Optimizing the Market Value of an Asset with Multiple Potential Indications

Background

Research and development (R&D) investment decisions may be the largest risk taken by drug developers. Their challenge is to identify the asset with the greatest potential to deliver high value in the real world at a reasonable cost of development. When a single asset has broad applicability, sponsors must perform a thorough evaluation of its scientific, regulatory, clinical, patient, and commercial elements to determine the best path forward, especially if they are positioning themselves for raising capital.

Objective

A sponsor with an early-phase dermatology asset that could have been developed for multiple indications engaged Premier Consulting to confirm which indication it should prioritize for initial development. Premier Consulting had previously analyzed the indications' respective regulatory pathways to determine the potential scope and scale of both programs. It was determined that the development program for one of the indications was likely to have more requirements and would be significantly larger and more complex than the other. The other development program, which had fewer regulatory requirements, was also known to have a larger patient population. The leadership of the company was planning to target the indication with fewer regulatory requirements but, before engaging institutional investors in order to raise capital, wanted to confirm the value of the two different development programs.

Strategy

Premier Consulting proposed a comprehensive assessment of the commercial opportunities and challenges within each of the proposed markets for the asset, to balance the regulatory assessments that had been previously completed and to confirm the proposed lead development program.



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Solution

Evaluate the patient journey

For both disease areas, we conducted a deep dive of the patient journey, identifying the unique unmet needs that could lead to disproportionate opportunities. The assessment showed that, although there were substantial unmet needs in the indication with a less rigorous development program, a plethora of over-thecounter (OTC) options and other barriers had historically limited the uptake of prescription products.

The patient journey analysis also highlighted the fact that patients had different aesthetic preferences for topical medicines that were based, in part, on their unique dermatologic conditions. This potentially complicated the formulation of a product that could be used for multiple indications and highlighted the importance of selecting the right indication.

Analyze the opportunities for market access

We also analyzed the then-current market access landscape and projected the future opportunities and requirements for reimbursement for both programs. This included evaluating current and future competition, confirming potential perspectives of competitive value and pricing, and identifying the future commercial risks for both programs. The assessment showed that the less rigorous development program would have significant challenges gaining access and reimbursement from payers.

The product would effectively need to compete with OTC options to gain any commercial uptake and traction. The lack of reimbursement not only lowered the overall value of the potential program but also deprioritized it from a lifecycle planning perspective, as the low prices that would be required to compete would cause the commercial efforts to become unprofitable.

Recommend a shift in product development strategy

Based on the patient journey and market access assessments, Premier recommended that the sponsor prioritize the indication with the more rigorous development program. The sponsor agreed with the recommendation, changed its formulation strategy, and updated its pitch deck to reflect the new insights. The sponsor was able to secure funding from an institutional investor and, armed with a clear regulatory and commercial strategy, is preparing to initiate its first-in-human clinical trials in early 2023.

Takeaway

Any product development strategy should be formulated with commercial outcomes in mind. To maximize product value and return on investment, it is critical to look beyond the clinical landscape and assess current and future commercial opportunities and threats, including pricing, reimbursement, market entry, and competitors. Indication prioritization assessments can help build clarity, certainty, and confidence, both internally and externally, especially when considered as part of a holistic evaluation of the development potential of an asset.

Project Description

To prioritize indications for an asset with a unique mechanism of action and two potential therapeutic

Therapeutic Area

Therapeutic

A repurposed topical drug adapted from a commercially approved product

Outcome

Based on Premier Consulting's indication prioritization assessments, the sponsor switched indications, secured funding, and began planning for first-in-human clinical trials.



