



Kineticos Case Study

In-Licensing



Innovation
Branding
Solution
Marketing
Analysis
Ideas
Success
Management

Solution

Market access factors implications played a critical role in evaluating an in-licensing opportunity for a large pharmaceutical company

Situation:

A multinational pharmaceutical company with broad manufacturing capabilities was considering horizontally expanding their portfolio to include biosimilars. Kineticos was charged with providing a detailed analysis of the market opportunity for two unique biosimilar licensing opportunities, as well as any gaps with respect to resource requirements that such an expansion would necessitate.

Process:

The engagement was commenced by conducting secondary market research (disease/treatment overview, market success factors, competitive landscape, etc.) to provide the sponsor with insights about the market opportunity and barriers to entry for both US and EU markets. Next, Kineticos identified, recruited and conducted 35 primary research interviews with prescribers, payers and patient advocacy groups to better understand unmet need and market access risks/opportunities. Upon concluding the research, Kineticos

- Mapped the sponsor's commercial strengths and weaknesses with market need for each potential biosimilar opportunity
- Identified synergies and gaps related to the sponsors' sales force, therapeutic focus, medical affairs, reimbursement, marketing, etc.
- Provided revenue forecasts with three scenarios – low, high, and base-case

Outcome:

Upon concluding the primary and secondary research, it became apparent that one of the potential opportunities was much more aligned with the sponsor's strategy than the other. The deliverable equipped the management team with the necessary facts, data and insights to confidently make a determination on the pursuit of the licensing opportunity. Ultimately, the client decided to invest in an alternative opportunity that represented greater commercial potential and was more synergistic to their current product offering.

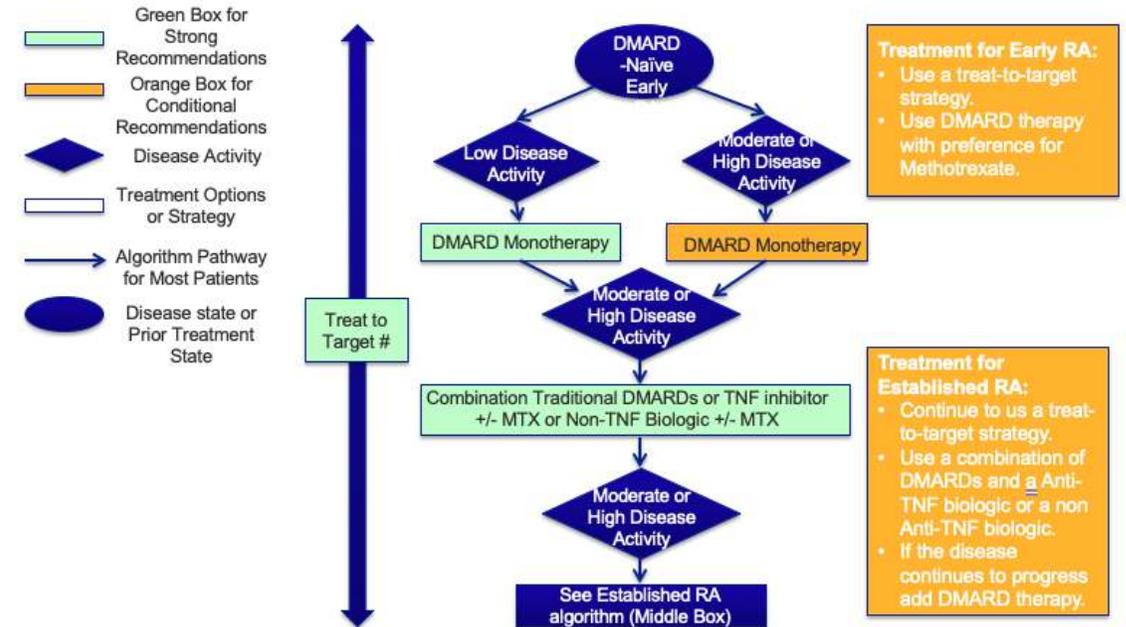
Kineticos conducted secondary and primary research from a clinical and commercial view to provide insights into global markets



Rheumatoid Arthritis Summary

| | |
|--|--|
| Disease Overview | <ul style="list-style-type: none"> Rheumatoid Arthritis (RA) is an autoimmune disease, in which the body's immune system attacks the joints known as the synovial membrane, or synovium, causing inflammation of the specific joints" (CDC, 2011; Costenbader et al., 2006). |
| Epidemiology | <ul style="list-style-type: none"> Rheumatoid Arthritis is categorized into three categories; mild, moderate, and severe. In 2016, there are 7.5M Global RA cases: 2.1M mild, 3.7M moderate, and 1.7M severe. By 2023, there will be a projected 8.5M international cases of RA. |
| Market Environment | <ul style="list-style-type: none"> The global RA market in 2015 was valued at \$17.89B at a 2.15% CAGR (US: \$11.6B at 1.94% CAGR; G5: \$3.25B at 1.95% CAGR) The drug market for RA consists of several classes of drugs or DMARDs (disease modifying antirheumatic drugs). These include Biologics including TNF and interleukin antagonists, biosimilars, JAK inhibitors, and other therapies such as methotrexate. Total sales of RA drugs in 2015 were \$17.4 billion globally. Methotrexate currently dominates the RA market in terms of treatment in patients with mild, moderate and severe cases. Introduction of two Remicade biosimilars will provide analog for potential Humira biosimilars |
| Estimated Humira Biosimilar Opportunity | <ul style="list-style-type: none"> 30% of RA patients fail to achieve clinical responses when treated with TNFα inhibitors (Rubbert-Roth and Finckh, 2009). Significant unmet need for drugs with more attractive safety profiles and more convenient ROA |

Rheumatoid Arthritis Current ACR Treatment Guidelines



Source: Singh, Jasvinder A. et al. "2016 American College Of Rheumatology Guideline For The Treatment Of Rheumatoid Arthritis". Arthritis Care & Research 68.1 (2016):1-25.

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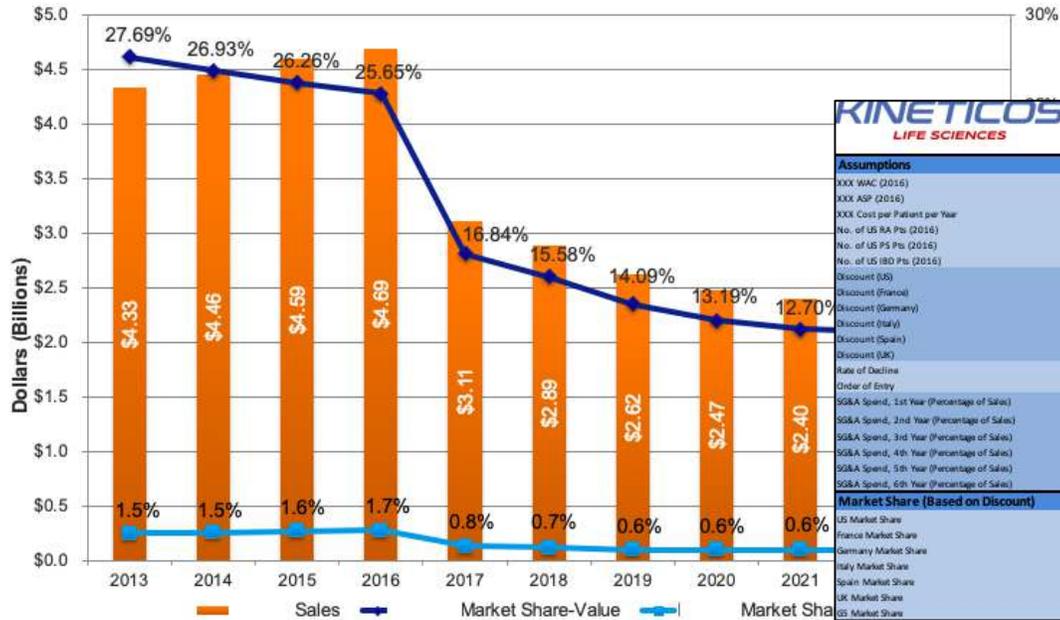
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Kineticos leveraged the research findings to create a 5-year projected forecast, which played a critical role in the go / no-go decision

Rheumatoid Arthritis REDACTED - US Sales



Note:
• REDACTED goes off patent in 2016

30 Source: Global Data- (RHEUMATOID ARTHRITIS) -Global Forecast 2013-2023

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Assumptions

| | |
|--|-------------|
| XXX WAC (2016) | \$1,918 |
| XXX ASP (2016) | \$849 |
| XXX Cost per Patient per Year | \$49,856.04 |
| No. of US RA Pts (2016) | 153,809 |
| No. of US PS Pts (2016) | 39,619 |
| No. of US IBD Pts (2016) | 39,932 |
| Discount (US) | 30% |
| Discount (France) | 25% |
| Discount (Germany) | 25% |
| Discount (Italy) | 35% |
| Discount (Spain) | 35% |
| Discount (UK) | 25% |
| Rate of Decline | 2% |
| Order of Entry | 2 |
| SG&A Spend, 1st Year (Percentage of Sales) | 45% |
| SG&A Spend, 2nd Year (Percentage of Sales) | 40% |
| SG&A Spend, 3rd Year (Percentage of Sales) | 30% |
| SG&A Spend, 4th Year (Percentage of Sales) | 25% |
| SG&A Spend, 5th Year (Percentage of Sales) | 25% |
| SG&A Spend, 6th Year (Percentage of Sales) | 25% |

Market Share (Based on Discount)

| | |
|----------------------|-----|
| US Market Share | 23% |
| France Market Share | 15% |
| Germany Market Share | 19% |
| Italy Market Share | 25% |
| Spain Market Share | 25% |
| UK Market Share | 25% |
| ES Market Share | 22% |

Indications

| | |
|----------------------|-----|
| Rheumatoid Arthritis | Yes |
| Psoriasis | Yes |
| IBD | Yes |

Note:

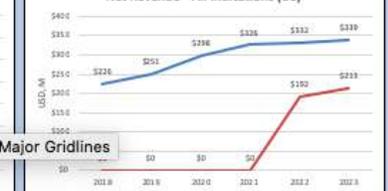
XXX sales: 1-92% CAGR

Total Net Revenue:

Net Revenue - All Indications (Global)

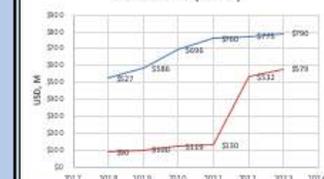


Net Revenue - All Indications (US)

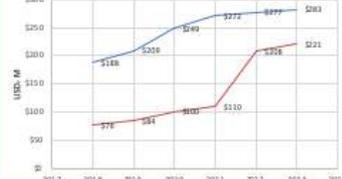


Individual Indications Net Revenue:

Rheumatoid Arthritis Net Revenue (Global)



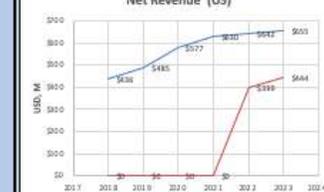
Psoriasis Net Revenue (Global)



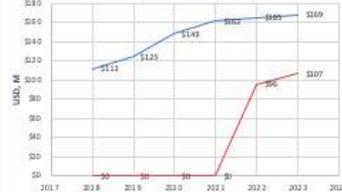
IBD Net Revenue (Global)



Rheumatoid Arthritis Net Revenue (US)



Psoriasis Net Revenue (US)



IBD Net Revenue (US)

