Syneos Health®
Insights Hub

Success Factors for Commercializing Cell and Gene Therapies

Introduction

Cell and gene therapies (CGTs), unlike many treatments, address the underlying causes of disease and may even cure an illness. In other cases, they may improve clinical outcomes dramatically compared with the standard of care, thus transforming the treatment paradigm.

The challenges in developing, testing and distributing CGTs have been described abundantly in scientific and trade literature. Less well known are commercial hurdles companies must overcome when launching these complex products and shepherding them through the full product lifecycle. Because many CGTs are new, there's little long-term data on safety and efficacy and they may represent a paradigm shift from chronic treatment to one-time cure. This leads to a shift in site of care from community centers to centers of excellence and requires a change in mindset with respect to patient ownership. In order to facilitate this shift, stakeholders need to be educated on the new paradigm as well as novel endpoints associated with CGTs. Site administration also can be burdensome due to challenges in extracting, transporting, storing and infusing the treatments. Making this a seamless process for patients requires increased levels of education, coordination and collaboration among manufacturers, providers and payers.

Companies at the forefront of CGTs are learning and evolving as they navigate these difficult straits. Nevertheless, for large pharmaceutical companies—and more particularly for smaller players—enlisting a partner with expertise in commercialization across the product lifecycle is instrumental to success. This ensures developers are able to focus on the key activities required for launch, especially those that are critical to commercializing cell and gene therapies, such as their integrated evidence generation strategy. This must be discussed at an early stage with stakeholders who can influence market acceptance. Understanding that missteps in early commercial efforts are common, an expert partner such as Syneos Health® can also help CGT companies course-correct and make necessary midstream investments to overcome initial setbacks.

This report will begin by presenting a typology of cell and gene therapies, with particular attention to product launches in the US market. We will then describe commercial challenges relevant to different types of CGTs and offer recommendations that can help manufacturers reach their commercial goals.

CGT landscape overview

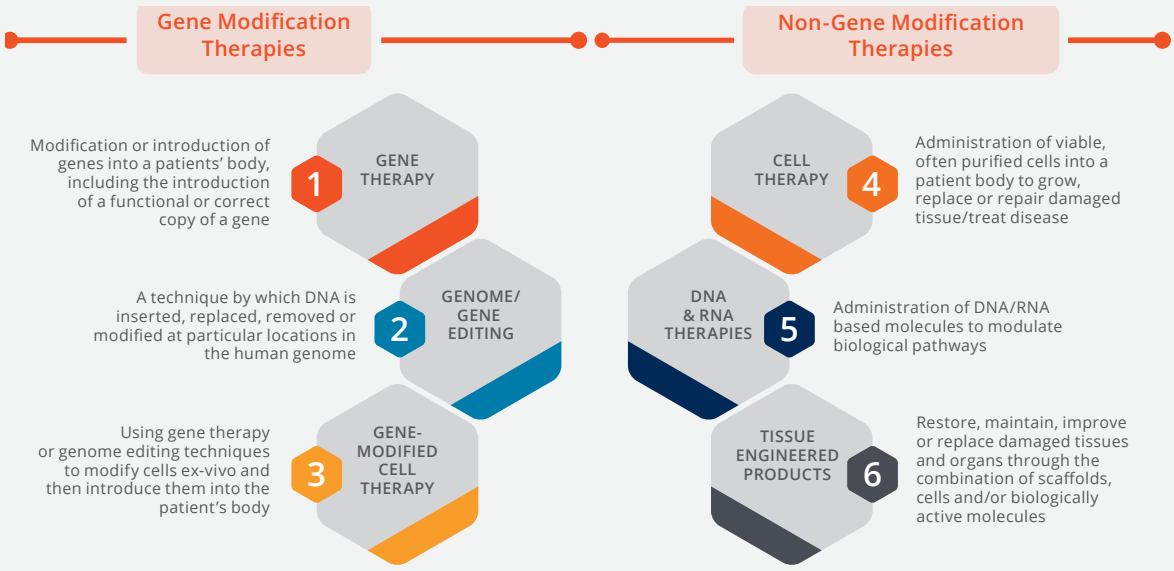
By any measure, the growth of CGTs over the past decade has been dramatic. Twenty-six[1] such therapies have been approved and launched in the US in this period with more than 800[2] others being studied today across various therapeutic areas. As of March 31, 2022, about 1,600 companies[3] showed interest in exploring, developing and investing in CGTs. The majority were private or small publicly listed companies focusing all their resources on CGTs.

Recognizing the huge untapped potential, the US Food and Drug Administration (FDA) has been easing the path to approval via fast track and breakthrough designation and with programs such as Project FrontRunner, an initiative from the FDA's Oncology Center of Excellence aimed at speeding CGTs and other novel treatments to cancer patients.

Typology and pipeline

CGTs comprise six major types of technologies: gene therapies, genome/gene editing therapies, gene-modified cell therapies (GMCTs), cell therapies, DNA and RNA therapies, and tissue engineered products (Figure 1). The first five are the focus of the current white paper.

Figure 1: Six CGT Technologies



1. Informa Business Intelligence Biomedtracker; Accessed March 9, 2022
2. Evaluate Pharma Company Profile Report; Accessed March 31, 2022
3. Evaluate Pharma Company Profile Report; Accessed March 31, 2022

Cell therapies and gene-modified cell therapies

Cell therapies and gene-modified cell therapies can be either autologous (patient's own cells) or allogeneic (third-party donor cells). Allogeneic cell therapies dominate among marketed and pipeline cell therapies, reflecting significant need for relatively standardized, readily available off-the-shelf treatments. Unlike the broader cell-therapy space, the GMCT pipeline shows a higher prevalence of autologous approaches. But with more advancements in the GMCT space, we expect allogeneic GMCTs will also outpace autologous assets (similar to the cell therapy landscape evolution).

Gene therapies

Gene therapies can be delivered to patients through viral and non-viral vectors. Currently, viruses are the most common vectors used in gene therapies due to their efficiency in delivering the genes to specific cell types. The non-viral methods are in development stages, with lipid nanoparticles (LNPs) being the leading non-viral delivery method. These have great utility in gene therapy, as they can be manufactured quickly and are scalable to the size of the material being delivered.

RNA & DNA therapies

RNA and DNA therapies use RNA/DNA to act on the biological pathways to treat or cure a disease. Of these, RNA therapies are the favored approach. Since RNAs do not require nuclear localization for transcription and have negligible risk of genomic integration, they can be developed more quickly and cost-effectively.

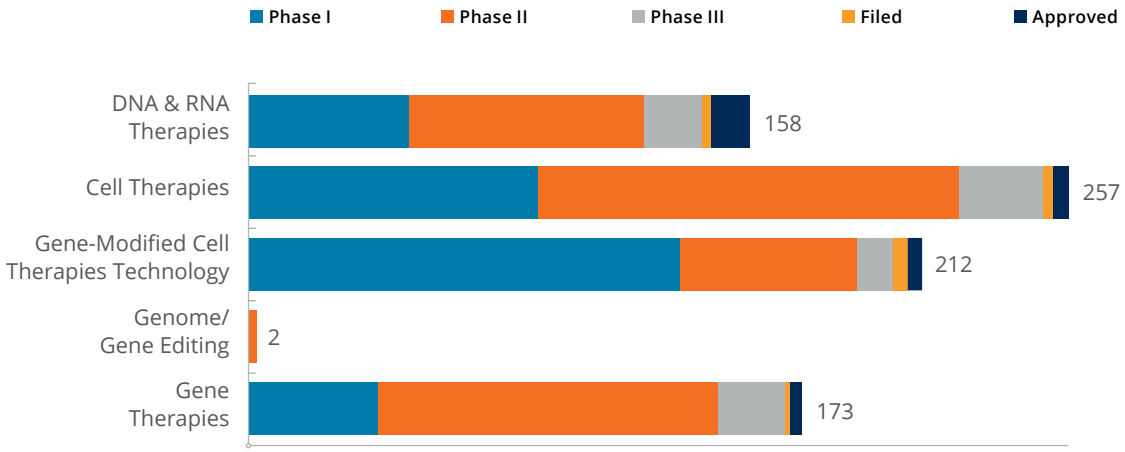
Genome/gene editing

Genome/gene editing is a relatively new therapeutic approach. CRISPR/Cas9 recently emerged as a breakthrough technology in the genome/gene editing space and is currently being studied in phase II studies. While CRISPRs were first identified in E. coli in 1987, it took another 25 years for scientists to understand their potential. CRISPR/Cas9 was discovered in 2012 and the first law that regulates the use of this technology was passed in 2019. Ethical concerns and complex genomic alterations were a few of the factors that led to limited development and delayed the use of this technology.

In the US, cell therapies dominate among all CGTs, with about 32% of biopharmaceuticals' current marketed and pipeline assets (Figure 2). GMCTs make up about 26%, followed by gene therapies and DNA and RNA therapies, with an equal split of about 20%. Cell therapies dominate as a result of a long history dating back to 1958. In contrast, the first gene therapy procedure was performed in 1990, more than 30 years later. GMCTs are now poised to outpace cell therapies owing to the recent increase in target discoveries for CAR-T cell therapies, among other gene-modified cell therapies. It's worth noting that the majority of cell therapies, gene therapies, and DNA and RNA therapies are in phase II, while most gene-modified cell therapies (GMCTs) are in phase I. This trend underscores recent, increased interest in GMCTs.

Figure 2: Marketed and Pipeline CGT Breakdown by Technology

(Data applicable to US only)



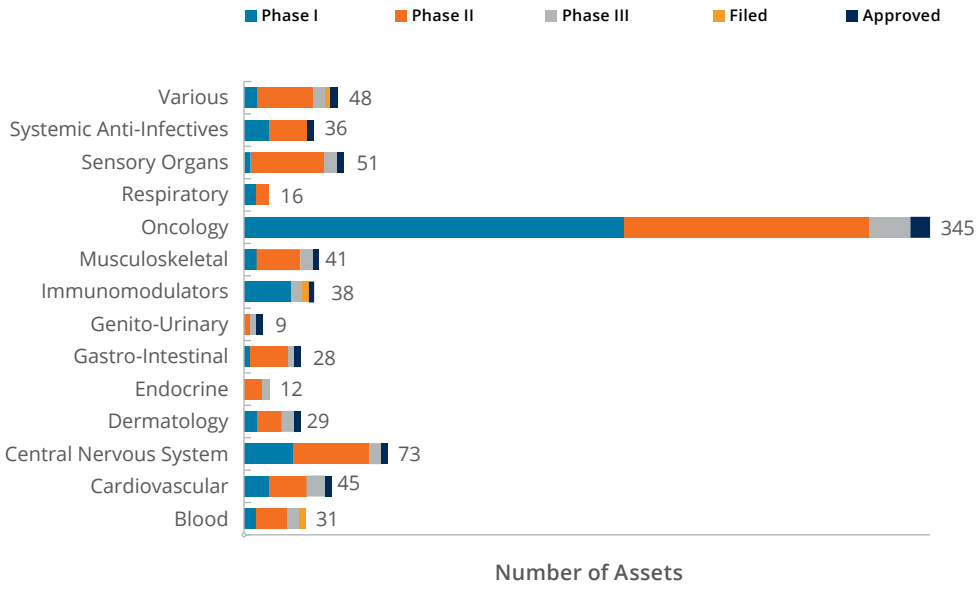
Data: Evaluate Pharma Pipeline Analysis as of March 31, 2022

Therapeutic breakdown

Oncology dominates the CGT landscape with more than 40% of marketed and pipeline assets across all phases (Figure 3). Cancer's high representation may be due to fast-expanding use of CAR-T cell therapies in clinical care. Treatments for diseases of the central nervous system, sensory organs and cardiovascular conditions also have a significant presence.

Figure 3: Marketed and Pipeline CGTs by Therapeutic Area and Phase (Phase I Through Approval)

(Data applicable to US only)



Data: Evaluate Pharma Pipeline Analysis as of March 31, 2022. Blood cancers are excluded from the Blood category, which includes diseases such as haemophilia A, haemophilia B, sickle cell disease, etc. "Various" designates assets relevant to multiple therapeutic areas.

CGT treatment journey

When compared with traditional biologics, developing CGTs entails a complex and lengthy process, from determining patient eligibility all the way through administration (Figure 4). Eligibility is established by gathering genomic, medical, and environmental data on the patient. After building the genomic profile via genetic testing and/or proteomic profiling, the patient is matched with the customized CGT treatment. Cell extraction via leukapheresis is typically the next step in the treatment process for autologous CGTs. For allogeneic CGTs, patient data is matched with donor data available in registry databases.

Once the cell collection step is completed (where required), either the sample or patient information is provided to the manufacturer for cell selection, enrichment and/or modification and expansion. The resulting formulation is harvested, packaged and shipped back to healthcare providers, who will administer the treatment to patients. Only specialized treatment centers, which typically engage highly trained specialists and have the necessary infrastructure, are authorized to administer cell and gene therapies to patients.

Figure 4: Patient Journey

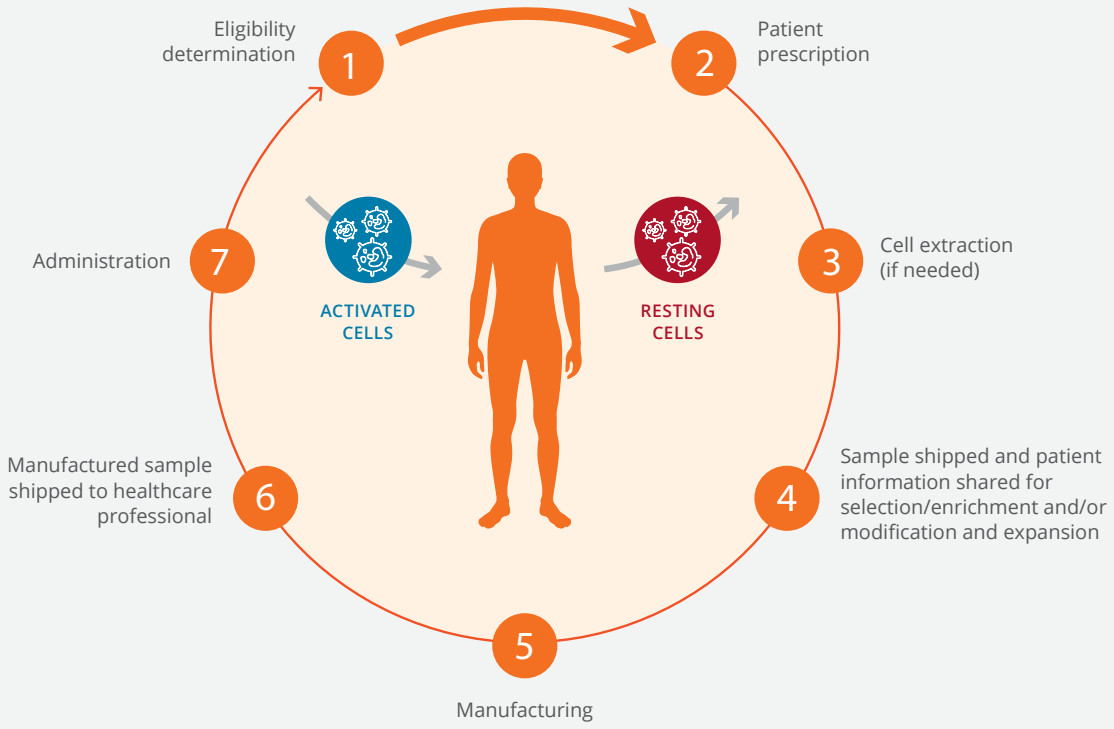
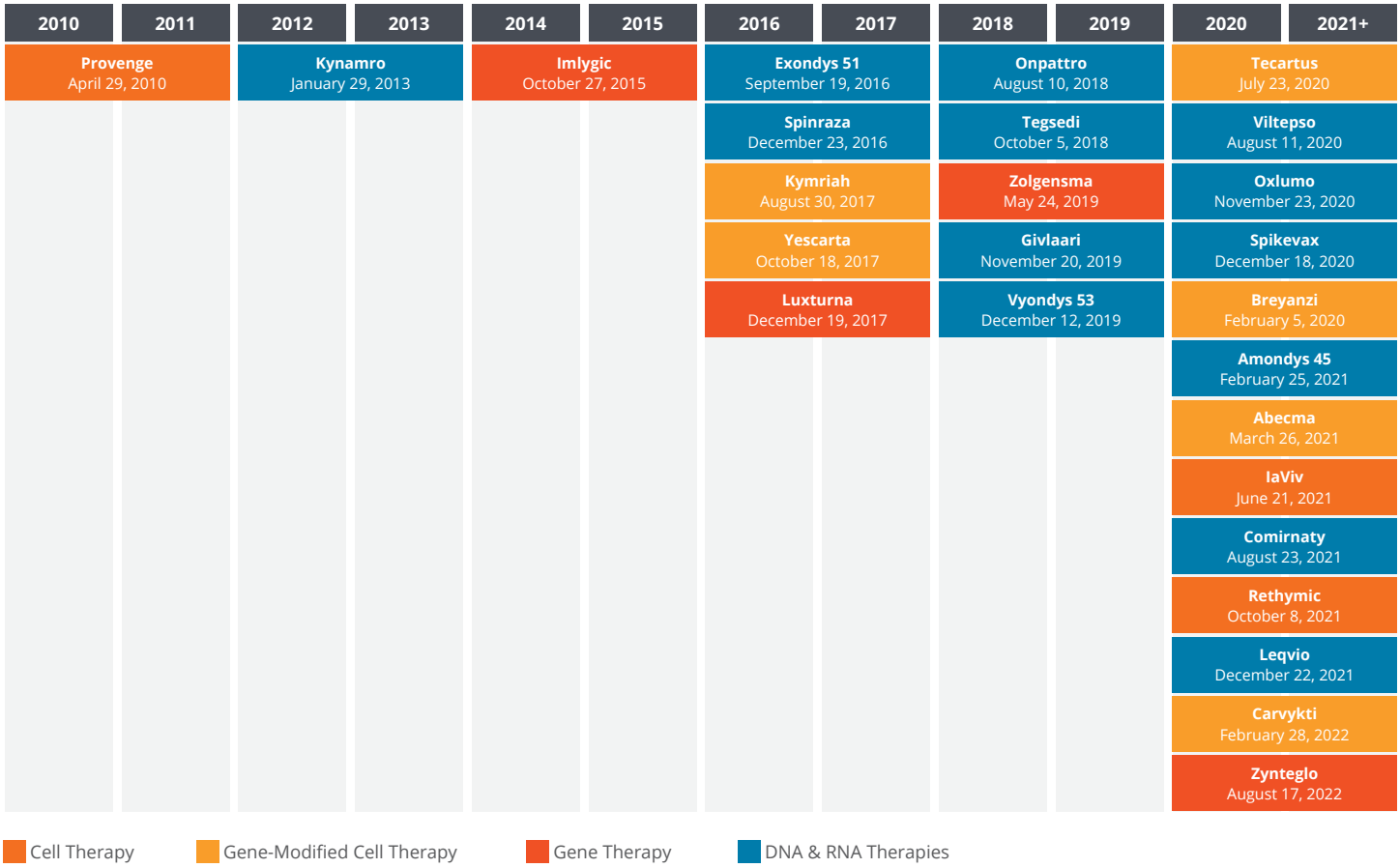


Figure 5: Approved CGTs in the US

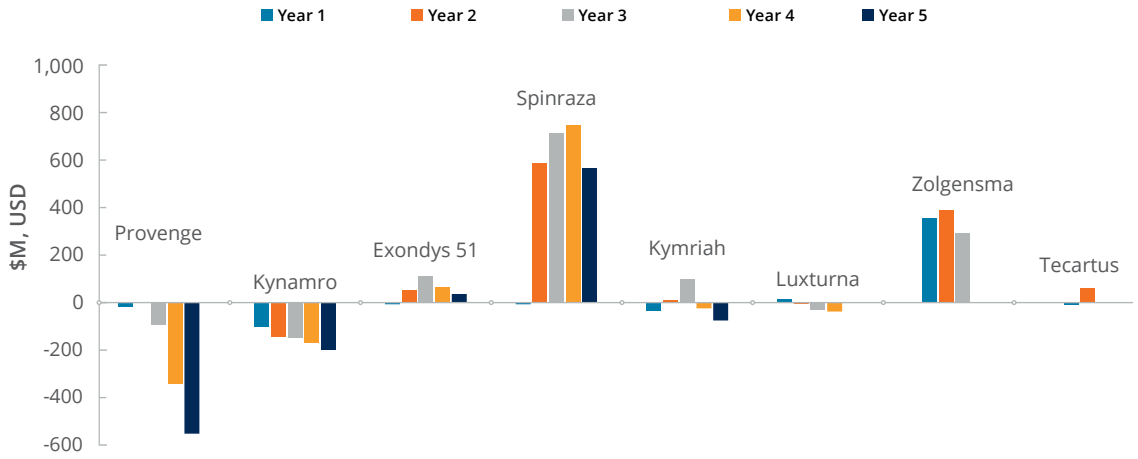


Data: Informa Business Intelligence Biomedtracker, as of August 18, 2022

Out of the 26 approved CGTs in the US, 22 were designated as orphan drugs. Thirteen approvals were fast track and 13 others were breakthrough therapies. Of the total, three therapies got both fast track and breakthrough designations. DNA and RNA therapies and CAR-T gene-modified cell therapies dominate US-approved CGTs, with a high proportion in the area of metabolic diseases (DNA and RNA therapies) and oncology (CAR-T gene-modified cell therapies).

Figure 6: CGT Commercialization—Analysis and Learnings

Difference Between Actual vs. Projected US Sales (Millions $)



Data: Evaluate Pharma Archived Forecast Report as of March 9, 2022

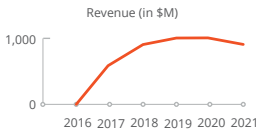
To better understand CGT commercialization best practices, we identified and investigated eight approved CGTs that had varying levels of success in meeting launch revenue projections.

Launches exceeding projections

Among the eight CGT use cases examined by Syneos Health, two spinal muscular atrophy (SMA) treatments, Spinraza and Zolgensma, consistently and significantly exceeded expectations. In the case of Spinraza, success came partly from an initiative expanding its use to the adult SMA population. For Zolgensma, innovative access programs created goodwill and increased market penetration.

Spinraza by BIOGEN

DNA Therapy for Spinal Muscular Atrophy

Launch Performance	Things That Went Well	Key Challenges/Hurdles
	• Extensive coverage and reimbursement six months after FDA approval (e.g., most US largest payers covered Spinraza in SMA types 1-3) • Successful market expansion into adult population (e.g., Biogen invested in global clinical trial to investigate the drug at higher doses in patients of all ages, not just children)	• Bottleneck due to challenging intrathecal administration process (e.g., delivery into the spinal canal requires 2-3+ staff and it costs $10K+); need for more training and centers able to deliver the therapy

Zolgensma by NOVARTIS

Gene Therapy for Spinal Muscular Atrophy

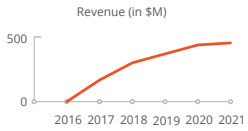
Launch Performance	Things That Went Well	Key Challenges/Hurdles
	• Global Managed Access Program (e.g., lottery system that offers up to 100 free doses per year in countries where Zolgensma is not yet approved) and robust pre-launch evidence generation that informed pricing; positive feedback due to unbiased approach • "Day One" access program (e.g., retroactive rebates, deferred payments, installment options, outcome-based arrangement); early patient access and global expansion • Production activities planned well in advance to avoid shortages	• Limited number of hospitals able to administer the drug at launch

Launches Meeting Projections

Duchenne muscular dystrophy treatment Exondys 51 performed slightly above expectations, while blindness treatment Luxturna was able to meet expectations on average. The factors for success in each case were different. Exondys 51 benefited from active and involved caregivers who lobbied FDA for approval. Luxturna differentiated itself through innovative pricing and access model programs.

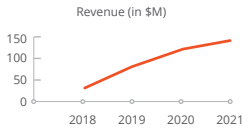
Exondys 51 by SAREPTA THERAPEUTICS

DNA Therapy for Duchenne Muscular Dystrophy

Launch Performance	Things That Went Well	Key Challenges/Hurdles
	• Active caregivers lobbied for FDA approval; quicker adoption due to extensive TV and newspaper coverage • Dedicated case managers assigned to support patients via SareptAssist program	• Reliance on outsourced service providers to provide pre-clinical and clinical development services[1] • Limited coverage due to Sarepta not providing substantial evidence that Exondys 51 would provide a clinical benefit[1]

Luxturna by SPARK (A ROCHE COMPANY)

Gene Therapy for Retinal Dystrophy

Launch Performance	Things That Went Well	Key Challenges/Hurdles
	• Surgical training to leading retinal surgeons on the administration procedure • Early engagement with payers about appropriate endpoints • Innovative pricing and access model (e.g., rebate program based on effectiveness, contract directly with commercial payers or their specialty pharmacies, reimbursement via installments spread over many years)	• Small target patient population (e.g., effective only for the 1,000 to 2,000 patients in the US with the recessive RPE65 mutation) • Medicaid best price provision was a major roadblock to proposal of spreading payments for Luxturna over several years

Launches Unable to Meet Projections

Of the eight drugs analyzed in our report, both Kymriah and Tecartus—for acute lymphoblastic leukemia and mantle cell lymphoma, respectively—experienced lower-than-expected sales in the first year but later showed improved results. Provenge, the prostate cancer drug, continued to experience lower than expected launch sales. Provenge did not meet demand at launch, the manufacturer course corrected, investing heavily in infrastructure that included a new commercial team experienced in prostate cancer, and was unable to meet the expected sales. Kymriah overcame first-to-market challenges thanks to extensive marketing investments and an innovative access model, including a money-back guarantee. Tecartus ran into restrictions related to risk evaluation and mitigation strategies (REMS). It countered these by leveraging an established network of treatment centers and investing in the manufacturing process. Kynamro, developed to treat dyslipidemia and hypercholesterolemia, did not meet expectations and was discontinued as of August 2019. According to executives at Ionis, the failure was mainly due to insufficient marketing efforts due to misaligned interests among partnering companies.[2]

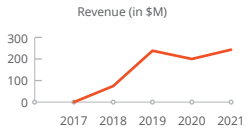
Provenge by DENDREON

Cell Therapy for Prostate Cancer

Launch Performance	Things That Went Well	Key Challenges/Hurdles
	• Re-launched with new commercial team experienced in prostate cancer after initial launch challenges • Heavy investment to develop infrastructure and cover demand after being unable to meet strong demand • Extensive patient support services and training services to medical staff post re-launch	• Difficulties meeting demand due to limited manufacturing capacity[3] • Complex administration and limited availability of funds resulted in scaling difficulties • Delay in securing payer coverage and high up-front cost incurred by providers due to buy-and-bill model were key barriers in product uptake[4] • Based on the HCP adoption challenges and competitive environment, there was a need for a stronger differentiation and value proposition[5]

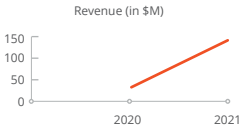
Kymriah by NOVARTIS

Gene-Modified Cell Therapy for Acute Lymphoblastic Leukemia

Launch Performance	Things That Went Well	Key Challenges/Hurdles
	• Money-back guarantee program and outcome-based contracts for first launch were viewed favorably by treatment centers; however, these were evolved for second indication • Increased product availability through expansion of certified treatment sites (350 qualified treatment sites in 2021) • Treatment sites selection based on FACT accreditation • Extensive support provided by field teams along the entire referral pathway	• Challenges due to being first CAR-T to market; extensive marketing investment required given the scale • Cell variability issues triggered multiple improvements to the manufacturing process

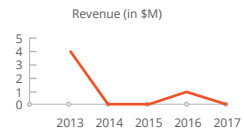
Tecartus by KITE

Gene-Modified Cell Therapy for Mantle Cell Lymphoma and Acute Lymphocytic Leukemia

Launch Performance	Things That Went Well	Key Challenges/Hurdles
	• Leveraged established network of treatment centers (e.g., at launch, patients could access Tecartus through 100+ authorized treatment centers) • Improved manufacturing process (e.g., 96% manufacturing success rate and median manufacturing turnaround of 15 days from leukapheresis to product delivery)	• Restricted access through the REMS program due to increased risk of CRS and neurologic toxicities[6] • Limited referral from community to centers of excellence due to patient ownership concerns[6]

Kynamro by IONIS

RNA Therapy for Dyslipidemia / Hypercholesterolemia

Launch Performance	Things That Went Well	Key Challenges/Hurdles
	• Addition of sales reps to counter initial slow start and intense competition	• Slow start coupled with intense competition[7] • Drug was priced well below Juxtapid, a similar product approved a month earlier • According to Ionis executives, company experienced marketing issues due to interest misalignment. Ionis partnered with Genzyme, later acquired by Sanofi, leading to organizational challenges[3]

Six Key Commercialization Challenges

In addition to the disease-specific considerations for commercialization, there are six key commercial challenges faced by CGTs, which manufacturers must address in order to ensure success.

1 Concerns with value proposition due to limited long-term data

With the high cost and potentially curative nature of these therapies, careful consideration of the clinical data is required both pre-approval and post-approval to convince stakeholders on the benefit/risk profile of their products. Stakeholders including payers may have concerns due to lack of long-term safety and efficacy data. Uptake may suffer as companies struggle to persuade providers and patients involved in treatment decisions.

Example: *Exondys 51 experienced a controversial approval process due to insufficient evidence, requiring Sarepta Therapeutics to do a confirmatory trial. This caused a delay in approval of five to six years from the timeline agreed on in the original approval letter.*

Strategic imperatives:

- Develop an integrated evidence generation plan leveraging market insights early in development and updating stakeholders as additional data becomes available
- Explore opportunities to leverage systems (e.g., hubs) to compliantly generate real-world evidence
- Establish a platform narrative to tell the long-term value story, highlighting plans to build infrastructure, attention to lifecycle management, etc.

2 Change in treatment paradigm due to shift from chronic treatment to potential curative

Lack of established referral networks and complexity of administration/process requirements may restrict utilization, at least initially, to select academic centers or centers of excellence (CoE). Adoption, therefore, often requires a paradigm shift in the patient journey. While the CoEs will be the main treating center, monitoring may be local due to distance/travel required for most patients.

Example: *Industry-recognized challenges with CAR-T cell therapy (such as Kymriah, Tecartus) referrals to CoEs may slow down uptake of these therapies as they enter the market. Community providers cannot administer CAR-T cell therapy in-office and need to refer patients to centers of excellence. Most physicians consider multiple factors when deciding to refer, such as CoE reputation, experience and relationship; location; and patients returning back to community centers.*

Strategic imperatives:

- Strive to shift the physician mindset with respect to “patient ownership”
- Educate physicians on their continued role in monitoring/managing in the new treatment paradigm
- Increase comfort with referrals to CoEs through education, referral network development, regional high-value influencer engagement and promotional efforts

3 Burdensome site set-up for facilities, including IT set-up, accreditation and provider training

One reason providers consider administration of cell and gene therapies to be burdensome is due to the IT system set-up requirement. This becomes increasingly challenging when several cell and gene therapies are available and require different systems to deliver the product. In addition, select therapies may have certification requirements and may require efforts to store, extract and infuse the therapy.

Example: *There were a limited number of hospitals that could handle complex administration of Zolgensma at launch. Novartis recognized the challenge and lengthy process to obtain and genetically modify a patient specimen. To ensure readiness ahead of the Zolgensma launch, the company onboarded 60 top medical centers to handle patient blood shipment and delivery.*[8]

Strategic imperatives:

- Integrate existing IT systems/platforms that are currently being utilized for similar therapies in order to reduce system set-up burden
- Optimize provider training and interaction requirements of the system to help with ease of use

4 Difficulty in meeting demand due to uncertainty in addressable population

Currently, most of these therapies are being studied in either rare diseases or niche patient populations, where there may be hurdles in patient identification. For products in established disease areas, it may be hard to identify the right patient type in conformance with reimbursement considerations, guidelines and availability of existing standard of care therapies. In addition, it may be hard to anticipate potential uptake as the market is constantly evolving and there are limited analogs.

Example: *Dendreon was unable to meet demand for one year after launch. The original expectation was to treat approximately 2,000 patients, but that proved to be about 2% of the potential demand. To address the problem, Dendreon had to invest heavily in a complex process of coordinating the collection, manufacturing and administration of Provenge.*

Strategic imperatives:

- Minimize patient drop-off/leakage by understanding overall patient journey and referral patterns
- Develop a robust forecast based on understanding uptake across patient profiles while optimizing manufacturing capabilities and inventory to avoid stock-out

5 Complex and long process of delivering therapy due to the unique combination of manufacturing, administration and regulatory/compliance requirements

With several stakeholders involved, it is important to understand the role of each group in managing process and behavior, as well needs. As CGTs are more individualized than other treatments, they demand closer collaboration between HCPs and manufacturers. Regulatory and compliance requirements governing the interaction and flow of information between the stakeholders (specifically healthcare providers and manufacturers) also come into play. Most of these therapies are anticipated to have longer turnaround times due to the nature of the process, which may lead to delays in delivery of the treatments. Furthermore, the clinical condition of the patients may change between diagnosis and administration of the therapy, during which time patients may become ineligible for treatment. Limited control or lack of understanding of the complex process, in addition to the logistics of delivering the therapy, may limit their availability at select centers

Example: *At launch, Kite was able to make significant improvements to the manufacturing process of its CAR-T, Tecartus, when compared with Novartis's CAR-T, Kymriah.[9] This shows substantial progress in shortening the turnaround. Specifically, Kite achieved 96% manufacturing success rate and median manufacturing turnaround of 15 days from leukapheresis to product delivery, while Novartis turnaround at launch was 3-4 weeks.*

Strategic imperatives:

- Maximize manufacturing efficiency to minimize turnaround time from patient sample collection to product administration. Build a system/platform for hospital ordering and tracking to facilitate seamless information exchange
- Set up an operating model with the right mix of field personnel to provide support at every step of the complex process

6 High cost of therapy along with reimbursement challenges

High wholesale acquisition costs of CGTs remain under the spotlight. Payers have vocalized concerns, especially in the absence of long-term data. Bundled diagnosis-related group (DRG) payment may not be sufficient for these expensive treatments, and hospitals may be reluctant to assume the risk of reimbursement

Example: *For most CGTs, including Luxturna, the Medicaid "best price" provision was a major roadblock especially in the context of value-based contracts, which may be structured such that prices drop to zero if some patients fail to respond. To counter this, Spark Therapeutics created a comprehensive pricing and access model for Luxturna that resulted in 80% of qualified patients being covered by insurance a month after approval.*

Strategic imperatives:

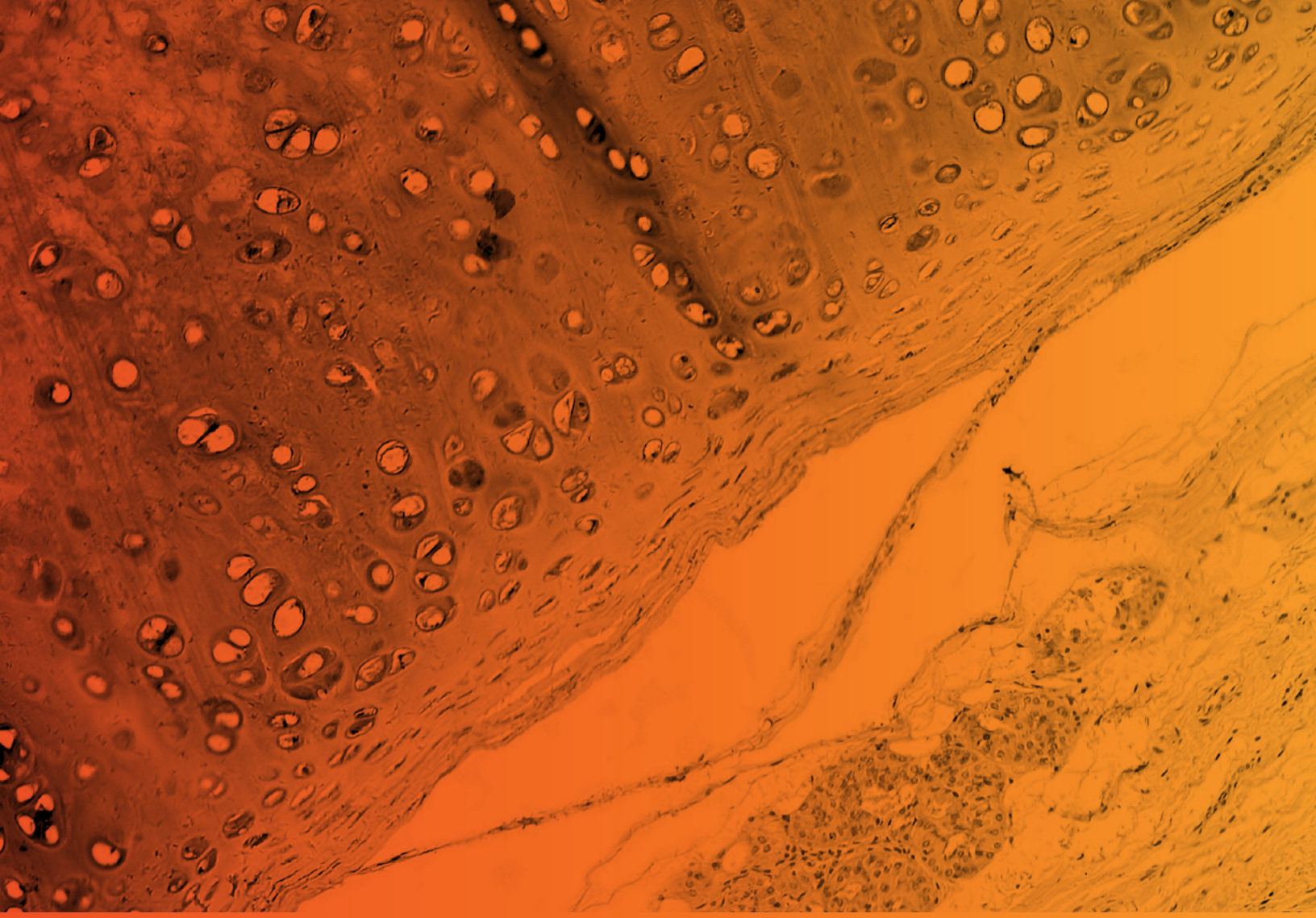
- To address concerns over cost, consider innovative reimbursement models—e.g., value-based approaches
- Early in development, understand payer requirements and expectations for coverage and reimbursement and ensure key elements are collected as part of evidence generation

Conclusion

Over the last few years, more than two dozen cell and gene therapies have launched in the US. Many of these CGTs have faced unique challenges post-approval. With increased interest and development of such therapies, manufacturers need to understand the specific hurdles associated with different treatments. The complexity in manufacturing and distribution has received considerable attention in expert circles and the media. In contrast, commercial challenges in bringing these therapies to the market get relatively little attention.

These hurdles can diminish the potential of CGTs and limit the value they can bring not only to treatment developers but also to patients. Commercial strategies at Novartis, Biogen and other major players have evolved over time. These companies are realizing the full potential of their CGTs by addressing the key challenges we have outlined above.

With the right strategic partnerships in place, many more biopharmaceutical companies can anticipate the hurdles and emulate commercial strategies that have been tested and validated in the market. At Syneos Health, our mission is to partner with ambitious CGT innovators, sharing and disseminating insights and best practices in this fast-evolving field.



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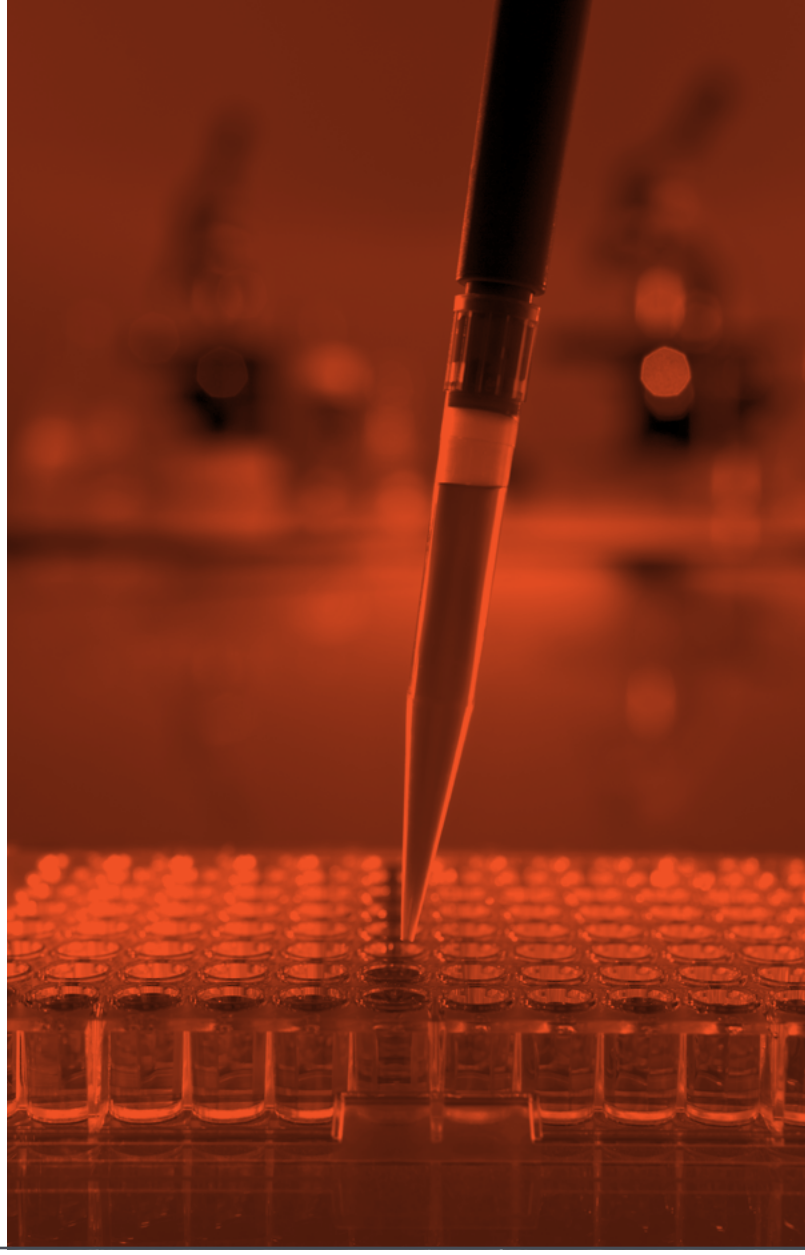

About the Syneos Health Insights Hub

The Syneos Health Insights Hub generates future-focused, actionable insights to help biopharmaceutical companies better execute and succeed in a constantly evolving environment. Driven by dynamic research, our perspectives are informed by our insights-driven product development model and focused on real answers to customer challenges to help guide decision-making and investment.

About Syneos Health

Syneos Health® (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization purpose-built to accelerate customer success. We lead with a product development mindset, strategically blending clinical development, medical affairs and commercial capabilities to address modern market realities.

Together we share insights, use the latest technologies and apply advanced business practices to speed our customers' delivery of important therapies to patients. We support a diverse, equitable and inclusive culture.

To learn more about how we are **Shortening the distance from lab to life®**, visit syneoshealth.com or subscribe to our podcast.

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