Laying the Groundwork for High-Science Brands

▶ Cell and gene therapies, immunotherapies, RNA interference (RNAi) – innovative scientific breakthroughs have the potential to change the course of treatment for severe diseases such as cancer and devastating rare diseases.

The gene therapy market is predicted to rise to $35.67 billion by 2027 from $3.61 billion in 2019 thanks to technological advances aimed at treating cancer patients affected by the disease through genetic mutations. While cell therapy products accounted for the larger share of the global cell and gene therapy (CGT) market in 2018 (76%), gene therapies are expected to outpace cell therapies by 2024, led by the promise of technologies such as CRISPR. Meanwhile, the immunotherapy market is forecast to reach $115 billion by 2023, and is predicted to become the oncology treatment of choice by 2026.

At the same time, however, COVID-19 has presented challenges to research with focus turning to treatment for the pandemic, resulting in fewer than expected applications for potential gene therapy drugs. In this more complex marketplace, with patients waiting for live-saving treatments for severe diseases, companies will need to adopt a more strategic approach to development and commercialization.

Advancing High Science in a Difficult Climate

As of June 2020, there were more than 750 trials of cell and gene therapies in almost 30,000 patients, according to a McKinsey report. However, the pandemic has dealt a blow to development due to the complex manufacturing and delivery processes involved with CGTs.

Furthermore, many high-science brands face challenges with achieving commercial success for many reasons. These include the higher cost of such products; smaller patient populations; the fact that treatment cycles are short, thereby reducing the already smaller pool of patients; and lack of robust long-term safety and efficacy data, which often requires companies to implement costly and difficult patient-monitoring and real-time data programs.

To mitigate the challenges involved in CGT development and commercialization, the McKinsey report says companies will have to make sure their manufacturing and delivery processes are more robust and work with patients and physicians to protect the commercial success of their products.

Processes start with trials and the McKinsey report recommends careful assessment of trials that can be started again, and where and when those trials can get under way, based on epidemiological data, local restrictions, and the capacity of the health system. Other measures include determining whether and how to adjust trial protocols, such as reducing patient visits and streamlining collection points. Companies might also look at alternative ways to bridge data gaps, such as verifying source data with electronic medical records. Strong relationships with the regulators will also be important to overcome issues, such as data gaps.

Many CGT manufacturers have been working to improve supply chain resilience, such as use of digital tools and analytics to gain better oversight of the supply chain and improve manufacturing capacity. Greater digitization will be important in ensuring remote access to documentation, particularly with more people working from home.

On the commercialization front, conventional marketing and advertising strategies are often not suited to CGTs and other high-science brands given the small, targeted patient populations involved. As such, companies will need to shift their models to new channels and approaches to meet the needs of specific patient and provider populations.

Another step CGT companies will need to take is to work with patients and physicians to gain greater trust. Virtual engagement with healthcare professionals, providing support to patients undergoing treatment – from support to determining eligibility, to getting access to treatment, to managing and monitoring the disease progression and therapy through digital tools. Physician and patient engagement also needs to take into account concerns of both parties. For example, physicians might

Understanding Next-Generation Medicines: The Market for CGTs

Cell and gene therapies (CGTs) are advanced biological products for treating chronic diseases, bone-related defects, several cancers, and rare diseases. Products include chimeric antigen receptor (CAR) T-cell therapies, genetic modulation-based gene therapies, and autologous and allogenic cell-based therapies, as well as CRISPR technologies to advance gene therapies.

Leaders in the area of CGT include: Novartis AG, Gilead Sciences, Vericel, MolMed, Anterogen, Organogenesis, Amgen, Dendreon, Orchard Therapeutics, and Spark Therapeutics. Meanwhile, several major companies are seeking alliances with or acquisitions of emerging CGT players, including Novartis, Roche, Gilead Sciences, Bristol-Myers Squibb, Celgene, and Pfizer.

As more CGTs come to the fore, there is also a growing market for new tools to help develop these therapies. These include GMP proteins, media, cell separation and activation reagents, viral and non-viral, cytokine release syndrome monitoring products, GMP antibodies, leukapheresis instrumentation, immunoassays (multiplex and singleplex) and bioreactors.

not know about the treatment, might worry about patient eligibility, or may not trust the technology; patients might be resistant due to fears over unfamiliar side effects or may be put off when they experience difficulty with accessing the treatment.

Companies also need to work closely with payers and adopt a carefully considered pricing and reimbursement approach, including steps to alleviate concerns over the potential upfront negative effect from the high price of the product and robust data on the longer-term treatment efficacy. Consideration also should be given to providing financing to patients who need to cover at least some of the cost themselves.

A successfully marketed gene therapy will need a well-vetted plan with clear labeling for the intended sub-patient populations, as well as the entire episode of patient care, experts say.

EXECUTIVE VIEWPOINTS

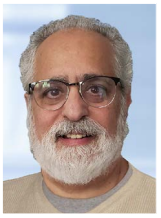
Seth Gordon
General Manager
EVERSANA ENGAGE

The Patient at the Heart

The patient should be at the heart of everything we do, regardless of the end audience. It is critical to create and understand a patient's journey and this is often skipped — big mistake. The patient journey allows us to truly understand the modes and mindsets patients go through, from diagnosis to treatment. The art of storytelling comes into play and is a powerful tool for education and awareness. The patient voice needs to be woven into messages, which allows us to avoid being too complex and foreign. We need to craft bite-sized messages that are approachable and empathetic.

Research is King

When we start with a human-centered design approach to solving the unmet need, we're able to better understand the needs and wants of the target audience and highlight any gaps that exist. We're also big believers in "workgroups," where we collaborate with each target audience and have an open dialogue around expectations, perceptions, and needs. We socialize and A/B test draft messaging and concepts to see how things are resonating. If it's not accessible and desirable at the end of the day, it's not something that will truly resonate with patients, providers, or caregivers/care partners.



Joel M. Schindler, Ph.D.
Senior VP
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Avoid Messaging Mistakes

While most physicians fancy themselves as being scientists, most are not, especially in the community setting. We shouldn't assume physicians fully grasp the science behind a high-science brand. We need to set realistic expectations for how much physicians really understand. Secondly, we shouldn't launch a brand without testing messages. High-science messaging is often too nuanced; that nuance must be market-tested, not just understood by the marketing team. Lastly, we can't forget to include an "ask" even with high-science brands. This allows us to be clear about exactly what action we expect physicians to take.

The Key Factors for Creating High-Science Brand Story

The biggest challenge when creating a brand story for high science brands is translating complex science into understandable messaging. Three key factors are content, simplicity, and relevance. When it comes to content, be VERY selective about what information is included. You can't and shouldn't include all the underlying science. Enagage the "KISS" model – keep it simple, stupid! Don't make the message more complicated than the science. And third, remember relevance — make sure the clinical relevance of the messaging is obvious and crystal clear.

Paulo Simas
Group President, Branding
W2O

Creating an Emotional Connection

The key factors to keep in mind when creating a brand story for high-science brands havn't changed much since last year, i.e. the most amazing innovations always risk failure when companies don't clearly articulate the benefit of these innovations for patients. To that end, we still see the most critical element of any brand story in the value the product or innovation creates for patients — not scientists. The key is creating an emotional connection between the science, the providers, and the individuals for whom they are caring.

Avoid Messaging Mistakes

The use of real-world data (RWD) by different stakeholders in the healthcare ecosystem is a big trend and it's only going to be more pervasive. From healthcare providers using RWD to improve outcomes, especially in oncology, delivering the right therapies to the right patients to life-science companies using RWD to generate evidence for regulatory submissions, expediting approvals or boost clinical trial recruitment. We are intimately involved in this space helping our digital health clients navigate the complexities of this category, ultimately trying to establish a unique and defendable position in this rapidly shifting category.