Rheumatoid Arthritis: Beyond TNF Inhibitors, 2016-2026

Description: Rheumatoid Arthritis (RA) is an autoimmune, inflammatory disorder wherein various components of the immune system begin to attack the body's own cells and tissues. The disease is characterized by pain and swelling in and around the joints. It is a systemic disease and is known to affect several joints at the same time or different joints at different times. Hence, it is also termed as migratory or flitting polyarthritis. It has been estimated that RA affects over 1% of the world population and the overall risk of developing the disease is higher in women as compared to men.

Owing to the complex nature of the disease, there is no cure for RA yet. However, in the past few years, several synthetic and biological treatments have been designed to achieve minimum disease activity, decrease inflammation and pain, prevent joint damage and reduce the pace of disease progression. Treatment strategies have evolved from the use of salicylates to non-steroidal anti-inflammatory drugs (NSAIDS), corticosteroids, synthetic disease modifying anti-rheumatic drugs (DMARDS), such as methotrexate (MTX), sulfasalazine and leflunomide, and gradually to biologic response modifiers.

MTX, one of the most popular synthetic DMARDs used to treat RA, was approved in 1988 and is generally used as a first line therapy. However, due to certain side-effects associated with treatment regimens involving higher doses of synthetic DMARDs and the fact that some patients fail to respond to such drugs have led to a shift in the market towards biologic therapies. The transition to biologic DMARDs has brought a significant change in this domain.

Biologics are a more targeted therapeutic option and result in significant reduction in disease symptoms and a decrease in disease activity in a large proportion of RA patients. Despite the known advantages, a subset of patients treated with biologics demonstrated the need of more innovative options, thereby prompting the drug developers to look for alternative therapeutic strategies.

Several biopharmaceutical companies have been active in this area since last few years while others have recently stepped in. Apart from focusing on already established mechanisms of action, these companies are trying to offer novel and innovative treatment options. A number of collaborations and partnerships have been inked between various companies to progress the R&D and commercialization activities. As more such new generation molecules reach the late stages of clinical development and eventually get commercialized, the unmet need for efficacious therapies in this domain is likely to be satisfied to a large extent.

The Rheumatoid Arthritis: Beyond TNF Inhibitors, 2016-2026 report provides a comprehensive analysis of the current market landscape of rheumatoid arthritis based therapies (specifically, non - tumor necrosis factor (TNF) inhibitors) and an informed opinion on how the market is likely to evolve over the next decade. RA is known to substantially affect patients' quality of life and is characterized by a more severe set of symptoms than those observed in patients with osteoarthritis.

The RA market is primarily populated by DMARDs that have been shown to alter the course of the disease and also improve radiographic outcomes. Biologic DMARDs including TNF inhibitors, such as HUMIRA® (USD 14 billion), Enbrel® (USD 9 billion), and REMICADE® (USD 6.6 billion), are counted among the best-selling drugs in this market. In recent years, treatment options for RA have increased substantially with the development of several novel drugs/drug classes. In addition to TNF inhibitors, a number of novel biologic DMARDs, such as T-cell costimulatory blocking agents (Orencia®), B-cell depleting agents (Rituxan®), interleukin-6 (IL-6) inhibitors (Actemra®) and interleukin-1 (IL-1) receptor antagonists (Kineret®), have been approved over the past few years.

In 2012, Xeljanz®, the first oral non-biologic DMARD belonging to the janus kinase (JAK) inhibitors drug class was approved in the US. The drug generated revenues worth USD 523 million in 2015 alone. In comparison to traditional biologic DMARDs, which are delivered through injections or infusions, JAK inhibitors, or Jakinibs, are a new class of drugs that have been optimized for oral delivery.

It is also worth mentioning that a number of pharmaceutical companies are developing drugs with novel mechanisms of action, namely Bruton's tyrosine kinase (BTK) inhibitors, spleen tyrosine kinase (SYK) inhibitors, RANKL inhibitors and adenosine A3 receptor (A3AR) agonists, which (along with Jakinibs) represent the next generation of drugs designed to treat RA.
During the course of our study, we identified over 80 non-TNF inhibitors that are either already marketed or in various phases of development for the treatment of RA; of these, five drugs are currently marketed and four drugs (a JAK inhibitor, a RANKL inhibitor and two IL-6R inhibitors) are in the pre-registration stage. Overall, more than 60% of candidate drugs are currently under clinical development. Drug development efforts in this domain are being actively led by a mix of pharmaceutical giants, mid-sized companies and start-ups.

Among other things, the report features discussions on:

- The current state of the market with respect to available drug classes, key players, phase of development of pipeline products (clinical and preclinical/discovery), route of administration, type of molecule and type of therapy.
- An in-depth analysis comprising of schematic representations, including a grid analysis highlighting the distribution of pipeline, an overview of the landscape of industrial developers (small, mid-sized and large players) and the geographical distribution of the companies involved in the development of RA therapeutics.
- Detailed profiles of drugs that have been recently (post-2010) approved/marketed or are in the late stages of development (phase III and above).
- Information on the mechanisms of action of novel drugs (non-TNF inhibitor) that are currently being investigated as potential treatment options for RA.
- Detailed comparative analysis of the key clinical trial endpoints for drugs that are already marketed or are in phase III of development and insights on the clinical development programs designed for phase III drugs (active comparator trials, important primary endpoints and scale of trials).
- A detailed analysis of the collaborations and agreements established amongst stakeholders in the past few years.
- Emerging trends and a discussion on the popularity of non-TNF inhibitors on Twitter over the last few years.

In addition to the above mentioned analyses, the report also provides an estimate of the likely future size of the market for RA therapies. Our forecast model is built on an understanding of existing market trends and the likely future opportunity for JAK inhibitors, anti-interleukins (anti-ILs) and other novel drug classes. We have provided informed estimates on the expected future sales of marketed and late stage candidates under each category, highlighting their respective shares in the overall market over the next ten years.

The research, analysis and insights presented in this report are backed by a deep understanding of opinions gathered from secondary research. Actual figures have been sourced and analyzed from publicly available data. Unless otherwise specified, all financial figures are presented in USD.

Example Highlights

- Although the DMARDs market is currently dominated by TNF inhibitors, non-TNF inhibitors, such as IL-6 inhibitors/IL-6R antagonists, IL-1 inhibitors, T-cell costimulation inhibitors, B-cell inhibitors and JAK inhibitors, have emerged as viable drug classes for the treatment of patients suffering from RA.
- We came across over 80 drugs/therapies in the non-TNF inhibitors development pipeline; of these, 6% represent marketed molecules, while 11% of the pipeline molecules are either under review by the FDA or in phase III of clinical development. Over 30% of the molecules are in the preclinical/discovery stage.
- JAK inhibitors and anti-ILs are the most popular drug classes in terms of the number of pipeline molecules that are in higher phases of development (pre-registration and phase III). Xeljanz® is the only JAK inhibitor that is currently commercially available; however, one such drug (baricitinib) is currently in the pre-registration stage, while three other JAK inhibitors (filgotinib, peficitinib and upadacitinib) are in phase III of clinical development. On the other hand, anti-ILs consist of two marketed (Actemra® and Kineret®) molecules, two in the pre-registration stage (sarilumab and sirukumab), six phase II product candidates (bimekizumab, clazakizumab, CNTO 6785, Dekavil, vobarilizumab and gerilimzumab) and four preclinical candidates.
- Big biopharmaceutical players, namely Amgen, BMS, Roche/Genentech and Pfizer, currently hold the major share in the overall market with the maximum number of marketed drugs in this domain. There are several mid-sized and large firms, including (in alphabetical order) AbbVie, Amgen, Astellas Pharma, Daiichi Sankyo, Eli Lilly, Galapagos, Gilead Sciences, GSK, Incyte Corporation, Janssen, Regeneron Pharmaceuticals and Sanofi-Aventis, which have RA therapies in late stages of clinical development. Additionally, there are small-sized players that have captured a significant portion of the preclinical/discovery pipeline. Some of these players include (in alphabetical order) Acetynol Pharmaceuticals, Aegera Therapeutics, Arrien Pharmaceuticals, Asana BioSciences, Atlantic Bio Sci, Avexxin, CASI Pharmaceuticals, CJ HealthCare, Immune Response Biopharma, Oscotec, Peptinov, Principia Biopharma, RedHill Biopharma, SBI Biotech,
TechnoPhage and Toleranzia.
- A number of stakeholders in the non-TNF RA drugs market have entered into collaborations with other players. We came across close to 50 deals that have been signed over the last decade for various purposes, including product development and/or commercialization (70%), research (16%), manufacturing (6%), technology licensing (4%), acquisition (2%) and product distribution (2%). There are instances where a company has entered into more than one collaboration; examples of such players include (in alphabetical order) AbbVie, Ablynx, Bird Rock Bio, Can-Fite Biopharma, Chugai Pharmaceuticals, Eli Lilly, Galapagos, Gilead Sciences, Janssen, Merck-Serono, MorphoSys and Roche.
- In order to address the growing concerns related to patient compliance, drug developers have shifted their focus towards the development of orally administrable drugs. Of all pipeline molecules, over 50% are being developed as oral therapies.
- The use of existing drugs as combination/add-on therapies has been shown to be associated with better outcomes and treatment effects compared to their use as monotherapies. In fact, 38% of the drugs in the clinical pipeline are being tested as add-on therapy/combination therapies. MTX is the preferred add-on/combination drug in most such clinical trials.
- It is necessary to highlight that key patents protecting multiple approved drugs are set to expire in the coming years. This is likely to have a significant impact on the market's growth in the mid-long term. However, we believe that the emergence of novel treatment options and the approval of late stage molecules is likely to balance the aforementioned decline. JAK inhibitors and non-TNF biologics are anticipated to capture the major share of the anti-TNFs market. Specifically, the JAK inhibitors market is expected to grow at a CAGR of 23.5% over the next decade.
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