By Robin Robinson

Trend: Innovative Product Launches

No pharmaceutical product launch is easy, but marketers will face even more challenges as more innovative products make their way up through the pipeline and on to the market.

Increasing complexity in the market and pressure on managing costs already create many challenges when it comes to new drug launches. Add to that the intricacies of innovative and combination drugs and the speed at which they need to launch, and challenges multiply. However, this shifting environment also presents opportunities for companies that proactively adapt their launch planning and execution to align with the changing markets and innovative products.

According to a recent McKinsey report, today's environment requires a systematic approach: pharma companies must assess unmet needs in a disease area, develop deep customer insight as a basis for a truly differentiated positioning, land the products safely in the market, maximize launch uptake, and use early experiences in the market to fine-tune ongoing launch activities.

Since many of the innovative products coming to market in the next few years will have small patient populations, will treat rare or previously undefined subsets of broader diseases, and will be high cost, taking the time to condition the market before launch will be critical.

"Specifically, product teams need to spend time building awareness of the disease, familiarizing providers with the etiology and how the disease impacts patients, and educating HCPs on how the mechanism of the new drug addresses the unmet need and benefits patients," says Joe DePinto, president, Cardinal Health Specialty Solutions. "Failing to appropriately invest in market conditioning or waiting until close to launch to prepare the market are common missteps with innovative products, and they often result in delayed or insufficient market uptake."

Will Reese, chief innovation officer, Cognizant Life Sciences, says combination therapies, in particular, present unique challenges to education and support, and a proactive approach is critical to support improved outcomes. "A successful launch requires teams, partners, MSLs, reps, and support staff to be immersed in both the product as well as the potential therapeutic combinations," he says.

"There is a significant opportunity for companies with products used in combination to share information, especially educational resources and access to support programs," he says. "It is not a simple proposition, but from a patient perspective, they shouldn't have to be additionally burdened by the complexity of a combination therapy because of corporate reluctance to explore new ways of working together."

Another key component necessary to a successful launch is starting access planning early to streamline the reimbursement process. Product teams should recognize that, in most cases, payers will demand more than clinical trial data to justify the approval of high-cost innovative products. "As early as Phase III, teams should plan studies to collect health economics and outcomes research to demonstrate the real-world value that the product can deliver to patients," Mr. DePinto says.

Novel entities add complexity and challenges to positioning the product, which is forcing pharma to rethink the way it communicates its brand to healthcare providers.

ANKIT PATEL
MDcentRx

Innovative tools have the potential to turn the entire field of medicine on its head, especially for the prevention of future problems, extension of life, improvement of outcomes and/or reduction of costs.

JASON BOTTIGLIERI
Infraredx

He adds that to fully prepare for this trend, product teams need to take a comprehensive view of their go-to-market strategy and examine the patient journey and the market delivery and access strategies before launch to identify potential gaps. "With small populations, product teams need to make certain that they are capturing as much of the available market as possible and to ensure that no patients who could benefit from treatment are failing to access the product," Mr. DePinto says.

Marketers, drug developers, regulatory leaders, and organizations, as a whole, should understand how their innovative drug fits into the disease treatment paradigm. "Our job is to help patients live longer and have a better quality of life through the development of drug therapeutics," says Ken Keller, president, Daiichi Sankyo Administrative and Commercial, Daiichi Sankyo Inc., as well as president and CEO of Luitpold Pharmaceuticals. "As our understanding of disease and our tools expand, add-on therapies, the importance of precise sequencing of therapies, and triplet combinations will likely be commonplace."

Cost considerations are at the top of the list of challenges with the launch of any innovative therapy. "As triplet and quadruplet drug combinations are created that produce meaningful benefits for patients, our challenge is to innovate solutions to the impending cost dilemma," Mr. Keller says.

Marketers need to take advantage of the initial buzz and excitement about a new target, as well as having the voice of the key opinion leaders behind them.

DR. ALBERT AGRO
Sublimity Therapeutics

Anyone operating in the pharmaceutical industry today must have a working knowledge of diverse areas of drug development.

KEVIN FLYNN
precisioneffect

Marketers will want to employ an omnichannel brand strategy that optimizes every channel with the goal of creating a unified, integrated brand experience.

ANNEMARIE CRIVELLI
Cambridge BioMarketing

"We are now in the infancy of new payment schemes that are based on drug outcomes on a patient-by-patient basis," he says. "I believe this trend will continue, as our therapeutic tools expand. A practical way to apply different payment models for the same drug used in a different patient type or disease setting, where its value may range from incremental to game-changing, would be a good starting point for ideation."

Moving to the marketing environment, there are unique challenges in the rare disease space around communication channels. According to Annemarie Crivelli, director, digital services group at Cambridge BioMarketing, marketers will want to use omnichannel marketing solutions to identify and engage the rare disease patient. This means employing a brand strategy that optimizes every channel with the goal of creating a unified, integrated brand experience that synchronizes messaging and anticipates information and support that audiences require. "Omnichannel methodology employs best practices across marketing and predictive technologies, including machine learning and AI, to aggregate transactional data, health data, and qualitative data to assess and optimize messaging that drives positive changes in human behavior," Ms. Crivelli says. "This real-time approach not only emphasizes efficiency for clients, it is a fundamental force for improving human health in rare disease states."

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JOE DEPINTO
Cardinal Health Specialty Solutions

In the oncology space, the treatment landscape for many different types of cancers has changed dramatically in the last decade, driven by tremendous advancements in scientific understanding of cellular biology, cell signaling, immune response, and other tumor-specific factors.

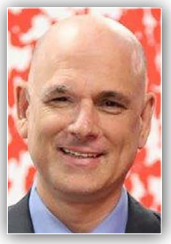
Equally important, the industry has begun to understand and demonstrate the clinical rationale and benefits associated with combinations of different mechanisms of action to improve upon the results that a single medicine may be able to demonstrate alone.

"Although combination therapies have demonstrated clinical benefits, they require us to think differently about our commercial model to successfully bring these innovations to the marketplace," says Jay Humphrey, VP, U.S. marketing, Takeda Oncology. "We are fortunate to live in a time of great therapeutic innovation; to meet the challenges ahead, companies must remain nimble, adaptable, and above all, focused on the patient."

For example, he says, consider the phenomenal pace of change over the past several years in treatments for multiple myeloma. Proteasome inhibitors and immunomodulatory agents have become the backbone within

Best Practices in Proving the Value Proposition of Innovative Therapies

Our experts provide tips on how to create solid value propositions for success in today's market.



ALBERT AGRO, PH.D.
CEO, Sublimity Therapeutics

The value proposition of an innovative therapy is centered around the new mechanism of action, the fact that it's first-in-class and therefore best-in-class.

Marketers are shaping the market, which becomes a bit of a challenge. The value propositions of innovative medicines have to be well understood from an efficacy and safety perspective, as well as from a particular patient population perspective as the drug is being developed, and those are the factors that the marketers will have to hang their hats on to drive value into that area.

JASON BOTTIGLIERI
President and CEO, Infraredx

When planning clinical trials, companies need to make sure to include economic endpoints.

Investing in health economics and outcomes research (HEOR) to show how the product links to reductions in healthcare-related costs associated with diagnosis, risk stratification and treatment — i.e., lower emergency room visits, fewer costly invasive procedures, reduced hospital stay time — is critical for a successful launch of any innovative device.

KEN KELLER
President, Daiichi Sankyo Administrative and Commercial, Daiichi Sankyo and President and CEO, Luitpold Pharmaceuticals

There is no substitute for a well-thought out, clinical trial program that is designed to accurately measure patient benefit and the resulting cost savings the new therapy could bring to society, such as reduced hospital stays, fewer surgeries or causing less severe side effects. Development programs that ignore societal costs do so at their own peril.

Demonstrating value to payers and population health managers is mandatory for an innovative drug to expect meaningful adoption. Clinical developers must be realistic and align their lenses, so they clearly understand how payers measure value. Then, we must tailor our trials to meet these expectations.

The magnitude of our scientific advances has created brand new treatment pathways, such as gene therapy and CAR-T therapy, which do not fit into any established economic model. It is paramount that drug developers prioritize the capturing of benefits and value, not only for those who directly benefit, but for all influencers who will benefit indirectly.

It is paramount for innovative pharmaceutical companies to construct organizations that work seamlessly across all functions, such as medical affairs, health economics and research outcomes (HEOR), and commercial.

MARTIN LOW
CEO, On Target Laboratories

The clinicians have to see the value of an innovative therapy and be able to articulate those attributes. They have to be willing to take a risk, not just with the patient but risk their own reputation and time and effort to try a new technology and to optimize it. Ultimately, that's what we're all here for: to benefit the patient.

WILL REESE
Chief Innovation Officer, Cognizant Life Sciences

Innovative therapies require a broader look at how value is defined within the healthcare system. The value proposition requires both a voice for the science and a voice for the patient experience delivered through outcomes. There is a significant opportunity to gather clinical and patient experience data through new partner models to better illuminate the value of therapy at launch and how it evolves over the long term as it becomes integrated into standards of care. Hope and social value are harder to quantify but are often at the heart of these therapies and provide the most significant investment returns for health systems.

triplet regimens. "We also have seen the importance of monoclonal antibody approaches, targeting CD38 or BCMA, and synergies with other mechanisms of action," Mr. Humphrey says. "We're now witnessing quadruplet regimens being investigated based on hypotheses that multiple mechanisms may suppress resistance mechanisms."

He notes that in today's environment there is a unique consideration for what "combinability" means in terms of the efficacy/toxicity profiles of the individual medicines and how they may work synergistically not just from an efficacy perspective, but also in how their toxicity profiles may be additive or not. And there is a new consideration of "financial toxicity," particularly when multiple branded medicines are combined together, which requires the industry and its partners to explore innovative pricing models with payers that appropriately reward innovation, but also balance the increased cost pressures that combination therapies introduce.

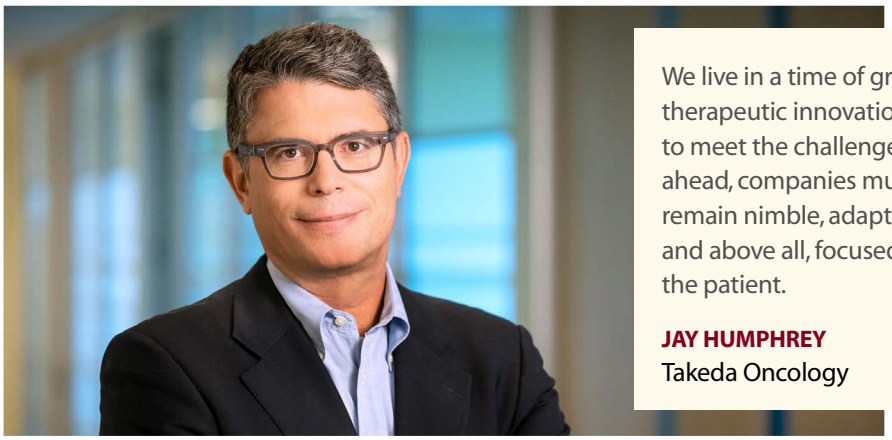
Importantly, optimization of combinations also requires companies such as Takeda to consider not just the medicines within its own portfolio but also the opportunity to collaborate with others.

"This means that as an industry we must rethink how we view competition," Mr. Humphrey says. "While it's important to focus on the attributes of a therapy to differentiate its value in the market, we must also recognize that today's competitors may be evaluated as tomorrow's combination partners. Therefore, it's critical to focus on the science and the use of the therapy across the treatment spectrum, wherever that may occur."

The Difference in Innovative Drug Launches

Innovative therapies offer a completely novel method, technology, or process that improves the diagnosis or treatment of a major global healthcare problem, such as cardiovascular disease, says Jason Bottiglieri, president and CEO, Infraredx.

"Innovation is not iteration," Mr. Bottiglieri says. "These innovative tools have the potential to turn the entire field of medicine



We live in a time of great therapeutic innovation; to meet the challenges ahead, companies must remain nimble, adaptable, and above all, focused on the patient.

JAY HUMPHREY
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There is an adoption curve that has to be accounted for when introducing new technologies in drugs.

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on its head, especially for the prevention of future problems, extension of life, improvement of outcomes and/or reduction of costs."

A difference between a traditional drug launch and an innovative product launch is that an innovative product needs to establish the benefit of the technology as well as the medicine. "Companies have to establish the benefit of the core technology," says Martin Low, CEO, On Target Laboratories. "There is an adoption curve that companies have to work with when they are introducing new technologies in drugs."

Mr. Low also states that the relationship with competitors is different with innovative products.

"When the product is based on a tried-and-true technology, it's all about one upping the competitor, but when a company is introducing a new technology, its competitors are also its partners in the sense of establishing the value of that technology," he says.

A greater understanding of the biology of disease, coupled with the availability of far more precise and effective scientific tools, is enabling more and more breakthrough innovative drugs to be launched. "These innovations provide greater benefits for more and more selective patient populations as the ability to precisely target and match a drug to a specific patient increases," Mr. Keller says.

The target for launches is no longer solely the physician. Marketers must take into account patients and their caregivers as well as payers.

"Physicians must routinely navigate a confluence of competing pressures when making treatment decisions, including but not limited to: formulary status, specific patient insurers, payer measurement benchmarks, and the fact that patients and their caregivers are accessing more information on their own," he says. "This places a higher priority on the development of launch strategies that activate patients and their caregivers."

These pressures also create the need to prioritize generating evidence of indisputable value of the given therapy for payers. "Pharma executives engineering a launch must effectively educate and create the adoption catalysts that link diagnostic advances to the new innovative drug," Mr. Keller says.

This is a pivotal moment in drug development as these novel entities have the potential to radically alter the course of disease progression. As a result, these novel entities bring forth unique factors and characteristics relative to traditional new drugs. "The era of 'one drug fits all' has transitioned into an era of targeted therapies and precision medicine," says Ankit Patel, director of product strategy, MDcentRx. "These drugs have dramatically shaken up the existing treatment paradigms."

For example, a targeted immunotherapy adds complexity to diagnosis and treatment selection based on the individuals' mutation status/protein levels. Another example of innovative medicine is that of gene therapy, which could now potentially cure a disease with a single use.

The uniqueness of these novel entities changes the patient journey for individuals suffering from hard-to-treat diseases. There is now an increased reliance on diagnostics than before, which is an additional step prior to treatment selection. These therapies also come

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KEN KELLER
Daiichi Sankyo / Luitpold

with unconventional treatment logistics, such as CAR-T, which isolates, engineers, and injects back a patient's cells to attack the disease.

Kevin Flynn, VP, director of medical services, precisioneffect, says when an innovative drug launches, the market needs to understand the technology and assimilate all the components of value rapidly. This requires marketers to connect the dots, see opportunities and synergies, and resolve obstacles, before launching into a hopefully receptive market. Innovation is a means, not an end, he says, and for patients, providers, and payers the bottom line is efficacy, safety, and value.

"The onus is on marketers to see big when launching an innovative brand into today's market," Mr. Flynn says. "We need to be connectors, and that means seeing the entire clinical and commercial landscape beyond the core technology."

Anyone operating in the pharmaceutical industry today must have a working knowledge of diverse areas of drug development. If you don't, you can't see market drivers or obstacles clearly. This can only happen if there is a merger of the minds: pharma executives and agency partners thinking about the brand and its value from Phase I forward."

Necessary Elements of Innovative Launches

As in most campaigns, two important stakeholders need to be included when developing a launch for an innovative drug: the physicians and the patients. And of course, cost is also a factor.

"It is no longer enough to just highlight

Patients shouldn't have to be burdened by the complexity of a combination therapy because of corporate reluctance to explore new ways of working together.

WILL REESE
Cognizant Life Sciences

Companies should consider using social media and advocacy groups to get patients interested and to educate them about the product before it's even launched.

DENIS CORIN
Q BioMed

the traditional, clinical aspects of a drug alone to effectively launch a product," Mr. Patel says. "These novel entities add complexity and challenges to positioning the product, which is forcing pharma companies to rethink the way they position and communicate their brand to healthcare providers."

First, a physician's understanding of the disease needs to be enhanced by contextualizing the novel mechanism of actions for these entities. Then, the product should be positioned in such a way that is intuitive and clear how to embed it into a treatment paradigm. This will allow physicians to appreciate the significance of the novel pathway and consider relevant usage of these therapies, Mr. Patel says. This could be achieved by incorporating the new understanding of the disease into messaging strategies.

Second, given the unconventional treatment logistics for some novel entities, it is imperative to ensure that physicians and staff have a positive experience with their first use.

With an increased number of products garnering quicker approvals and entering the market, physicians may feel overwhelmed and maintain status quo for treatment selection. Brands have an opportunity to develop and socialize messages that convey the value of the novel pathway and its position within the patient journey. Lastly, Mr. Patel says, in order to build upon the launch of such products, care should be taken to coordinate the brand's messaging across channels. This entails messaging through media and personal promotion to be in lockstep with one another to capture a physician's attention.

Albert Agro, Ph.D., CEO of Sublimity Therapeutics, agrees that marketers should be very much in tune with prescribers.

"They have to maximize the information that they distribute around the key benefits of the molecule, be it an efficacy advantage or safety advantage, and utilize that data," he says. He suggests starting with the target product profile as a base case scenario and then the job gets easier once more real-world data is available. "Marketers need to take advantage of the initial buzz and excitement about a new target as well as have the voice of the key opinion leaders behind them," he says.

According to Q BioMed, a biomedical acceleration and development company, innovative drug campaigns should use social media and advocacy groups to garner interest in the new product.

"These days there's quite a reliance on social media, patient advocacy groups, and other advocacy groups that drive the demand and a lot of the information flow," says Denis Corin, CEO and chairman of Q BioMed. "Patients and their caregivers — and in our case, parents of very young children — will spend a lot of their time sourcing this information for themselves," he says. "The idea is to use social media and advocacy groups to learn about the product before it's even launched."

Specifically in rare disease, there is significant demand even before a drug is commercially available, because there's nothing available for those patients to look at as a therapeutic option. "From an innovative standpoint, demand is driven from patients and the advocacy groups, rather than from pharma companies pushing information out to those groups." PV

TGaS Research: Innovative Drug Launches

TIM WOHLGEMUT
Senior VP, Strategic Initiatives, TGaS Advisors, a Division of Trinity Partners

The biopharma product launch game has changed, and those who play it well are reaping rewards (e.g., Kite and Juno). TGaS has studied how the most innovative companies structured launch preparation to drive value. We've seen that innovative therapies require equally innovative commercialization. According to our data, launch for innovative products has changed in three primary ways: when planning starts, the number of capabilities deployed, and the accessibility of those capabilities for precommercial companies.

When commercial launch planning starts: Data show that commercial considerations must be addressed earlier than ever before, particularly since many innovative therapies have been granted fast-track status. Thus decisions on which indications to pursue first and the right end-points for trials now require payer input and commercial support many years prior to the planned launch.

Number of capabilities deployed: The reduced emphasis on sales, combined with increased attention to market access, patient and Hub services, together with the evolution of medical affairs, means commercial executives must wear many hats to get the job done well. There have never been so many commercial factors to consider and choices to make before launch.

Accessibility of commercial infrastructure: The complexity of innovative launches requires partnerships with vendors and other companies to complete the commercialization infrastructure picture. The good news for pharma executives is that support for precommercial companies planning to commercialize innovative products themselves has never been more accessible than it is today.

Source: TGaS