Regulatory Pathway & Market Potential in The US

Case Study

FutureBridge

Case Study : Regulatory Pathway & Market Potential in The US (1/2)

Client	A large biopharma company
Industry	Pharma
Products	Innovative Drugs/ New formulations

Context

- A large biopharma company was interested to understand the regulatory landscape & market opportunity for entry in the US with two of its proprietary products. These products are approved as ready to use injection in Europe and are manufactured in the US FDA approved plants

Business Objective

- The client is interested to build a robust business case for the market opportunity of its products in the US. The business case must contain validated assumptions, detailed intelligence on various pathways that should be considered, forecast model and available opportunity.

Engagement Scope

1 Regulatory Intelligence

- What is the regulatory pathway to register the target products with the US FDA?
- What should be the regulatory strategy and timelines involved in the process?
- How learnings from similar success stories in the past could be used to strategize market entry?
- What could be the targetable patient pool with given products in the US?
- What is the current market (value/volume) for other similar products in the US market?
- What could be the overall market potential for the modified target products in the US market?

2 Market Sizing

- What are the key market trends and drivers in the US?
- What are restrains and market entry barriers for target products?
- What is the current market size of the given products across the US (volumes and value)?
- What would be the potential market share of target products based on technical and clinical attributes of the product?
- What is the market potential for the target product with the given improved attributes?
- High level cost matrix for the targeted products in the US

3 Outcomes

- How to register the client's product which has no originator in the US?
- What should be the regulatory strategy and timelines involved in the process?
- What is the overall market potential of the client's product in the US market?
- How should the product be positioned, such as substitute, etc.?
- Is promotion be necessary to drive adoption of the product?
- Who might be potential partners for out-licensing the product in the US market?

Case Study : Regulatory Pathway & Market Potential in The US (2/2)

Research Methodology

Secondary Research

- Conducted desk research studying technology specific portals / blogs / journals / magazines, databases for company & products, expert opinions sites, conferences / seminars, Regulatory agencies, etc.
- Referred paid data sources such as market research reports, patent & scientific literature, etc.

Primary Research

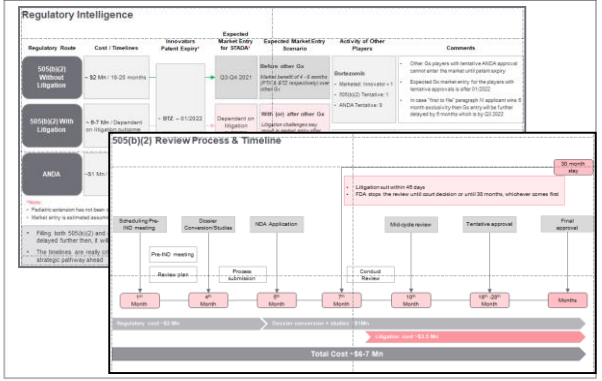
- Opinion & key insights from experts across value chain to validate findings

Benefits to Client

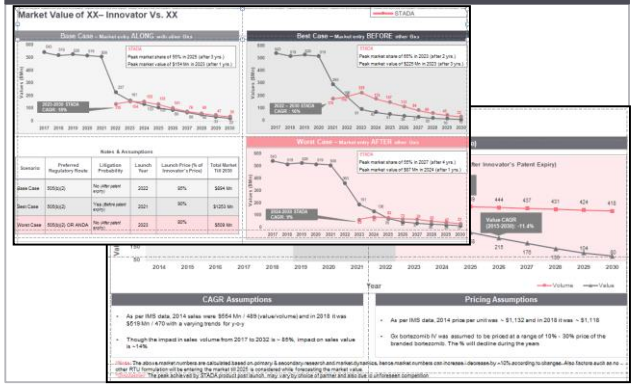
- Overview of regulatory strategy for product and associates costs, timelines
- Market size of Product in the US
- Product positioning in the US and promotion activity
- Shortlist of partners for out-licensing

Sample Analysis

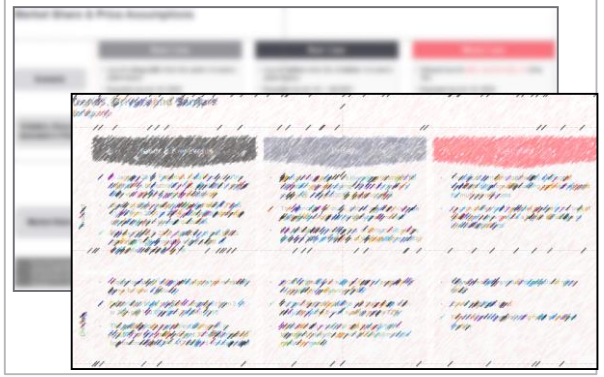
1 Regulatory Intelligence



2 Market Sizing



3 Outcomes



Thank you

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