REVERSING THE COMPLEXITY OF ONCOLOGY COMMERCIALIZATION

How to solve for launch challenges in a chaotic ecosystem

Anne Marie Robertson
Senior Vice President, Strategy & Marketing

Ellen Cappellino
Senior Vice President, Market & Patient Access

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As physicians, patients and caregivers tirelessly fight complex diseases, a growing number of drug manufacturers are gearing up to launch their new oncology therapy. These high-science therapies are entering the market at rapid rates: Presently, there are 500 active cell and gene therapy agents in clinical development, with a great momentum building for immuno-oncology treatments. By 2024, EvaluatePharma predicts that oncology therapeutics sales will hit $250 billion worldwide; and by 2030, the National Cancer Institute forecasts that the world will have 22.2 million cancer survivors.

There is no question about the incredible clinical impact these long-awaited therapies can have on patients and the industry in its entirety, but it also means that launching in the oncology space is not the same as it was 20 years ago; the traditional commercialization models simply do not account for today's complex landscape and crowded market.

Pharma manufacturers must now understand how to navigate influence points within the healthcare ecosystem and support their patients through the navigation of access, reimbursement and affordability barriers.

The Cost of Launch Is High, With Only a 34% Success Rate

While the oncology drug pipeline is rapidly growing, stringent competition and an evolving provider environment are putting intense pressure on manufacturers to build effective commercialization infrastructures and launch products at unprecedented speeds, which comes at a steep price. Prepping for launch and the first five years of commercialization costs $265M on average and can range anywhere from $150 to $450M, yet 66% of drugs do not meet launch expectations. Both experienced and first-time launchers have to invest significantly in preparing for launch, with first-time launchers incurring additional investments to build up the infrastructure.

This pre-launch stage in the product life cycle is pivotal for product success. Without the necessary financing and resources, emerging oncology drug manufacturers cannot take the risks needed to successfully commercialize. In addition, oncology drug manufacturers face higher compliance and competitive risk, a leaky patient funnel with unique needs, and industry trends that provide consistent pushback.

Oncology Drug Manufacturers Now Require a Launch Strategy Aligned to Product Archetype

Oncology drug commercialization is complex and chaotic, requiring new, innovative approaches to ensure the right patient receives the right therapy. Unlike traditional launch plans designed for blockbuster products, oncology drug commercialization requires agility, as the time from Proof of Concept to Phase 3 to Approval can be short depending on the disease state and stage of the target patient. Different tumors require different strategies. Patients with lung cancer, breast cancer or colon cancer, for example, can be found through screening and may have multiple lines of therapy over many years, including targeted therapies and chemotherapy. Their needs in terms of navigation, patient services and financial assistance are much different than patients with pancreatic cancer, who are frequently diagnosed at a late stage and have a short post-diagnosis lifespan and acute needs. Many hematologic diseases have become chronic, with multiple therapeutic options, while CAR-T innovation is providing curative therapy for some patients. Additionally, there are now multiple companion diagnostics and targeted therapies for patients with thoracic malignancies.

Additionally, the oncology market in the United States is becoming more controlled because more patients are accessing care in systems using treatment guidelines. For example, the NCCN publishes regularly updated Clinical Practice Guidelines in Oncology (NCCN Guidelines) that cover recommended management for 97% of patients with cancer. The guidelines are used by as many as 95% of oncologists in the U.S. in clinical practice and are relied on by public and private insurers to determine oncology coverage policies. Providing some economic data to guideline committees is required, and oncology innovators need to capture that data.

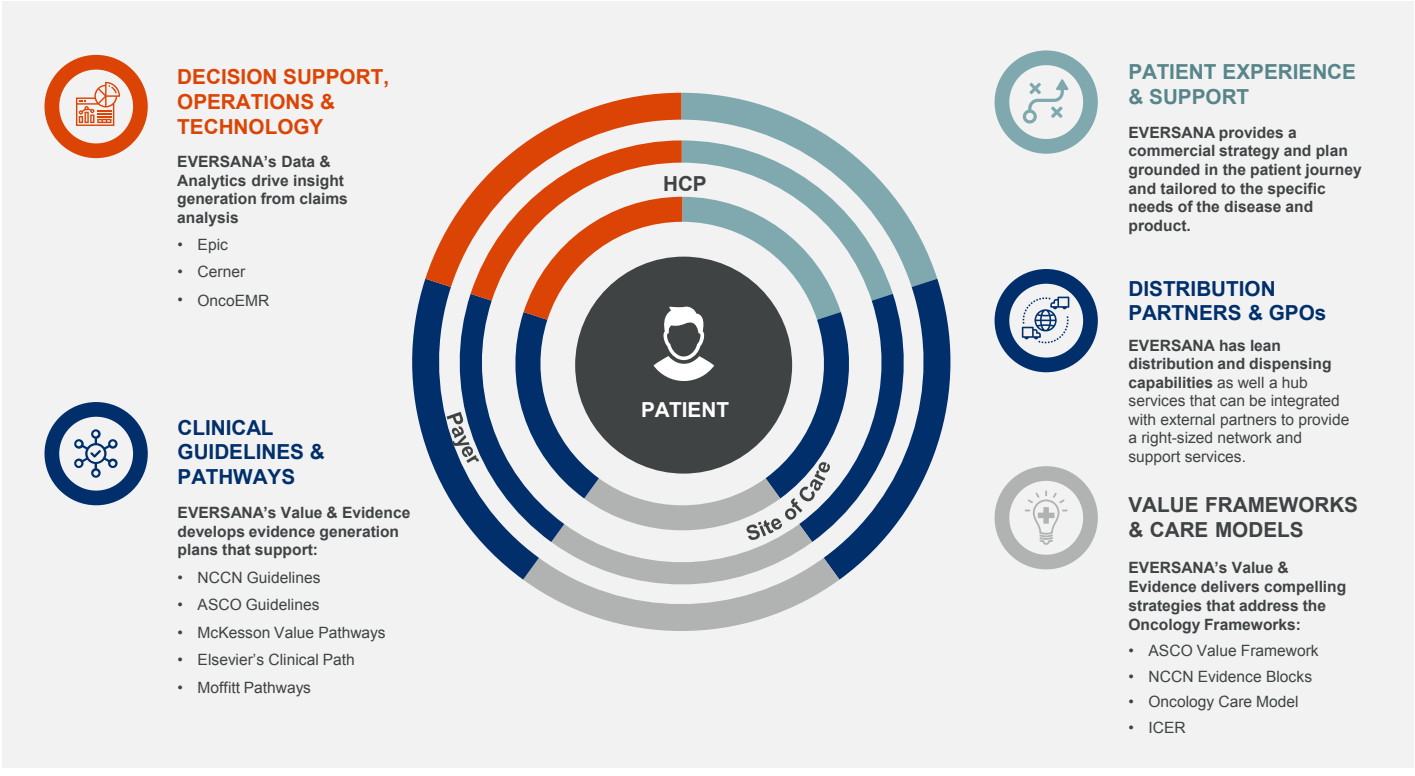
This means that oncology drug manufacturers need to understand and plan for the journey the patients will take in the disease areas of interest. Manufacturers should consider:

- Is a companion diagnostic part of the plan? Is it stand-alone or part of a screening panel?
- Is the innovative therapy first line?
- What is directly impacting the initial diagnosis and care plan? Or is it part of the relapsed and refractory journey, when the patients and their providers have a high understanding of the patient's care system and coverage or financial needs?
- Is the therapy going to be provided by a healthcare provider or self-administered?
- What level of support does the patient need beyond what is usual and customary at the site of care?

It's not enough to name a brand and make a launch campaign anymore. Manufacturers have to plan exactly how their product impacts the lives of the patient, the caregiver and the providers.

At EVERSANA, we develop commercial models that are specific to product and patient needs using our system of archetypes. As a part of this process, we consider whether the product is administered by a healthcare professional or taken by the patient at home with the help of a caregiver. We define the value story for products with our experts in access and evidence, and we leverage data and analytics to support appropriate omnichannel messaging. Most importantly, we imagine how the product impacts each patient's journey and how it improves their quality of life.

EVERSANA has the Experience and Capabilities Needed to Successfully Commercialize a Product Within the Complex Oncology Ecosystem



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Patient Onboarding Is Key to Commercialization Success

Work in oncology was already changing prior to COVID-19, and the pandemic accelerated those changes in the system. Most notably, patients and providers are now interested in and comfortable with telemedicine and remote follow-up visits to solve some of the issues caused by long commutes for patients. However, there's also been a shift in how physicians interact with field reps: They have higher expectations for their interactions and will grant access only when true value has been established.

Additionally, oncology practices want even more informational content from manufacturers, specifically information on product efficacy, economics and cost to patients. For example, practices welcome Field Reimbursement Managers (FRMs) to help them navigate affordability for their patient because FRMs are the key drivers in patient pre-authorization and billing and coding processes. They play a vital role in the prescription and adoption of specialty drugs by focusing solely on supporting provider offices. They work closely with the staff to overcome complex processes and procedures that can hinder speed to therapy for patients. Additionally, with their connectivity to the hub and specialty pharmacy, FRMs have the ability to learn about pre-authorization obstacles as they happen and can immediately close this loop while working closely with office staff to submit accurate pre-authorizations for patients.

Key Field Deployment Roles in Oncology Drug Commercialization

Field Reimbursement Managers – navigate affordability barriers at the site of care and pharmacy to ensure patient access and affordability

Medical Science Liaisons – translate key insights from the product's clinical trial to help HCPs effectively identify which patients would best benefit from therapy

Clinical Nurse Educators – illustrate how new therapies fit into the treatment paradigm and discuss side effect management

National & Key Account Managers – deliver the product's value story to facilitate access with organized providers, group purchasing organizations, pathway organization and payers

A New and Proven Commercialization Model for Oncology Therapies

In the past, manufacturers preparing for launch had only three options: sell their product to a big-box pharmaceutical company, license or co-promote their product to a company with an established infrastructure, or launch internally with their own team.

While these three options are traditional, common pathways to commercialize, they cause manufacturers to lose ownership in an investment that takes years – sometimes decades – to develop. Oncology drug manufacturers should not be forced to turn over the significant value of their asset to a larger company that will ultimately take on the commercialization; nor should they have to invest more than $200MM over three years to commercialize on their own.

Today's unpredictable landscape, coupled with inevitable industry pressures, is forcing manufacturers to seek a more complete commercialization approach with less risk and more value. EVERSANA's end-to-end, integrated model, EVERSANA™ COMPLETE Commercialization, is uniquely designed to address challenges in the oncology drug pipeline with agility and data-driven solutions. With an infrastructure based on product and patient needs, EVERSANA COMPLETE provides manufacturers the flexibility and expertise to customize their strategies and build functional service areas for a successful launch.

Today's oncology drug manufacturers need to leverage three key elements:

1. A deep bench of industry experts with proven oncology experience
2. An agile, fit-to-scale model that addresses the unique needs of each product
3. All commercial services under one roof

Not only does EVERSANA offer a fit-to-scale approach for partners, but our end-to-end commercialization platform is also backed by a deep bench of industry experts in every facet of oncology and pharmaceutical commercialization, such as field solutions, patient services and hub and market access. Even an established pharmaceutical company launching a product may have limited visibility into channel, patient services and their agencies because they're still outsourcing all of those services. With one accountable commercialization partner to make decisions with, manufacturers can enable connectivity between services to manage costs, lower compliance and competitive risks, and increase speed to launch in today's complex market and, ultimately, provide timely patient access.

Case Study: Launching a New Therapy for HER2-Positive Metastatic Breast Cancer

Launching an oncology product is extremely complex and difficult, no matter how large or experienced a company may be. When MacroGenics partnered with EVERSANA, they had less than five months to launch their first product in the midst of the global pandemic. To meet their timeline and streamline launch, MacroGenics needed a commercialization partner with an end-to-end platform that would allow them to build their capabilities expeditiously and strategically.

MacroGenics' treatment was for patients who had been on at least two prior lines of therapy. By the time they launched the product, three other new products had just launched into the same market, creating additional competitive pressures.

PARTNER PERSPECTIVE

Small, emerging pharma companies need to protect their cash flow. Our relationship with EVERSANA allowed MacroGenics to continue investing in our pipeline while also launching our new therapy.

Strong leadership is critical to commercialization success. If we had tried to do this on our own, it would have doubled the amount of time that it look to launch.

-Paul Norris, *Vice President Commercial Strategy and Planning at MacroGenics*

Without any infrastructure of its own, MacroGenics partnered with EVERSANA to immediately begin launch execution rather than spending 10 months trying to build infrastructure and relationships with commercial services providers on their own.

MacroGenics received FDA approval in December 2020, and this partnership allowed the product to reach the market by March with field teams deployed in early April. EVERSANA's team worked hand in hand with MacroGenics from the inception of launch to align on key strategic ideas and ensured they matched the product's urgent need for speed amid COVID-19 circumstances.

By deploying an innovative provider engagement model built on access and science, which was driven by data-based insights, the launch strategy was able to focus on these key differentiators:

- **Access-focused Strategy:** Key account directors increased awareness in the provider space to secure product access.
- **MSL Deployment:** A medical team built and fostered strong relationships with key external experts.
- **Non-personal Promotion:** Extensive digital marketing strategies provided a 360-degree surround-sound alignment of in-person promotion.

With EVERSANA's disruptive, non-traditional commercialization model, MacroGenics was able to focus their launch on science, access and meeting patient and provider needs while continuing to fund their pipeline. Additionally, MacroGenics had the benefits of minimizing risk and exposure while reducing their upfront cash investments – a critical need for small and emerging pharma launching in the oncology space.

The Only Proven Complete Commercialization Expert in the Industry

EVERSANA has been implementing our complete, full-scale, customized model for product commercialization into client strategy for the past two years – proving that EVERSANA COMPLETE provides manufacturers across therapeutic areas full access to launch strategy, execution and partnered outsourced services through a patient-centric and value-based model.

We understand the deep financial risk that manufacturers take when commercializing, which is why we've invested over half a billion dollars (and counting) – so manufacturers and investors don't need to. In partnering with EVERSANA, manufacturers and investors alike:

- Maintain full ownership of their assets.
- Capture full revenue potential through maturity.
- Optimize their launch performance.

Our model is enabling a critical factor that no company has ever dared to achieve: organic connectivity and synergy throughout all stages of commercialization. Guided by one dedicated commercialization leader and supported by a deep bench of industry experts, oncology drug manufacturers can partner with EVERSANA to maximize streamlined communications and operational efficiencies. Employing a single team with one shared goal can enable manufacturers to overcome external pressures, mitigate risk, successfully bring their product to market and provide long-term value for all stakeholders.

[1] JAMA Netw Open. 2020 Mar; 3(3): e200841