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ACCELERATED APPROVAL PATHWAYS:

Manufacturers Left to Grapple With Risk Versus Reward

Oncology and hematology are extremely complex, crowded and chaotic therapeutic areas. Presently, there are 500 active cell and gene therapy agents in clinical development, with 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.

With **30%** of drug approvals by the FDA occurring in the oncology and hematology space, there is considerable focus by biotechnology manufacturers to fulfill the unmet need of cancer therapies that can extend throughout the span of the patient's life.

This unmet need in the disease area, coupled with the pace of the biotechnology industry, causes these high-science brands to face unprecedented pressure to accelerate their speed to market to make a positive clinical impact on patients and the industry. As a result, more teams want to participate in the accelerated approval process. Accelerated approvals allow the FDA to fast-track drug approvals in disease states where patients have little to no quality treatment options. Early access to therapy for a serious or life-threatening condition can directly correlate to creating better patient outcomes.

To complete their application, manufacturers must then conduct confirmatory, post-approval trials. With the patient's best interest top-of-mind, manufacturers must wager the risk of proceeding. The FDA is becoming more stringent, particularly on confirmatory trials, leading to an increased likelihood of product withdrawals due to negative data.

For example, after confirmatory trials did not meet overall survival endpoints, respective drug manufacturers voluntarily withdrew the indication to treat metastatic small cell lung cancer (SCLC) for Opdivo® (nivolumab) in December 2020 and Keytruda® (pembrolizumab) in March 2021.[1] Based on early phase 1 and 2 data, the FDA granted accelerated approval for Opdivo® in August 2018 and Keytruda® in June 2019 for metastatic SCLC with progression after platinum-based chemotherapy and at least one prior line of therapy.[1] Alternatively, an FDA Oncologic Drugs Advisory Committee (ODAC) voted 7 to 2 in favor of the continued approval of atezolizumab in combination with nab-paclitaxel (Abraxane) for the treatment of patients with advanced or metastatic triple-negative breast cancer (TNBC) with tumors positive for PD-L1 expression.[2] For atezolizumab's indication in urothelial cancer, the committee voted 10 to 1 to maintain its approval of atezolizumab for first-line treatment of patients with urothelial carcinoma who are not eligible for cisplatin.[2]

Accelerated pathway approvals are a monumental achievement for brands and patients, but a product withdrawal immediately places years of research and labor, cash flow and headcount in jeopardy. Large pharma companies with greater resources may be able to recalculate as necessary to relaunch their therapy; however, emerging and small manufacturers may have more difficulty redesigning clinical plans and completing additional trials.

Accelerated pathways also pose a challenge for manufacturers that do not have a commercial infrastructure in place to bring a product to market. Manufacturers are tasked to build effective commercial

systems but may need to put them on pause in case of delays. Manufacturers are launching products at record 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 expectations.

Launching in the oncology market is not the same as it was 20 years ago. Manufacturers leveraging traditional go-to-market playbooks in the oncology and hematology space struggle to identify and integrate adequate people, data and infrastructure because the strategies were designed for blockbuster products. Unlike launches for products that treat common ailments, oncology and hematology drug commercialization requires agility and an innovative commercialization model that is nimble and agile enough to respond to smaller patient populations in the indication, competition, changing patient journeys and evolving interactions with the FDA.

In addition, oncology and hematology drug commercialization requires strategies unique to tumor and product needs. Therapies for specific tumor types vastly differ in terms of strategy in pre-market education, patient volume, cost and financial assistance, market access shaping and patient services programs. For example, patients with lung cancer, breast cancer or colon cancer 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. There are now multiple companion diagnostics and targeted therapies for patients with thoracic malignancies.

Both large and small pharma companies that will work with the FDA this year will need to adjust their commercialization process to account for market conditions and the impact of confirmatory trials, further complicating product launches in this area and driving costs to commercialize. Experienced and first-time launchers will have to invest significantly in preparing for launch, with first-time launchers incurring additional investments to build up the infrastructure. Manufacturers launching in oncology for the first time should outsource commercialization to mitigate the risk and gain more value.

Even an established pharmaceutical company launching a product faces risk in today's environment. These brands experience limited visibility into their channel distribution, patient services and agencies because they're outsourcing to multiple vendors. One accountable commercialization partner, with all commercial services under one roof, enables 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.

EVERSANA's end-to-end, integrated model, **EVERSANA ONCOLOGY Commercialization™**, is uniquely designed to address challenges in the oncology drug pipeline with agility and data-driven solutions. With a deep bench of oncology experts and an infrastructure designed to cater to tumor type and therapy needs, EVERSANA ONCOLOGY Commercialization™ provides manufacturers the flexibility and expertise to customize their strategies and build functional service areas for a successful launch.

CITATIONS

[1] Berberabe, MPH, Anthony. "ODAC Panel Approves 4 of 6 Anti–PD-1/PD-L1 Drugs in Accelerated Approval Program." Vol. 10, issue 8, Targeted Oncology, MJH Life Sciences, 16 June 2021, https://www.targetedonc.com/view/odac-panel-approves-4-of-6-anti-pd-1-pd-l1-drugs-in-accelerated-approval-program.

[2] Optum. "Withdrawn approvals for cancer therapies: Why it's happening and how it impacts you." 2022.