prmaconsulting®

pricing, reimbursement
& market access

Navigating access for a potentially curative gene therapy

CLIENT SITUATION

A biotech company specializing in delivering gene therapy was developing a novel, potentially curative treatment for hemophilia B.

CHALLENGE

The company needed a market access roadmap that would address likely HTA and reimbursement barriers in the EU5 countries for this rare disease and for a novel drug class.

PRMA CONSULTING SOLUTION

- Set out the challenges associated with introduction of a gene therapy generally, and for hemophilia specifically. This was based on an overview of how other gene therapies and hemophilia drugs had been handled in each market.
- Critically reviewed the company's clinical trial, planned evidence generation program, and target product profile against the key HTA, pricing, and reimbursement requirements in each country, in order to identify any evidence gaps.
- Developed a pragmatic, yet robust, market access roadmap setting out the key activities needed to minimize the risk in each country.
- The roadmap detailed the timelines and sequence of activities, with a description of the objectives, methodology specific to the situation and product, expected outputs, and interdependence and risks involved in each activity. It also included an approximate budget and financial forecast breakdown over the course to market.
- Recommended the organizational structure that should be put in place to coordinate EU and US market access for the product.

CLIENT VALUE

- The executive team now have a clear understanding of the priority and supporting activities required to minimize payer concerns and uncertainty as they prepare for launch, and the level of investment needed.
- A market access team has been set up and the company is implementing our recommendations as they await clinical trial results.

IF YOU WOULD LIKE TO DISCUSS THE MARKET ACCESS CHALLENGES FOR YOUR PRODUCT, PLEASE CONTACT US

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