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PART OF FISHAWACK HEALTH

Forecasting global value assessments for a rare-disease drug

SUMMARY

This case study describes how an emerging biotechnology company developed a robust multi-national pricing and commercialization strategy for a drug to treat an ultra-rare neurodegenerative disorder.

Pre-launch pricing, market access, and value proposition strategy were some of the services provided to this emerging biotech when they partnered with the policy, access, value, and evidence experts from Avalere, Policy Analysis Inc., and PRMA Consulting - all part of Fishawack Health.

Anticipating global payer value assessment to strengthen pricing and commercialization strategy

The client sought to determine how payers in priority markets would assess their product's value given clinical trial data (e.g., endpoints and patient groups), product characteristics, and market dynamics in each country of interest (i.e., US, EU, UK, Canada, Australia, and Japan).

The expert team from Avalere, Policy Analysis Inc., and PRMA Consulting were engaged to strengthen the client's pricing and commercialization strategy by:

1. Implementing a structured review of published literature on the indication.
2. Analyzing the coverage and reimbursement landscape for each of the client's target markets.
3. Convening advisory board meetings for US and global payers.

CHALLENGE

Anticipating global payer perception and reimbursement

The emerging biotech faced difficult questions about how payers would react to the product, given the endpoints and patients included in the clinical trials.

The ultra-rare target indication posed significant challenges in anticipating payer perceptions and reimbursement:

- a largely uncharacterized indication typically identified via differential diagnosis
- lacking a diagnosis code
- having an unknown prevalence
- affecting a heterogeneous patient population.

The client sought expertise in value engagement to anticipate payers' value assessments of the product.

They wanted to mitigate any risks to adequate reimbursement, forecast consequences for revenue, and synthesize business intelligence takeaways for future clinical trial design and pre-launch planning.

SOLUTION

A three-stage partnership involving a literature review, landscape analysis, and advisory boards

1. Implementing a structured review of published literature on the indication

A structured literature review of academic articles and health technology assessments (HTAs) on the indication was conducted. Our experts assessed the epidemiology, disease burden, standard of care, clinical guidelines and recommendations, unmet needs, and health economic indicators such as quality-adjusted life-years.

We also reviewed the emerging biotech's clinical trial protocols and data to identify gaps in evidence generation.

2. Conducting a coverage and reimbursement landscape analysis for each of the client's target markets

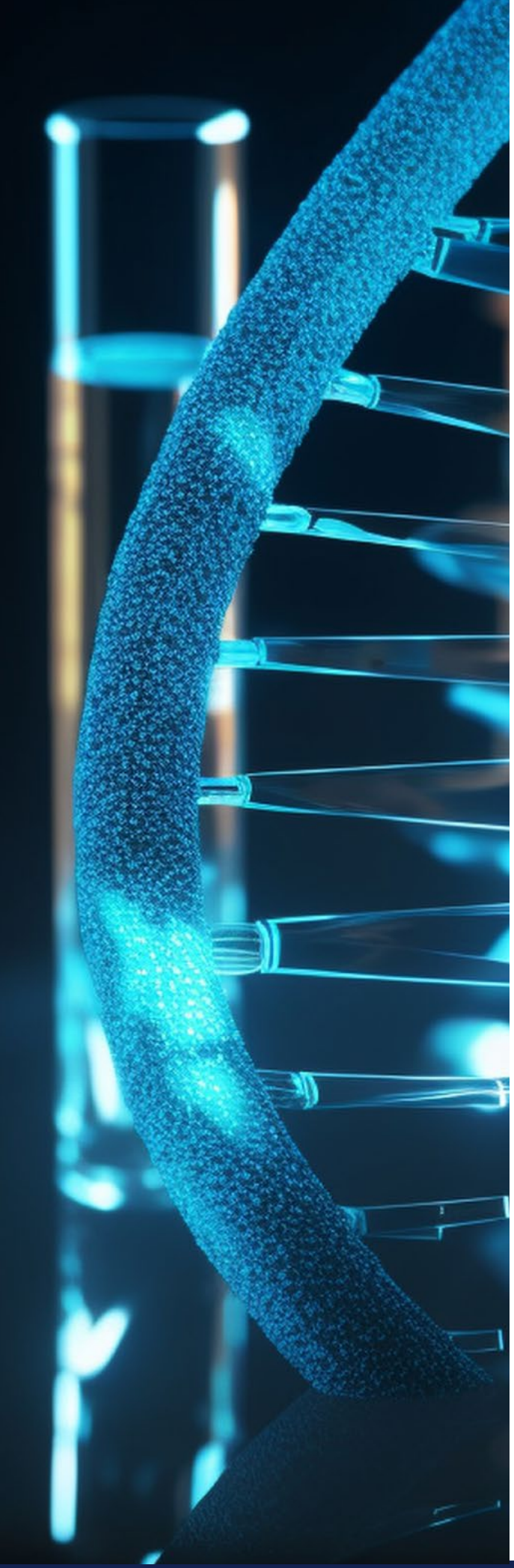
Our experts assessed the coverage and reimbursement landscape for a set of analogue products in US and international markets. For each analogue, we analyzed how clinical development programs translated into product labels and payer reimbursements.

3. Convening advisory board meetings for US and global payers

Using this information, we convened two advisory boards, one on the US market and one on international markets.

The advisory boards included physicians, payers, pharmacy benefit managers, patient advocates, HTA experts, and other stakeholders.

They assessed the target product profile; provided guidance on pricing, reimbursement, and access strategy; evaluated coding barriers and opportunities; and identified clinical and real-world evidence programs that could be incorporated into the commercialization strategy for each market.



OUTCOME

A robust multi-national pricing and commercialization strategy

From the insights and recommendation gain from our partnership, the emerging biotech has been able to:

- anticipate payer value assessments of their product across a range of complex international markets
- better articulate the value proposition for the product
- refine their pricing strategy in line with reimbursement and access challenges
- deepen their general understanding of how regulators, payers, and HTA bodies assess different clinical trial endpoints
- gain learnings for the future that will enable more refined clinical trial designs to maximize the value propositions and reimbursement potential for their products.

Get in touch to leverage our connected policy, access, value, and evidence solutions

Avalere has combined its healthcare consulting expertise with Policy Analysis Inc. (PAI) and PRMA Consulting, as a single capability within parent group, Fishawack Health. Our strong US and global connections bring truly integrated innovative data, technology-driven solutions, and experienced-based insights to today's most complex healthcare challenges.

Get in touch for a confidential conversation about how we can support you with your policy, access, value, and evidence strategies.