

Pharma **VOICE**  
THERAPEUTIC  
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# ARTHRITIS

## AND OTHER INFLAMMATORY DISEASES

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## Arthritis and Other Inflammatory Diseases

**Overview:** Inflammatory disease occurs when the immune system attacks the body's own tissues. According to the CDC, 54.4 million adults in the US are diagnosed with arthritis, with the most common arthritic conditions being osteoarthritis and rheumatoid arthritis (RA). As the population grows and ages, it is predicted that the prevalence of arthritis will continue to increase<sup>1</sup>. Additionally, the FDA reported nearly 300,000 children received an arthritic diagnosis as of 2016<sup>2</sup>.

In this eBook, ThinkGen reports on the current state of the arthritis and inflammatory disease market, approved treatments and those in development, and key trends having the most impact on the future of patient care. Will Leopold provides additional insights from his recent discussions with key opinion leaders (KOLs) in rheumatology on their perspectives and predictions on these topics.

### History of Biologic Treatment

Before the development of biologic therapies (Remicade, Enbrel) in the late 90's, arthritic conditions were often fated with poor outcomes such as severe physical deformities and increased rates of morbidity. The discovery of biologic agents has fundamentally changed the course and impact of disease for patients: *'That just doesn't happen today,'* explains one of the KOLs we interviewed. Today, we have significantly more effective therapy options that can slow or even halt the progression of disease and substantially improve patient quality of life. The pharmaceutical industry has invested heavily in these clinical therapies, as well as patient support programs, to drive improved patient outcomes. In fact, 4 of the top 10 selling biologic agents are approved for the treatment of an arthritic condition or inflammatory disease<sup>3</sup>.

### Overview of Class and Available Treatments

The inflammatory disease market, and specifically arthritic conditions, is now crowded with treatment options, giving healthcare practitioners (HCPs) a robust armamentarium from which to choose. Under some circumstances, some HCPs present patients several comparable therapies and provide patients with a choice of which best fits their lifestyle. Rheumatologists who treat arthritic conditions describe the field as 'rewarding', with the possibility of achieving remission for a sizeable portion of their treated population.

| Class  | Example  |
|--|--|
| Tumor Necrosis Factor- $\alpha$ (TNF) Inhibitors | adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade)                        |
| B-Cell Inhibitors                                | belimumab (Benlysta) and rituximab (Rituxan)   |
| Selective Co-stimulation Modulators              | abatacept (Orencia)  |
| Interleukin Inhibitors                           | ixekizumab (Taltz), sarilumab (Kevzara), secukinumab (Cosentyx), tocilizumab (Actemra) |
| Jak-Inhibitors                                   | Tofacitinib (Xeljanz), baricitinib (Olumiant) and upadacitinib (RINVOQ)                |

Despite access to these *‘truly miraculous’* drugs, as one physician describes treatments today, there are still a portion of patients who don’t respond immediately or at all. The NIH estimates that approximately 30-40% biologic treated patients fail first-line treatment<sup>4</sup>. A common challenge HCPs face today is selecting the ‘right’ treatment that an individual patient will likely achieve a response both quickly and safely.

The ability to predict outcomes through biomarkers and novel mechanisms of action are key unmet clinical needs in this market.

There are several “hot topics” being discussed by KOLs that are likely to impact the future of patient care in the management of arthritic conditions. KOLs share their perspective on key trends and how pharmaceutical manufacturers can help shape the future of inflammatory disease.

### **Novel MOAs/ Targeted Therapy**

KOLs are excited about novel mechanisms of action (MOAs) they can add to their current arsenal of relatively effective treatments, as well as therapies in the pipeline that inhibit multiple targets. As we continue to learn more about the etiologies of inflammatory diseases, KOLs hope to see options with an increased rate of response in the pipeline vs. ‘me-too’ biologics. HCPs explain that improved efficacy, and onset of action specifically, is critical to delay the progression of these chronic diseases.

One KOL is excited for dual mechanism of action and believes these drugs are more potent without the increased chance for side effects. “We’ve been involved with many clinical trials [for agents targeting multiple proteins], and it is absolutely amazing how potent these are.”

It is also important to consider route and frequency of administration. While IV and subcutaneous therapies have been the predominant choice of therapy for years, newer JAK inhibitors have increased interest in oral therapy options. Long-acting options, that can be administered less frequently with similar or better efficacy, would also be of interest.

### **Next Generation Biomarkers**

One of the greatest challenges healthcare providers experience when treating their patients with biologics is the uncertainty of response from one individual to another. Patients are often treated with multiple lines of therapy before finding an effective regimen.

Biomarkers, and being able to identify therapies that may be more (or less) effective for a given individual, is of great interest to the medical community. KOLs are hopeful that biomarkers will support and inform their selection of biologics and eliminate the guesswork and variability in a space with many treatment options. Additionally, validated biomarkers may provide the evidence to improve access of preferred therapies first line. Biomarkers may also contribute to cost savings for the patient and healthcare system. “[Biologic] drugs are still going to be expensive, so if we can identify which drugs will work, and for who, I can save a lot of money.”

### **Biosimilars**

The industry has been talking about biosimilars for nearly a decade, but we will have to wait a bit longer to see the full effect of these options in the United States.

Biosimilars entered the market in 2016 as cost-effective alternatives to established biologics like Humira and Remicade. The FDA has approved 14 biosimilars to treat inflammatory arthritis, however only three Remicade biosimilars are currently available for doctors to prescribe. The remaining 11 are held up in court and suffer from other legal delays<sup>5</sup>.

According to one KOL, the main benefit biosimilars offer is expanded access and lower cost to the patient and health system. Therefore, if the cost savings are not significant, he will continue to treat with the legacy biologics of which he has decades of experience. “I do believe they’ll be as effective and that they’ll be as safe. [However], I like to credit the companies that took the risk [to develop the original biologic] and have a product with proven efficacy for many, many years.”

As time and innovation marches on, the once highly anticipated impact of biosimilars for inflammatory disease is becoming diluted. Many KOLs express greater interest and benefit in developing novel mechanisms of actions, targeted treatments, and biomarkers.

### **Step Therapy Legislation**

HCPs are frustrated by the common practice of step therapy in inflammatory disease, which is when insurers require patients to try lower-cost therapies before approving the HCP’s or patient’s preferred choice.

Many insurers require arthritis patients to try two or more different drugs prior to getting the one their HCP had originally ordered. It is not uncommon for HCPs to be forced to prescribe a product ‘they know won’t work’ or find themselves fighting with insurers to prescribe evidence-based medicines.

The impact on timely disease management and patient outcomes is significant. Patients will often trial a drug for several months, followed by a several week or months “wash out” period without the drug, before moving to the next therapy. Even HCPs who submit prior authorizations, and are approved, experience delays in providing their patients with appropriate care. In a market where inhibiting disease progression matters, HCPs do not take this challenge lightly.

HCPs are not the only ones taking note. In some cases, pharmacies are helping physicians by taking on the burden of insurance paperwork to obtain drug rebates. Twenty-nine states have passed legislation to limit step therapy requirements, and reforms are on the horizon at the federal level<sup>6,7</sup>. The ability to prescribe the physician’s recommended treatment, or to more quickly to submit and obtain prior authorizations, is a key opportunity for improved patient care and outcomes.

## **Virtual Engagement - The ‘Amazon’ of Arthritis Care**

One KOL explained the future of patient care is ‘the amazon of medicine’. Our on-demand and pandemic-influenced culture has increased patient expectations for convenient and practical care options such as telemedicine and medicine delivery – they want to be seen and treated today. Even big retailers, such as Walmart, Amazon, and Google, are beginning to catch on, and aim to play in this space.

Telemedicine, or ‘Tele-rheumatology’, may also help alleviate the stress of heavy patient volumes anticipated with the aging and growing population with rheumatic and musculoskeletal diseases<sup>8</sup>.

This KOL predicts that, “The whole standard of practicing medicine is going to change... In the future you’ll be in the clinic 1-2 days a week and the rest [of the time] you will be seeing patients virtually and having their meds delivered to them.” Though in-person visits will continue to be necessary and preferred, it is hard to ignore the benefit of timely care and early intervention: “Telemedicine can serve as triage and let me assess which patients need to come in sooner rather than later.” There may also be opportunities to educate patients and HCPs through preferred digital platforms and social media (e.g., short series of ‘TikTok’-type videos, gamified learning, and virtual doctor meetings).

## **Conclusion**

The treatment of patients suffering from arthritis and other inflammatory disease has come a long way in the past 30 years. Even so, HCPs expect the industry to continue to research and develop more targeted therapies and guidelines for effective treatment selection. Additionally, virtual engagement, stoked by the pandemic, is not going anywhere. Pharmaceutical manufacturers are expected to evolve their communication by utilizing technology to engage with and educate providers and patients.



## NOTES

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