Prism Ideas

Case study

Development of a Strategic Medical Plan for a New Molecule

Background

Prism Ideas was approached by a mid-size pharmaceutical company (annual sales >$3bn) during the development of a new molecule. The new molecule was to be a follow-on product to an existing marketed therapy that was nearing patent expiry. The new molecule had been rationally designed to cause fewer side effects than the marketed product. However, the development of the new molecule posed several challenges to the company, both in terms of existing market dynamics within the competitive landscape and as a result of the properties of the new molecule. First, the market size for the indication of the old drug was very small. The opportunity for the new molecule was further limited by the pending patent expiry of the old drug, which opened the way for generic competition. In addition, most patients would be adequately treated with either the old drug or a generic competitor. Unattractive market dynamics were compounded by the fact that the new molecule had not shown efficacy in any animal models although it had been shown to be active in healthy volunteers when administered once daily.

Challenge

...the team at Prism Ideas was asked to use its experience in drug development and commercialisation to design an appropriate clinical development programme.

The client company needed to develop the molecule in-house in a specialist indication following proof of concept (PoC) studies to support the product launch. Subsequently, it needed to demonstrate PoC in a larger indication to provide opportunities for out-licensing. As the client company had previously worked with Prism Ideas in other therapeutic areas, the Prism team was asked to use its experience in drug development and commercialisation to design an appropriate clinical development programme.

Solution

Prism Ideas undertook a three stage process:

Stage 1: Review potential indications

Stage 2: Establish summary development strategies for the top indications

Stage 2: Support the implementation of development studies

Prism Ideas undertook an extensive review of the scientific literature, including congress abstracts, to identify all possible therapeutic applications of the new product.

Stage 1

Prism Ideas undertook an extensive review of the scientific literature, including congress abstracts, to identify all possible therapeutic applications of the new product. The clinical potential for each indication was considered and prioritised by evaluating the market opportunity. The market factors considered included: competitive environment (including molecules in development), hurdles to market entry and size of opportunity. The prioritised list of indications was reviewed internally amongst the Prism Ideas team and, once finalised, with the client company.

Stage 2

Using the agreed prioritised list, Prism Ideas performed a more in-depth analysis of the regulatory and competitive environments for each proposed indication as well as obtaining formal feedback through opinion leader interviews. From this information, Prism Ideas designed summary development strategies for each indication including a summary PoC study outline.

Stage 3

Following further review with the client company, Prism Ideas implemented initial PoC studies in the two priority indications. Two elements of Prism Ideas' experience were central to the successful implementation of the PoC studies. First, Prism Ideas was able to work in partnership with both US and EU key opinion leaders to develop the study designs. Second, Prism Ideas' physicians provided medical oversight of the initial PoC studies; this supported the investigators and ensured optimal recruitment and allowed Prism Ideas to oversee the safety of the new molecule.

Conclusion

The continuity afforded by retaining Prism Ideas from initiation through to delivery allowed the client company to maximise its investment.

The client company used the integrated Prism Ideas approach from beginning the strategic discussions to the tactical implementation of the programme. The continuity afforded by retaining Prism Ideas from initiation through to delivery allowed the client company to maximise its investment. In addition, the probability of success has been improved by investing in studies with a higher probability of meeting the study endpoints and corporate goals. Furthermore, the client company has seen economic benefits by not wasting money on studies in therapeutic indications where a PoC may have proved positive but where other aspects of the molecule or the competitive environment would have made commercialisation impossible.