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Keytruda's "Tru" Underdog Story: From Last on the Asset List to Merck's Top Selling Product

EXPERT

Keytruda is currently one of the most well-known immunotherapy drugs on the market.

Known generically as pembrolizumab, Keytruda generated $17.2B in revenue at the end of 2021. The drug is Merck & Co.'s top-selling product globally, designated to treat 16 types of advanced cancer. With numerous clinical trials, FDA approvals, and D2C television ads, the therapeutic has grown worldwide recognition from medical and consumer audiences.

Most biotechnology drug candidates have humble beginnings. Keytruda is no exception. The original PD1 antibody program that would eventually become a global phenomenon was once a major industry underdog. Considered to be one of Merck's lowest priority assets in 2009, the multinational pharmaceutical company shut down the program and placed it on the to-be-out-licensed list.

How did the PD1 antibody program transform from one of Merck's lowest-valued assets into its top-selling product? A combination of sheer luck and robust marketing strategies.

Background: Surviving Multiple Acquisitions and Industry Skepticism

Before landing in Merck's portfolio, Keytruda's origins can be traced back to the Dutch pharmaceutical company Organon. Born out of Organon's 20-person US division, the original PD1 program sought to yield agonists. The reverse results occurred, with the program delivering above-average antagonists. Scientists were left perplexed by what exactly to do with this data.

According to one of the program scientists, there was a high level of doubt in the immuno-oncology industry "because nothing in tumor immunology ever worked." Despite producing promising initial results, the program faced a significant uphill battle.

To complicate matters further, Schering Plough acquired Organon in 2007. The program continued despite being listed as "low if not dead last" on the list of Schering's assets. More favorable results were generated, propelling Schering to give the green light for submitting the IND (investigational new drug) application. The IND immediately stalled when Merck acquired Schering in 2009.

The PD1 program was valued as next to nothing and was soon set to be out-licensed.

Market Monitoring Reignites the Potential of Merck's PD1 Program

Exterior market changes drove Merck to reverse its PD1 decision fully, pulling the program back in at the very last second.

News from top competitor Bristol Myers Squibb (BMS) completely stopped Merck. BMS had recently acquired Meradex, adding an earlier stage PD1 molecule to their pipeline that produced positive results. Know known by the brand name Opdivo, the early-stage drug positioned BMS as the emerging market leader in 2010.

BMS submitted its IND application in 2006, positioning Merck as years behind after neglecting to finish its program application. However, as history shows, Merck was ultimately able to undercut BMS' success, immediately shifting strategies to effectively compete.

Paving Inroads in the Face of Adversity - Strategic Mindset Propells Long-Term Success

The IND application for Merck's PD1 program was immediately reignited in 2010 but was still a long time away from actual approval. Merck still needed a solid commercial strategy to compete.

Merck capitalized on what can be considered to be an industry loophole. After carefully considering potential patient groups to orient their studies toward, Merck ultimately decided to focus on refractory melanoma patients as their priority go-to-market end users. The patient group featured one key factor: sufferers did not respond to available treatments, demonstrating a glaring unmet need that needed to be filled in the industry.

Typically, new drug candidates would also need to feature a comparator arm to prove superiority against the current standard of care for the specific condition and the placebo group. The selection created a rapid inroad for Merck, enabling them to qualify for a fast, single-arm trial.

Subsequently, while networking at a global industry conference, Merck's head of non-clinical safety, Joseph DeGeorge, obtained insight into the FDA's soon-to-be-launched breakthrough designation (BTD). What is the program's focus? Accelerating the approval of drug candidates that treat patient groups with high unmet needs.

A year later, Merck officially received BTD status for Keytruda. Rather than immediately sharing the news, Merck kept quiet to prevent competitors from forming similar inroads. After years of setbacks, Keytruda was able to enter the market through strategic marketing and business decisions rapidly.

Rerouting Business Efforts When Speed Bumps Occur

Keytruda represents a true underdog story in the expansive pharmaceutical industry. From nearly dropping to receiving rapid FDA approval, Merck's efforts demonstrate the power of identifying strategic inroads within a market.

Keytruda's accomplishments demonstrate that the typical industry course of action should not always be taken. While standard practices have become commonplace for a reason, pharmaceutical developers should consider out-of-the-box avenues to enter the market. Beyond patient communities and new industry developments, these inroads can often be found within multiple market entry avenues.

Practical market analysis and strategic pivoting can ultimately deliver new opportunities for short- and long-term success.

- Content by the BDMT Global Team

If you are interested in potential partnerships and long-term relationships with the companies mentioned in this article or others in the U.S. and/or S. Korea, contact Suzy at sim@bdmtglobal.com.

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