatments, boost patient and market access and improve the coordination of care. Developers will also need to navigate complex logistical and supply chain considerations to build an effective distribution strategy. And they'll need to think about how all these needs will evolve over time.

In the rest of this report, we'll look closely at six recently approved or late-stage investigational cell and gene therapies. We'll talk about why each innovation is so exciting, and we'll describe the biggest obstacles that the treatment will need to overcome to be accessed by real-world patients.

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ENCELTO: Cell-based gene therapy implant for the treatment of rare degenerative retinal disease

Approved by the FDA for treatment of macular telangiectasia type 2 (MacTel), a rare neurodegenerative disease that leads to gradual vision loss, Neurotech's ENCELTO (revakinagene taroretcel-lwey) offers new hope to patients with this progressive disease.[5]

This therapy leverages a highly innovative delivery system. Administered through the surgical implantation of a small, semipermeable capsule about the size of a grain of rice into the vitreous chamber of the eye, ENCELTO uses a platform that enables the sustained, long-term delivery of therapeutic proteins into the disease-affected cells. The capsule contains genetically engineered human retinal pigment epithelial (RPE) cells that were engineered to continuously produce recombinant human ciliary neurotrophic factor (CNTF). This protein's ongoing release promotes the survival of photoreceptors in the eye, helping to slow the progression of MacTel.

ENCELTO's delivery system was designed to take advantage of the eye's unique physiology, which is essentially compartmentalized, making it possible to administer therapies locally and in small volumes without invoking strong inflammatory responses. The capsule's semipermeable exterior membrane allows the therapeutic protein to leave it and travel to the retina at the back of the eye while protecting the RPE cells from the host's immune system.

"ENCELTO is exciting for several reasons," said Louis Cicchini, Ph.D., director of scientific affairs for cell and gene therapy at Cencora. "It is the first allogenic cell therapy for an ophthalmic indication, and the first time a device like this has been used to localize the secretion of a therapeutic protein from genetically modified cells. The capsule is removable if the treatment isn't well tolerated. It can also be reinserted for redosing later on, which is important because the RPE cells are live cells that may eventually die."

Before ENCELTO, there were no approved treatments to slow or stop vision loss in MacTel patients. This therapy offers new hope by targeting the underlying disease mechanism rather than just managing symptoms.

Commercialization Challenges

Patient Access

ENCELTO is already being administered to patients. It's likely there will soon be growing demand for the treatment outside the academic health centers and centers of excellence (CoEs) where CGTs are most often administered.[6] Improving patient access by administering the drug in a greater range of community settings is an important goal for a number of CGTs, but there may be more immediate pressure to accelerate progress for this one. Administering ENCELTO is particularly challenging because it involves a surgical procedure that only a limited number of specialists are qualified to perform.

Logistics and Supply Chain

ENCELTO needs careful handling. The encapsulated therapy cannot be frozen but is temperature sensitive, with a finite shelf life. Unlike most CGTs, which require a cold chain, ENCELTO needs to be kept warm during shipment and storage. Transport suppliers accustomed to working with ultra-low-temperature shipments will need to adapt their processes to accommodate ENCELTO's unique requirements.

Provider Awareness

Increasing provider awareness through targeted physician education programs — especially for ophthalmologists and retinal surgeons — can accelerate patient identification, empowering health care providers (HCPs) to direct more of the people who can benefit from this treatment to the sites that can deliver it.

TECELRA: T-cell receptor therapy (TCR-T) treating synovial sarcoma

Groundbreaking because it is the first FDA-approved cell therapy to treat solid tumors, Adaptimmune's TECELRA (afamitresgene autoleucel) was conditionally approved by the FDA in August 2024 under the Accelerated Approval pathway.[7] TECELRA offers a targeted immune therapy for a cancer that has historically been hard to treat, synovial sarcoma.

A rare and aggressive form of soft-tissue cancer that originates in the body's connective tissues, including the muscles and ligaments, synovial sarcoma primarily affects young adults and is most prevalent in men under 30. The disease tends to develop in the extremities — commonly the arms or legs — and is characterized by a high risk of recurrence and metastasis. Treatment options have been limited, and outcomes are often poor, indicating a significant unmet clinical need.

While chimeric antigen receptors (CARs) are engineered to identify and target antigens on the surface of cancer cells, they cannot "see" cancer-associated proteins (such as the intracellular cancer-testes antigen MAGE-A4) inside the cell. In contrast, T-cell receptors (TCRs) are human leukocyte antigen (HLA)-restricted, so they can detect proteins (including MAGE-A4) inside the cancer cell via HLA-presentation on its surface. This means that TCR-T cells can identify and target cancer cells that "display" tumor-associated antigens on HLA molecules, whereas CAR-T cells cannot.

CAR-T therapies have shown success in treating leukemia and other blood cancers where targets are surface-expressed, but TCR-Ts promise broader applicability, including in the treatment of solid tumors where cancer-specific proteins remain in the cell. This approach allows the immune system to target cancer cell tumors that other forms of immunotherapy cannot reach.

Because TECELRA uses the patient's own T-cells, the treatment is tailored to that person's individual immune profile and tumor characteristics. Administering TECELRA requires collecting the T-cells from the patient, transporting them to the manufacturing facility, genetically modifying the cells, then freezing them, retransporting them and delivering the treatment by infusion.

Commercialization Challenges

Patient Identification and Access

TECELRA is indicated for a very specific subgroup of patients with a rare cancer. Their tumors must express the MAGE-A4 antigen on one of a handful of common HLA types, a dual-biomarker requirement that limits the size of the eligible patient population. Because TECELRA has been approved as a second-line treatment, these patients will have already failed one round of therapy, and many are very sick. Identifying them quickly and ensuring there are no delays in getting them started on TECELRA (including for insurance coverage verification or other financial issues) may be of lifesaving importance.

Logistics and Supply Chain

Manufacturing an autologous therapy like TECELRA is challenging because the process is complex and patient-specific. T-cell collection, shipping, treatment manufacturing and infusion must be precisely timed and coordinated. Ensuring uniform potency and purity across batches can be difficult, as can maintaining the strict cryogenic conditions needed during transport and storage.

HCP Education and Patient Monitoring

HCPs and other members of the medical community must be made aware of TECELRA and understand its potential advantages over other treatments. They must also learn about strategies for mitigating treatment-associated risks, including that of cytokine release syndrome (CRS), which affected 75% of clinical trial participants receiving the drug.[8] Ongoing patient monitoring for CRS symptoms is critical and should be in place for at least four weeks after TECELRA is administered, with medications and resuscitation support readily available if needed.

RP1: Investigational oncolytic virus targeting advanced melanoma

Replimune's RP1 (vusolimogene oderparepvec) leverages the ability of a virus (in this case, a proprietary strain of herpes simplex type 1 that has been genetically engineered) to infect and destroy tumor cells while minimizing harm to healthy tissue.[9]

RP1 is being developed to help patients with advanced, unresectable cutaneous melanoma — when this aggressive form of skin cancer has spread beyond the possibility of surgical removal. It's intended for use in conjunction with the immune checkpoint inhibitor OPDIVO (nivolumab) in patients whose disease has progressed while they were on an anti-programmed cell death protein 1 (anti-PD-1) therapy.

"As an oncolytic virus, RP1 is interesting because this represents the next generation in therapeutic cancer vaccine technology," Cicchini said. "RP1 is innovative because it kills cancer cells by expressing both an immune system activator and cell-cell fusion component. Studies also suggest both injected and non-injected lesions reduce in size, so it has both a dual mechanism of action and dual anti-tumor effects, which is very exciting.

Designated a breakthrough therapy by the FDA in November 2024, the RP1 virus expresses a fusogenic protein after infection. This protein promotes cell syncytia (in which multiple tumor cells merge together), creating, in essence, an expansive factory where more virus particles will be made. Cells with multiple nuclei will undergo programmed cell death, so RP1 can boost viral production while promoting tumor cell death. RP1 also includes a cytokine intended to boost an immune response by stimulating the recruitment and activation of immune cells. The goal is not only to kill tumor cells directly but also to trigger a systemic immune response against the tumor, potentially leading to long-lasting immunity.

Early clinical trial data suggest that RP1 is more potent than T-VEC (talimogene laherparepvec), the only oncolytic virus treatment for melanoma currently approved in the U.S.[10] Clinical trials have targeted patients whose tumors have progressed on immunotherapy, and response rates to RP1 have been promising.

This is a treatment for a very common indication; if approved, it may see immediate patient demand outside of academic health centers and centers of excellence. RP1 is administered by injection: The treatment needs to be injected directly into the tumor, though this can take place nearly anywhere in the body, including in viscera or deep lymph nodes.

Commercialization Challenges

Patient Access and Administration

RP1 is part of a complex and fairly long treatment program. It needs to be injected directly into the tumor biweekly for up to eight cycles if well tolerated, adding up to 16 weeks of treatment. Patients typically also receive concurrent treatment with nivolumab, which may continue for as long as 20 months after the RP1 treatment is complete. This makes appointment scheduling (which is critical for the treatment's success) tricky, especially if the patient must travel a long distance to a specialized site. Relatively few facilities can support the safe handling and intratumoral injection of this treatment.

Patient Access

Melanoma is a relatively common cancer, and as many as 40% of patients with advanced cases may ultimately become eligible for RP1 after failing anti-PD-1 therapy.[11] If post-approval demand for this treatment *does* surge, there will be an immediate and pressing need for creative thinking about how to expand access.

Financial Considerations

As a genetically engineered herpes simplex virus, RP1 requires specialized facilities and expertise to manufacture. Producing gene therapies tends to be costly, raising affordability and reimbursement concerns that are even more challenging when patient populations are expanding rapidly. Order-to-cash concerns are also an issue: Because it's a multidose regimen, will the entire course of treatment be paid for at once? Or will each dose be invoiced separately?

PRGN-2012: Investigational gene therapy for rare disease caused by human papillomavirus (HPV)

Designated a breakthrough therapy by the FDA, and submitted under the Accelerated Approval pathway in December 2024, Precigen's PRGN-2012 (zopapogene imadenovec) is an adenovirus vector-based gene therapy designed to treat human papillomavirus (HPV)-positive recurrent respiratory papillomatosis (RRP), a rare chronic disease in which nonmetastatic masses grow in the throat.[12] Most of these lesions aren't neoplastic or metastatic, but they can transform into cancerous cells. Thus far, treating this disease has involved repeated surgical removal of the lesions.

PRGN-2012 is a therapeutic vaccine that stimulates immune responses against cells infected with HPV genotypes 6 and 11. It uses an adenoviral vector to infect normal cells, which then express HPV antigens in bulk, eliciting an immune response that also targets the PRR lesions (which are expressing the same HPV antigens). PRGN-2012's ability to reprogram the patient's own immune system to attack HPV-infected cells is potentially curative, addressing the root cause of the disease rather than its symptoms.

"This therapy addresses an unmet medical need in an area where there has been little to no progress in improving the standard of care in recent history," Cicchini said. "It's a therapeutic immunization against a virus that is causing painful and debilitating abnormal cell growth. You're basically teaching the body how to fight off disease, rather than just addressing the symptoms."

The treatment has achieved promising results in clinical trials, with more than half of participants requiring no surgeries to remove the masses for at least a year after treatment. Its approval could set a new precedent as an immunotherapy for an HPV-related disease. Precigen is investigating the use of the same adenovirus vector platform to treat recurrent metastatic cervical cancer.

Commercialization Challenges

Patient Identification and Access
RRP is a rare disease, with fewer than 28,000 patients having been identified in the U.S. to date. Identifying and targeting the members of such a small population may be difficult. Enabling access to this new therapy — which will likely be very expensive for patients if not covered by payers — may require innovative pricing models, such as outcomes-based compensation agreements.

Logistics and Supply Chain
PRGN-2012 is an off-the-shelf preparation that does not require patient-specific manufacturing, but it does require a specialized facility that meets current good manufacturing practice (cGMP) standards. This therapeutic is administered through subcutaneous injection in a three-dose regimen. Precigen's in-house manufacturing facilities must be able to scale up to meet the projected demand from patients, who will require three times as many doses as there are patients to be treated. The preparation will likely require a cold chain, which tends to increase distribution costs and restrict the number of provider facilities that can offer the treatment. When a small patient population needs a treatment offered at only a few facilities, many members of this group will benefit from travel assistance, especially when they need to stay near the center administering the vaccine for the entire three-dose treatment regimen.

Physician Education
The HCPs who will administer this treatment will need to be trained to monitor for and manage immune-related events that may occur after dosing. They'll also need to be educated on the benefits this treatment demonstrates over the existing standard of care (repeated surgeries).

ECUR-506: Investigational in vivo gene therapy treating rare metabolic disorder in pediatric patients

iECURE's ECUR-506 (also known as GTP-506) was designed to treat Ornithine Transcarbamylase (*OTC*) deficiency, a rare genetic metabolic disorder caused by mutations in the *OTC* gene.[13]

The deficiency impairs the liver's ability to detoxify ammonia, leading to a toxic accumulation that can cause neurological damage, seizures, coma and death, primarily in infancy. ECUR-506 aims to insert a functional *OTC* gene into the affected cells, providing a permanent genetic correction.

ECUR-506 uses two adeno-associated virus (AAV) capsids carrying two different payloads — one creates a targeted cut at a well-characterized "safe harbor" site in the liver genome, while the other contains the functional *OTC* gene to be inserted at that site, enabling permanent expression of that healthy gene. This innovation, which enables precise and efficient gene insertion in vivo, makes it possible to safely insert the gene into the genome so that it will not be lost when cells divide (as would happen with a more traditional AAV vector model). This way, the healthy gene will be replicated as the infant grows.

Currently, the only potential cure for *OTC* deficiency in an infant is a liver transplant, followed by a lifetime of immunosuppression. This therapy aims to be a less invasive but potentially curative alternative.

ECUR-506 is the first use of in-vivo, meganuclease-based gene-editing to reach clinical trials.[14]

Commercialization Challenges

Patient Access and Administration

OTC deficiency is an extremely rare disease, affecting approximately 1,000 newborns around the world each year. This limits the size of the addressable market for the treatment. Early and accurate diagnosis is critical for giving neonates timely access to ECUR-506, but genetic testing may be delayed, especially when HCPs aren't familiar with *OTC* deficiency. ECUR-506 is administered as a single intravenous dose, but only centers with specialized expertise in gene therapy and rare metabolic disorders will be qualified to deliver it. Because it's administered in infants, dosage calculations must be precise. Severe side effects are possible, so immunomodulators should be on hand during administration.

Manufacturing and Logistics

The technology used by ECUR-506 is highly innovative, requiring advanced manufacturing to produce the viral vector, maintain consistent product quality and meet cGMP standards. Like many CGTs, this gene replacement therapy requires cold-chain storage and transport.

Patient and Caregiver Support

Having an infant with a life-threatening rare disease is extremely stressful. Many families would benefit from psychosocial support services, as well as extensive education to help them understand the therapy, its benefits, possible adverse events and side effects, and the importance of long-term patient monitoring.

V940: Investigational individual mRNA therapy for adjuvant treatment of solid tumors

Developed by Merck and Moderna to aid in the treatment of solid tumors, V940 (mRNA-4157) consists of a single synthetic mRNA encoding up to 34 neoantigens, selected to match the unique mutational signature of the patient's tumor using next-generation sequencing and proprietary algorithms.[15] Once administered by intramuscular injection, the mRNA will be translated into neoantigenic proteins in the patient's cells, which are then processed and presented to the immune system, priming T-cells to recognize and destroy cancer cells expressing those same antigens. V940 is given in conjunction with KEYTRUDA (pembrolizumab), an anti-PD-1 immune checkpoint inhibitor, to enhance immune response and improve clinical outcomes.

Currently in clinical trials as an adjuvant therapy for patients with high-risk melanoma after complete surgical resection, V940 is also being evaluated as a potential treatment for additional cancers. Early-phase studies demonstrated mechanistic proof of concept, and the clinical trials that have been conducted so far have been very promising.

Commercialization Challenges

Manufacturing at Scale
This is a multidose custom treatment. Manufacturing begins with the biopsy of the patient's tumor, and each dose must be produced individually using tumor neoantigens identified via bespoke sequencing and bioinformatic analysis. V940 addresses a very common indication, so a scalable and efficient commercial strategy will need to be applied upon its approval.

Patient Access
Patient-specific manufacturing elevates treatment costs, which have exceeded $100,000 per patient for similar RNA-based therapeutics.[16] Payers may be reluctant to cover these costs without real-world evidence of long-term efficacy. Because V940's administration must be coordinated with that of KEYTRUDA, scheduling patient travel and monitoring appointments may be especially challenging.

Bringing tomorrow's most transformative therapies to market

These and other cell and gene therapies promise to revolutionize the treatment of a growing number of diseases, bringing new hope to patients with difficult-to-treat conditions or diseases that were once considered untreatable. CGTs remain at the cutting edge of drug discovery, but the number of approved CGTs is predicted to skyrocket in the next few years. As it does, developers will need to overcome scientific, financial and operational obstacles to successfully commercialize these products.

The patient journey is markedly different in CGT treatment than with traditional pharmaceutical products, as is the product lifecycle. These differences extend from the early preclinical discovery phase through maturity and they encompass a broad array of functional areas. Drug developers accustomed to traditional commercialization strategies will find they need to think differently to achieve success with CGTs.

In particular, they'll need to overcome CGT-specific barriers, including:

- **Patient support:** Because they're so novel, many patients are unaware of CGTs that might help them, and even when they learn about these treatments, many hesitate to try something new. Comprehensive patient support services can help educate patients as they progress along the treatment journey. Assistance with travel, copayments, care coordination and after-therapy follow-up communications can also make it easier for people to access CGTs, as can provider education services that help prospective prescribers understand available treatment options, reimbursement supports and eligibility criteria.

- **Regulatory considerations:** Regulatory agencies have developed a variety of initiatives to accelerate drug development, some of which specifically target CGTs. Understanding and using the appropriate programs and designations can make it faster and easier to navigate FDA and EMA requirements, as can the right manufacturing, distribution and pharmacovigilance strategies.

- **Logistics and supply chain issues:** CGTs require customized storage and transportation. Many formulations are time- and temperature-sensitive, requiring precise tracking to ensure that the right environmental conditions are maintained throughout the product journey and that it will reach the site of care at the right time. CGT supply chains are complex, and centralized end-to-end oversight is needed for quality assurance. Mishandling, contamination or processing errors could compromise the product, which can put the patient in danger. This often-overlooked piece of the puzzle is mission-critical for the success of CGT treatments.

- **Demonstrating treatment value:** CGTs are relatively expensive, and payers typically require evidence that they perform better than the previous standard of care. With a comprehensive approach that includes clinical, economic and quality-of-life data, developers can show that the therapy's potential benefits justify its cost. New reimbursement models, such as outcomes-based contracts, are also showing promise for cost management.

- **Commercial distribution:** Most CGTs are administered in academic health centers and CoEs, in large part because these facilities can support complex dosing regimens, perform surgical procedures and meet storage and handling requirements. However, there are often more patients in community settings who could benefit from these therapies, and a long-term strategy might include strategic partnerships that enable this network to expand over time.

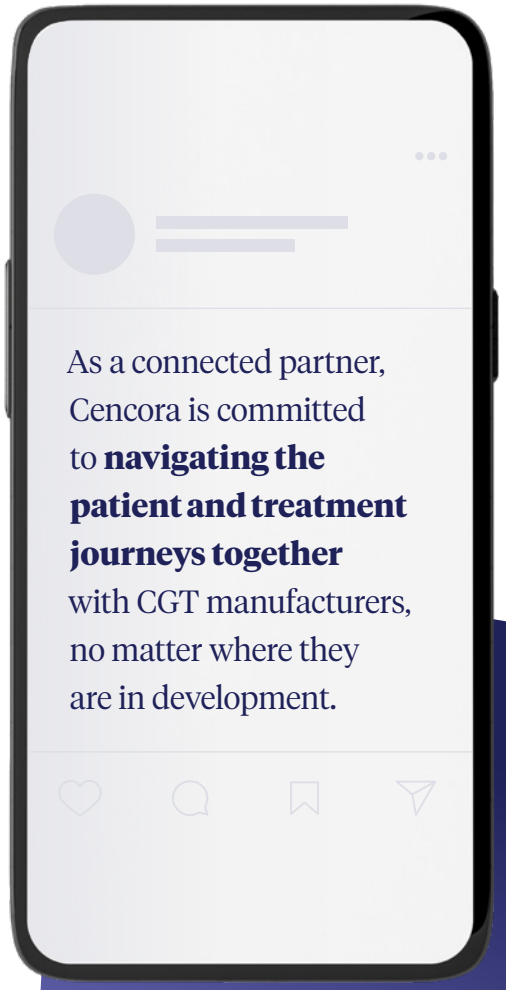
None of these barriers to successful commercialization exists in a vacuum. Instead, they're interdependent variables that require a centrally coordinated, end-to-end approach so that all parts of the process contribute to the success of the whole. Central orchestration can ensure supply chain resilience, while real-time visibility and process updates help optimize the treatment experience throughout the patient journey. When drug developers, providers and commercial partners all have situational awareness, decision-makers can be confident they're doing what's best for patients.

"The real value in what we deliver is that it's an integrated offering," Kevin Chinn said. "We offer a suite of solutions that encompass the entire product and patient journey. We give the therapy developers full visibility, so they always have a line of sight into their program, like an air traffic controller. To achieve this, we have established relationships across the entire health care ecosystem and built out efficient solutions, using analogous experiences as a guide."

Conclusion

Excitement about the latest developments in the CGT field continues to build. Nearly every day, it seems as though the latest innovations are pushing the cutting edge of science. But for these therapies to transform the standard of care, they'll need to be commercialized. When drug developers leverage the expertise of a commercialization partner to bring CGTs to market, they can keep their focus on what's most important to them — developing and manufacturing a treatment that might save lives.

Cencora has a proven history of bringing complex, transformative therapies to market on a global scale. With end-to-end expertise in global strategies and key local markets, Cencora is ready to deliver strategic guidance along with implementation support across a broad array of functional areas. As a connected partner, Cencora is committed to navigating the patient and treatment journeys together with CGT manufacturers, no matter where they are in development.



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