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PharmaPoint

**SARILUMAB (RHEUMATOID ARTHRITIS) –
FORECAST AND MARKET ANALYSIS TO 2023**

Executive Summary

The table below presents the key metrics for Sarilumab in the 10MM Rheumatoid Arthritis (RA) pharmaceutical markets (US, France, Germany, Italy, Spain, UK, Japan, Australia, China, India) in 2023.

Sarilumab: Key Metrics in the 10 Major Pharmaceutical Markets	
Key Events (2013–2023)	Level of Impact
Launch of Sanofi and Regeneron's sarilumab in 2018 across the 6MM, and Australia	↑↑
Launch of Sanofi and Regeneron's sarilumab in 2021 in Japan	↑↑
2023 Market Sales	
US	\$121.2m
5EU	\$42.4m
Japan	\$21.2m
Australia	\$3.3m
China	N/A
India	N/A
Total	\$188.1m

Source: GlobalData
 10MM = US, France, Germany, Italy, Spain, UK, Japan, Australia, China, and India
 6MM = US, France, Germany, Italy, Spain, and UK
 5EU = France, Germany, Italy, Spain, and UK
 N/A = Not Available

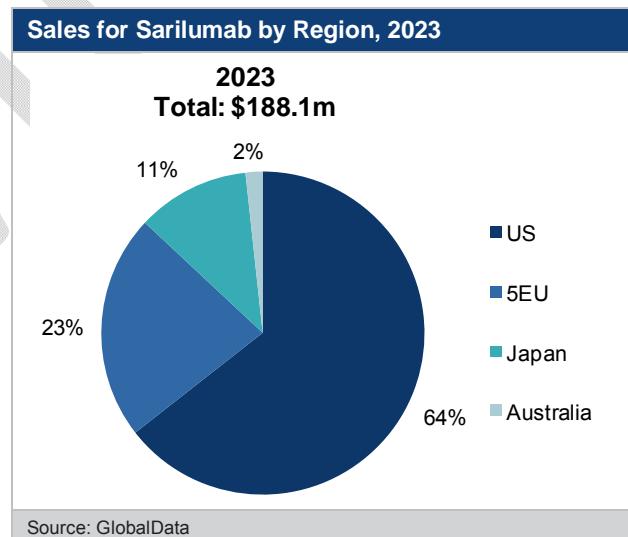
Sales for Sarilumab in the Rheumatoid Arthritis Market

GlobalData estimates sales of Sarilumab at the end of the forecast period in 2023, in the seven major markets (7MM) and Australia at \$188.1 million increasing from \$47.8 million in 2018.

Major drivers for the growth of Sarilumab in the RA market over the forecast period are:

- Sanofi backing.
- Likely to be available in two device types: a prefilled syringe and an auto-injector device
- Utilize data from head-to-head studies versus Enbrel and Actemra to drive the uptake of sarilumab, if positive outcomes are observed.
- Major barrier to the growth of Sarilumab in the RA market over the forecast period is:
- The launch of sirukumab during roughly the same timeframe as sarilumab will mean intense competition for both drugs.

The figure below illustrates the global Sarilumab sales by region during the forecast period.



Executive Summary

What do the Physicians Think?

The RA market is very competitive, and the new entrants are expected to be met with some resistance and experience slow uptake, as the market is currently dominated by the anti-TNFs, and rheumatologists feel comfortable with the long-term safety and efficacy of this class of drugs.

"We at least have a reasonably good handle on what the long-term or relatively long-term safety profile of [the] anti-TNFs is. They're not perfect, but at least we know what the issues are, and there are concerns, I think, with the [the] long-term safety profiles of some of the new agents that have come through. And so, given that we rheumatologists feel more comfortable with the anti-TNFs..., we know what to look out for. Then, for any new players..., it can be difficult to compete because the concern is always, well, maybe the new drug might have long-term side effects, and so we better use the ones that we've got more — [that] we're more familiar with."

[EU] KOL

"Unless we can upfront identify a group in whom it's [a pipeline agent] going to be effective..., [or] unless it's marketed at a significantly lower cost than its competitors, what will happen is that the [new] drug will be used fourth or fifth line, etcetera. Because if it costs the same as a currently available biologic, the currently available biologics have got a stronger history, [a] longer history of maybe safety and efficacy data, [so] why would

you choose to use the new one unless you'd actually tried and failed [with] the old ones? The problem with that, of course, for the new ones, is that they end up being tried on often the most difficult rheumatoid [arthritis] patients, and so, often they don't work."

[EU] KOL

One of the greatest challenges with the introduction of new biologics in the RA market will be to target these drugs to the right patients. Many rheumatologists believe that the future of RA is in individualized medicine, where biomarkers determine the best course of action for each patient.

"I think the patients find the whole process [of finding an effective therapy to be] very difficult. They often lose faith in our approach to treat their disease well. It may have an impact on their adherence to medication in the future. We kind of keep dropping and changing between one thing and another thing. How do they know that the fifth thing is going to work when the first four haven't? Actually, adherence to drugs is a big issue in people with long-term conditions [such as RA], and the fact that it can take us a long time to find something that works, I think, is a big issue in the context of that for the patients as well."

[UK] KOL

Executive Summary

“I think it will be very difficult for rheumatologists to manage this huge number of different drugs that are available without us having some kind of strategy for establishing which groups of patients each particular drug would be most effective in, and so that kind of takes us down to [the] personalized medicine route, and I think that’s what companies need to be looking at as they’re developing these new agents....We need to work out who to treat with what — who to treat with what drug, based on identifying biomarkers that predict [the patient’s] response, which could be ones that you measure in the blood or [the] ones that you measure from the joint, but I think that will have to be the direction of travel.”

[EU] KOL

One of the greatest unmet needs in RA is the affordability of drugs, as the biologics cost upwards of \$30,000 per year in the US. Biosimilars are expected to launch over the forecast period from 2013–2023 in all 10 markets covered in this report, changing the market dynamics and offering a less expensive alternative to the branded biologics.

“If a biosimilar is only half as expensive [as the originator brand] — which it’s probably not, [as that’s] probably overly optimistic — it’s still way out of the reach of most patients if they have [health insurance] coverage problems. Yes, it will help the overall system, but [it will] probably not help the individual patient very much. [I would prescribe biosimilars when they are available] sure, absolutely....You would potentially replace the innovative product with a biosimilar whenever you have that option. The only reason you do that, obviously, is cost. In most cases, it’s not going to be my decision; it’s going to be the decision of whoever is paying for it....It will be helpful, but it’s not going to be a big game-changer....Two thirds of [what is already] a heck of a lot of money is still almost a heck of a lot of money, and most people don’t have that.”

[US] KOL

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Introduction

2 Introduction

2.1 Catalyst

The Rheumatoid Arthritis (RA) market will grow over the 2013–2023 forecast period, driven by a number of new product launches, such as:

- Novel biologics
- Anti-interleukin (IL)-6 biologics
- Small molecules, including janus kinase (JAK) inhibitors

Other factors that will drive market expansion are growth in the emerging markets of China, India, and Australia, where product launches extend product lifecycles. In addition, there will be an increase in the prevalence of RA across the 10 major markets (10MM) covered in this report.

The loss of patent protection for the anti-tumor necrosis factor (TNF) marketed brands will allow for the emergence of biosimilars, such as Celltrion's Remsima (infliximab)/Hospira's Inflectra (infliximab), which is a Remicade biosimilar. The patent expiries begin in 2015 and 2016, respectively, for the current market leaders:

- J&J's Remicade
- AbbVie's Humira
- The catalysts and objectives for this report are to:
- Determine the impact that biosimilars will have on the RA market
- Assess the uptake of JAK inhibitors, including Pfizer's Xeljanz (tofacitinib) and other pipeline agents
- Identify the unmet needs in the RA market
- Determine the remaining opportunities in the RA market

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2.2 Related Reports

- GlobalData (2014). PharmaPoint: Ulcerative Colitis – Global Drug Forecast and Market Analysis to 2022, Event-Driven Update, September 2014, GDHC005EPIDR
- GlobalData (2014). PharmaPoint: Crohn's Disease – Global Drug Forecast and Market Analysis to 2022, January 2014, GDHC77PIDR
- GlobalData (2014). PharmaPoint: Atopic Dermatitis – Global Drug Forecast and Market Analysis to 2022, November 2013, GDHC66PIDR
- GlobalData (2014). PharmaPoint: Systemic Lupus Erythematosus and Lupus Nephritis – Global Drug Forecast and Market Analysis to 2022, October 2013, GDHC65PIDR
- GlobalData (2014). PharmaPoint: Psoriasis – Global Drug Forecast and Market Analysis to 2022, May 2013, GDHC48PIDR
- GlobalData (2014). PharmaPoint: Rheumatoid Arthritis – Global Drug Forecast And Market Analysis To 2023, December 2014, GDHC93PIDR
- GlobalData (2014). Rheumatoid Arthritis – US Drug Forecast and Market Analysis to 2023, December 2014, GDHC264CFR
- GlobalData (2014). Rheumatoid Arthritis – 5EU Drug Forecast and Market Analysis to 2023, December 2014, GDHC265CFR
- GlobalData (2014). Rheumatoid Arthritis – Japan Drug Forecast and Market Analysis to 2023, December 2014, GDHC266CFR
- GlobalData (2014). Rheumatoid Arthritis – Australia Drug Forecast and Market Analysis to 2023, December 2014, GDHC267CFR
- GlobalData (2014). Rheumatoid Arthritis – China Drug Forecast and Market Analysis to 2023, December 2014, GDHC268CFR
- GlobalData (2014). Rheumatoid Arthritis – India Drug Forecast and Market Analysis to 2023, December 2014, GDHC269CFR
- GlobalData (2014). Enbrel (etanercept) (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC492DFR

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- GlobalData (2014). Humira (adalimumab) (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC493DFR
- GlobalData (2014). Remicade (infliximab) (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC494DFR
- GlobalData (2014). Simponi (golimumab) (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC495DFR
- GlobalData (2014). Cimzia (certolizumab pegol) (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC496DFR
- GlobalData (2014). Orencia (abatacept) (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC497DFR
- GlobalData (2014). Actemra/RoActemra (tocilizumab) (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC498DFR
- GlobalData (2014). Rituxan/MabThera (rituximab) (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC499DFR
- GlobalData (2014). Biosimilars (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC500DFR
- GlobalData (2014). Xeljanz (tofacitinib) (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC501DFR
- GlobalData (2014). Iguratimod/T-614 (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC502DFR
- GlobalData (2014). Methotrexate (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC503DFR
- GlobalData (2014). Sirukumab (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC505DFR
- GlobalData (2014). Clazakizumab (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC506DFR

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- GlobalData (2014). Cosentyx (secukinumab) (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC507DFR
- GlobalData (2014). Tregalizumab (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC508DFR
- GlobalData (2014). Mavrilimumab (Prolia) (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC509DFR
- GlobalData (2014). Denosumab (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC510DFR
- GlobalData (2014). Baricitinib (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC511DFR
- GlobalData (2014). Peficitinib (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC512DFR
- GlobalData (2014). Decernotinib (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC513DFR
- GlobalData (2014). Filgotinib (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC514DFR
- GlobalData (2014). Masitinib (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC515DFR
- GlobalData (2014). RAVAX (Rheumatoid Arthritis) – Forecast and Market Analysis to 2023, December 2014, GDHC516DFR
- GlobalData (2014). Rheumatoid Arthritis – Current and Future Players, December 2014, GDHC1041FPR

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2.3 Upcoming Related Reports

- GlobalData (2015). Opportunity Analyzer: Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis – Global Drug Forecast and Market Analysis to 2024, to be published in March 2015
- GlobalData (2015). PharmaPoint: Atopic Dermatitis – Global Drug Forecast and Market Analysis to 2022, Event-Driven Update, to be published in January 2015
- GlobalData (2015). PharmaPoint: Systemic Lupus Erythematosus and Lupus Nephritis – Global Drug Forecast and Market Analysis to 2022, Event-Driven Update, to be published in January 2015

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Appendix

9.8 About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

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