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PART OF FISHAWACK HEALTH

Determination of the acceptability of specific endpoints in adjuvant treatment of EGFRm non-small cell lung cancer

SUMMARY

The client wished to evaluate the nature of likely payer challenges and evidence requirements for a treatment in different lines of therapy, including the adjuvant treatment of EGFR-mutated (EGFRm) non-small cell lung cancer (NSCLC).

CLIENT SITUATION

The objective of the project was to inform the design of any potential trials so that key vulnerabilities in evidence could be addressed and the feasibility of launch success assessed.

OUR APPROACH

A situation analysis was conducted to understand the market access landscape in NSCLC.

We analyzed the heath technology assessment (HTA) outcomes of both the newly launched, first treatment for adjuvant EGFRm NSCLC, and of analogs positioned in the adjuvant treatment of different diseases, to understand how payers' approaches to uncertainty of evidence were changing as the number of adjuvant therapies increased.

A detailed gap analysis identified areas in which payers were likely to challenge HTA submissions, such as selection of appropriate comparators, stratification of patients, and endpoints.

Key vulnerabilities

Focus was brought to critically important areas of potential challenge. In the adjuvant setting, data about overall survival as an endpoint is highly uncertain at a stage when the patient will undergo resection, which is intended to drive a curative outcome.

An evidence generation strategy was developed to enable alignment of global cross functional stakeholders around priorities and mitigation plans for the assets in adjuvant EGFRm NSCLC.

A workshop enabled teams to define the pros and cons of clinical trial design, e.g., appropriateness of endpoints used in other adjuvant settings: (invasive) disease-free survival, event-free survival, and recurrence, and of ctDNA.

CLIENT VALUE

Global cross-functional stakeholders and affiliates were able to access the PRMA Healthcheck® digital application to inform their discussions about the feasibility of potential comparators, endpoints, patient-reported outcomes and levels of evidence required for each of four potential indications.

Key risks relating to the evidence of incremental benefit in each stage of disease were identified. The risks and challenges in different lines of therapy, including the adjuvant setting, informed a second workstream about the pricing and optimal launch sequence by indication of the client's asset.

A comprehensive evidence generation strategy helped coordination and alignment of mitigation plans to optimize market access.

The workshop facilitated by PRMA Consulting helped cross-functional teams to debate which endpoints would be most relevant in the adjuvant setting, considering that adjuvant treatment was not well established in this disease area, and to understand the impact on the commercial value of the asset if launched in the adjuvant setting after it was established in a later disease stage.