SUCCESS FACTORS IN LAUNCHING A RHEUMATOID ARTHRITIS ASSET

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Of the hundreds of disease states that fall under the immunology banner, the rheumatic diseases remain the largest category (Figure 1). The market is dominated by a number of billion-dollar brands, and researchers with Cowen and Company anticipate the rheumatology market to grow from $36 billion in 2012 to $52 billion by 2017. The rheumatoid arthritis (RA) category in particular is highly competitive, consisting of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, conventional disease-modifying antirheumatic drugs (DMARDs), targeted oral treatments, and biologic DMARDs, including five anti-TNFs, one interleukin-6 (IL-6) inhibitor, and two other monoclonal antibodies.

Crowded with expensive products, the RA market presents both opportunities and challenges. Manufacturers looking to launch a new product in the RA space, need to be acutely aware of the unique elements shaping the market. In this article, we will examine the distinctive characteristics of the RA market and offer success factors for launching a new biopharmaceutical product into this highly competitive space.

Support Adherence Programs

Patient support programs are a cost of entry for any new RA entrant. These programs are critical drivers of pharmaceutical adoption and patient adherence in the space. Patient adherence rates for RA are notoriously poor for several reasons, including access to the drug at the point of sale, abandonment due to affordability, side effects, and plan rejection. Based on data on file on four rheumatology drugs, Adheris (a company that offers direct-to-patient medication adherence programs) found that, on average, about 35% of new patients discontinue their drug therapy after 30 days from the initial (index) fill, and on average, about 85% of new rheumatology patients discontinue their therapy at 360 days after the index fill.

Manufacturers will need to think creatively about adherence, utilizing digital technology, specialty pharmacy programs, virtual

Figure 1

Immunology Market Growth 2011-2016 (US, EUCAN, JP)*

![Immunology Market Growth Chart](chart.png)

Source: IMS HEALTH Confidential and Proprietary; IMS Health Incorporated. IMS2Q11 MTA Worldwide growth projections from reports for major markets. Decision Resources, DataMonitor, and Evaluate Pharma projections. Campbell Alliance analysis.

Note: CAGRs were calculated over a five-year period from 2011 to 2016.

* Bubble sizes represent current (MAT 2Q 2011) global market sizes (all markets).

† Sales exclude antineoplastic agents that are used in the off-label treatment of SLE.
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Support communities, and other unique avenues to create a desire among patients to stay on their prescribed drug. It will also be necessary to leverage existing customer support centers and relationships with specialty pharmacies to implement programs to minimize patient barriers, such as insurance verification, co-pay assistance, and patient education.

Manufacturers need to develop easy-to-use patient support programs, accessible via a single site or toll-free number, to help keep the patient on the brand once a prescription is written. Manufacturers can also establish a case manager or a patient navigator role to become a patient’s single point of contact for access.

Clearly Differentiate the Brand

RA is the largest immunology market, and a crowded one at that, with numerous players already available and a well-stocked pipeline of new products on the way. For any new product entering the space, clear differentiation and simplified messages that resonate with stakeholders will be critical.

Appropriate evidence must be gathered at the clinical stage to differentiate a brand not only from other drugs in its class but other treatments for the indication in general. This has implications in everything from clinical attributes to the types of trials that are run. A major question in this regard is whether the brand should be tested against a comparator or a placebo.

Backed by an evidence package showing their success when compared against placebo, two recent new rheumatology market entrants attempted to face off against a pair of entrenched, dominant players. In these cases, the new entrants were unable to make a significant splash in the market when measured against the real-world safety and efficacy results of the market’s established brands. To turn the heads of physicians and payers, the brands may have been better off gambling on emerging victoriously in a head-to-head clinical showdown with their earlier-to-market rivals.

A head-to-head study may become the cost of entry in RA, due to recent FDA guidance on developing drugs for the treatment of RA. Due to the availability of effective RA therapies and the medical community’s focus on early control of disease activity, FDA believes that it is important to limit the exposure of patients to placebo or ineffective therapies for a prolonged period of time. As a result, the new FDA guidelines state that “studies longer than 12 weeks should include an active comparator as the control or provisions for escape to rescue treatment for patients with active disease.” (Guidance for Industry -- Rheumatoid Arthritis: Developing Drug Products for Treatment)

Early collaboration between clinical and commercial—as early as the end of phase I—will be important in navigating the implications of FDA’s new guidance.

Prepare for REMS

An important consideration for any new RA product is an FDA-required risk evaluation and mitigation strategy (REMS). Manufacturers will need to plan for the possibility of a primarily communications based REMS requirement, though not likely to the degree of REMS requirements that are seen in oncology or pain.

This planning will involve collaborating with Regulatory to evaluate and plan a response to the FDA in the event a REMS becomes necessary. It will then be necessary to be prepared to develop the REMS program itself based on the FDA requirements and to create a communication plan for a rapid resubmission to the FDA based on the formal response. The economics of the REMS program will need to be assessed, and field forces will need to be appropriately prepared to address questions or concerns. In the event of a REMS requirement, manufacturers will also need to ensure appropriate awareness of data in the general community and update speakers appropriately.

Train a Sales Force to be Competitive

A strong sales force able to address customer needs and to be competitive in a crowded market starts with selecting the right team based on the appropriate skills necessary to win, backed by an effective training plan. Manufacturers should leverage market research and customer insights to determine field team skill sets and resulting training needs. They should also establish a cross-functional team (e.g., Medical, Marketing, Market Access) to design the training curriculum.

Training sales reps in RA requires a three-pronged approach focused on skills, knowledge, and behaviors. Further, sales training should not be one dimensional. Sales personnel should not only be thinking about sales, and account managers should not only be thinking about payers. Incentives and rules are unique for different functions. Nonetheless, account management, reimbursement training, sales training, and medical training all need to be tied together to create an all-encompassing approach to selling not only the product but also its associated support services.

Instead of having each team come up with its own training plan, the teams should be brought together to create a training map detailing who needs to be trained for what, based on their needs. Then all the teams will be trained in a similar manner, but at different levels. A medical science liaison (MSL) may get a 100-level managed markets course, for example, whereas the account manager will get a 400-level course. But
everyone is trained on the same issues so that they can at least understand and empathize with the customer and possess the right skill sets to help. This is important because RA is already crowded and served by a number of manufacturers. New entrants cannot afford to allow an opportunity to pass and must be prepared to address potential issues, even if not in their direct line of responsibility.

Customer-facing team members also need to be trained to recognize the complexities of the rheumatology practice. Every practice will have its own policies regarding interactions with pharmaceutical sales representatives. Successful reps are the ones who respect practice policies and develop good relationships with the physician and the staff members.

In conducting primary market research with 12 rheumatology practice stakeholders, Campbell Alliance found that rheumatology practices expressed interest in receiving new information and materials prior to launch. The research also found that rheumatology practices recommend that reps schedule appointments and increase the frequency of their calls at launch.

**Shape the Market**

Companies entering the RA market with an asset in a new drug class or with a new mechanism of action will tap physician advocates to help shape the market for the brand ahead of the launch. Shaping market perceptions can be achieved via multiple channels.

Given the crowded RA market, brand teams should not only focus on identifying existing key opinion leaders (KOLs), they should also identify and cultivate future KOLs. A peer-to-peer nomination approach should be applied when identifying KOLs. Panelists should be asked to identify areas of interest, and capabilities (e.g., presentation skills) should be included to identify key KOLs for different commercial and clinical activities. The medical and commercial team should also develop a congress plan during phase 2 trials. Congresses should be prioritized, and MSLs should be trained to develop relationships with national and regional KOLs. A strategy to capitalize on KOL engagement during regional congresses will need to be defined.

A publication strategy is also necessary. Beyond the pivotal trials, the publication strategy could include a focus on clinical unmet needs, patient perspectives, health economics, and mechanism of action.

As the market evolves, brand advocacy is no longer just the domain of the physician. Given the cost and the severity of the disease, RA patients are much more engaged in their treatment. As a result, engaging with patient advocacy groups is just as important as engaging with physician advocates--maybe even more so.

Outside of formal patient advocacy organizations like the Arthritis Foundation, several patient advocates or bloggers have become very influential in educating patients about their treatment options. Social media platforms like Twitter® or Facebook® will also continue to increase patient participation in medical care through the development of

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**Critical Success Factors for an RA Launch**

- Generate head-to-head clinical evidence to clearly differentiate the brand from competition
- Plan for a REMS if the regulatory team identifies the slightest chance that the FDA will require one; lack of planning may delay launch
- Establish the company as a viable scientific and commercial leader/option within the RA community (e.g., American College of Rheumatology, Arthritis Foundation)
- Identify, develop, and engage advocates among existing RA KOLs; identify and cultivate rising-star/future KOLs
- Clearly identify the appropriate patient type for the brand and communicate its differentiated efficacy profile to rheumatologists
- Identify meaningful insights on patients to determine key elements that may activate a patient on the brand
- Minimize patient barriers by implementing patient support program supported by a hub and a single “navigator” to motivate patient adherence
- Demonstrate compelling value proposition to include unmet need, efficacy, safety, price, and cost-effectiveness, particularly with payers
- Establish well-defined rules of engagement between the company and launch stakeholders to ensure seamless execution
- Appropriately resource and staff launch team to prepare for launch
- Create an integrated approach to customer-facing team training curriculum--knowledge (e.g., clinical, reimbursement), skills (e.g., negotiation), and behaviors (e.g., ask for business)
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communities and interaction with healthcare providers.

These platforms will enhance the search for information and healthcare providers, while online communities empower patients and providers to interact at new levels. It is important for the market-shaping team to leverage these platforms to accelerate clinical research and to develop patient communities to activate the RA patient and seek advice to develop actionable and meaningful strategies.

Develop a Compelling Promotional Campaign

Different types of RA patients exist. Some patients are aware of treatments but choose treatments based on economics and product attributes. Other patients are knowledgeable and actively engage in treatment discussions, choosing the best option given their condition. These two groups can be activated via consumer campaigns. The majority of patients simply accept a prescribed treatment and can be targeted via physician-oriented campaigns.

Figure 2

Faster Uptake for Simponi

0 to 3% from Q2’08 to Q1’10 (7 quarters) for Cimzia
0 to 3.7% from Q2’09 to Q1’10 (3 quarters) for Simponi

Source: Campbell Alliance Insights, 2013
Direct-to-Consumer (DTC) advertising may not increase the total potential market opportunity but may accelerate the growth rate and enable a brand to reach higher market share faster. Cimzia, launched in 2008, did not utilize DTC advertising. Simponi, launched in 2009, focused heavily on DTC advertising. The resulting gains in market share are shown in Figure 2.

**Develop a Pricing Strategy**

The arrival of new oral therapies in the rheumatology space is adding to the competitive pressures. In November 2012, FDA approved Pfizer’s oral drug Xeljanz™. The Janus kinase (JAK) inhibitor is approved for the treatment of adults with moderately to severely active RA. Other oral drugs in the pipeline include AstraZeneca’s fostamatinib—the first oral spleen tyrosine kinase (SYK) inhibitor—and Lilly’s baricitinib—a JAK1 and JAK2 inhibitor. Both products are in phase III clinical development.

Competition in the rheumatology space could become even more intense in future years as biosimilars threaten to emerge (Figure 3). Payers, physicians, and patients are struggling with the rising cost of biologics used in therapeutic areas such as RA. While the clinical value of these products is well recognized, biologics have a significant budget impact. As a result, payers are continually looking for ways to manage costs without sacrificing quality, and biosimilars represent a promising solution.

Securing optimal access and reimbursement will be critical for physicians to adopt biosimilars, but the reimbursement question will come second in their minds to ensuring the biosimilar’s efficacy data is in line with that of the reference product. Patients, meanwhile, may be reluctant to switch to a generic product that does not offer the same quality of patient support—such as patient assistance programs for specialized products like Humira™ or Enbrel™. On the other hand, patients will value products with efficacy similar (or better than) that of their current treatment, with no added side effects. Most importantly, out-of-pocket payments for both non-insured and insured patients will likely be reduced if switching to a biosimilar-based treatment.

The launch of novel oral drugs and the entry of biosimilars due to patent expirations will likely reshape the RA market landscape. As a result, pricing strategy and a payer value proposition will be very important to a launch strategy.

For the treatment of inflammatory conditions, drugs in the anti-TNF class are expected to remain popular among physicians and patients because of their track record of efficacy and safety. The high cost of these drugs is a burden for payers, however.

According to Cowen and Company research, physicians identify increasing pushback from payers regarding this drug class, and physicians are spending considerable time and effort on prior authorizations. Payers are also increasingly using step therapy and differential tiering of the anti-TNF products to control costs, Cowen reports.

**Figure 3**

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The launch of novel oral DMARDs (e.g., Pfizer’s Xeljanz) and the entry of biosimilars due to patent expirations will likely reshape the RA market landscape.

Meanwhile, in Europe, cost-containment policies are set to impact drug prices, with mandatory price cuts observed in several EU markets in line with austerity measures. As a result of these trends, ensuring market access will remain a key concern of any launch strategy.

The launch team should develop a compelling value proposition that is customized for each customer group: patient, payer, physician, and other office staff with whom the customer-facing team interacts. Deep customer insights must be married with the clinical and market evidence to develop the brand’s value proposition, and the key messages in the brand’s value proposition should be tested with each customer group to assess the relevance and credibility of the message. The value proposition should inform the pricing strategy.

**Resource Appropriately**

Launch teams should be established at least two years prior to launch. Resources will be required to support market research, strategic planning (brand planning, launch strategy, and planning), and market shaping (PR, congress, advocacy group, and KOL engagement). Dedicated members of the market research and managed markets groups should be allocated to the brand during the launch period.

The focus of the launch team will evolve to tactical execution one year prior to launch. Sales team leadership should be in place a year prior to launch, and the sales teams should be on-boarded three to six months prior to launch when there is a strong FDA approval signal. At this point, scenario planning should be conducted to determine an appropriate field team hiring plan. A contract sales organization partner may also be considered to minimize risk.

Account managers may also be assigned a year prior to launch to help with account profiling and establishing relationships. At least three to six months should be allocated for recruiting.

Launch teams should start engaging in marketing activities three years prior to the launch.

**Conclusion**

The RA space is extremely crowded, with patient adherence issues centered around access, affordability, side effects, and plan rejection. At the same time, biosimilars and innovative new product classes are reshaping the market landscape. For any company entering this space, it will be important to have a multifaceted focus on patient advocacy, clinical/commercial collaboration, sales training, physician and patient advocacy, pricing strategy, and market access. The challenges are great, but the rewards of a successful RA brand launch can be greater.
RESULTS.

It’s a pretty simple word that’s used a lot in the business world, but what does it really mean?

When you cut through all the clutter, “results” means performing beyond expectations, eradicating challenges, and achieving your business goals. It means not just dreaming it. But actually doing it.

Campbell Alliance is purpose-built to help biopharmaceutical and medical technology companies achieve results. Whether it’s seizing the leadership position in a new market, solving seemingly impossible challenges, or developing innovative approaches for success, we don’t quit until the desired results are delivered.

We offer the insight to help leaders develop powerful strategies, as well as the knowledge to ensure they’ll work in the real world. And through our relationship with inVentiv Health, we bring the global implementation capabilities needed to put even the most ambitious plans into action.

Delivering results is what we do. Let’s get to it.