FRESH prespective

Client Success Stories
European Pricing & Market Access

Specialty Pharma

Foster Rosenblatt

Business Situation

- Our client was considering launching their in-line therapy in the EU, and wished to conduct a market access landscape assessment relevant to various indications

Approach & Methodology

- F|R prepared and conducted qualitative TDIs with 10 European payers to test their receptivity to the product in the various indications, and in order to determine the appropriate coverage that their product would receive for the various indications
- Interviews covered a broad range of topics including disease state, burden, and current unmet needs
- Payers rated product attributes and key messaging for the product on relevant parameters such as credibility, relevance, and impact on market access

Deliverables & Business Outcomes

- Assessed the impact of several key attributes on payers' willingness to cover, as well as identified drivers & barriers to access
- Developed strategic recommendations with the goal of optimizing market access for the European launch of the products

Executive Summary
Product X Exclusivity – EU Payer Findings

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Overall, the post-ACS indication was well received by the European payers

Country	Interest	Expected Reimbursement	Expected Coverage	Price Comparator
	Very Low – Very High	*Marginal Benefits*	PA to Label, with Patient Restriction	XXXX, branded price before generic entry
	Very Low – Very High	*ASMR4 or ASMR5*	PA to Label, with Patient Restriction	XXXX, branded price before generic entry
	Very Low – Very High	*Restricted*	PA to Label, with Patient Restriction	XYZ
	Very Low – Very High	*Class A – Minor Benefits*	PA to Label, with Patient Restriction	XYZ
	Very Low – Very High	*At National Level*	PA to Label, with Patient Restriction	XXXX, branded price before generic entry

F|R Conclusions

- In general, payers were interested in the indications, but remained prudent in their evaluation
- Main key takeaway message about the clinical design are (1) the population of the enrolled patient should be representative of the European population, (2) composite endpoints should be avoided, (3) diabetic patients should be evaluated, (4) MACE data and CV Mortality are the most important endpoints
- Main key takeaway about the clinical comparator are (1) placebo with statins could be accepted given that there are no good TG-lowering agents on the European market, (2) fibrates could be used, although they are not efficacious, (3) Ezetimibe to be considered as this becomes more and more the add-on therapy to statin
- Product X is most likely to be reimbursed; however, it will be significantly restricted in most regions, due to the high amount of cost-effective medications available for this indication

Note that n-value are low, and data are only indicative, instead of being representative. Moreover, one limitation of this research stems from the fact that payers questioned were former members of their respective organization and while knowledgeable, the accuracy of their answer may be subject to variation

Product X Exclusivity in EU
Feedback on post-ACS Product Profile

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Payers considered the post-ACS indication as a strong indication, with a good trial design

Overall Impression of Product X and Trial Design

- Both Payers considered the post-ACS indication as moderately strong
- When evaluating a drug for reimbursement, efficacy is always the primary driver of the TC decision, followed by safety in the requested indication
- Comparator drugs ideally would be another TG-lowering agent, and it must be approved by the TC
- Both payers agreed that this improvement was modest, and they would be more convinced if shown significance data in CV death reduction

"Even if the improvement is minimal, this product shows enough efficacy to be accepted for reimbursement"– Payer #1

Trial Component	Comments
Trial Design	Overall good. In CV Prevention, trials need to be long term (> 5 years ideally) to confidently evaluate the product's impact
Patient Population	Should be similar to post-ACS patients in terms of age and comorbidities
Choice of Comparator	Preferentially another TG-lowering agent recommended by guidelines such as fibrates, vitamins, OM-3
Endpoints	Composite Endpoints are to be avoided
Additional Comments	If the indication is for ACS, Product X may be restricted to specialists. If it is directed towards the broader population, it may be prescribed by any HCP

Reimbursement Level

ASMR-4, with 65% coverage from social security

- Based on efficacy, Product X is most likely to receive and ASMR-4, but it could also receive an ASMR-5, as there are no CV death or mortality data that are shown
  - With a 4% ARR, Product X most likely will obtain ASMR-4
  - With a 15% ARR, Product X may obtain ASMR-3.
  - Mortality and CV death data are important to obtain a preferential ASMR rating

"Without cardiovascular death or mortality benefits, you will receive an ASMR4 or ASMR5 rating" – Payer #2