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LONDON, UK (GlobalData), 28 November 2012 - **Humira** (adalimumab) has a strong reputation as a top **anti-Tumor Necrosis Factor** (TNF) and **Rheumatoid Arthritis** (RA) **therapy**, but a **new report** by healthcare experts GlobalData states that the future emergence of the anticipated **cheaper biosimilars**, and new novel oral RA products, may well see the blockbuster begin to loose its lustre.

In this new report*, pharmaceutical industry analysts estimate that Humira will be the "world's top-selling medicine" in 2012, reaching US$9 billion in sales. Since the drug's approval in 2002, an estimated 370,000 patients have used Humira, with the drug's versatility allowing its use in the treatment of multiple immunological diseases, including RA, spondylitis, psoriasis, Crohn's disease and ulcerative colitis.

However, the next few years are due to see several biologics specific for RA, hit the patent cliff, including Humira, due to lose patent protection in the US, Japan and the EU in 2016, 2017 and 2018 respectively. Humira presently commands a substantial annual cost of therapy, reaching a high of $26,632 in the US, but GlobalData predicts that the US will have a biosimilar approval pathway in place for Humira's patent expiry. Competition from biosimilars is expected to quickly emerge as a result of this, and the newfound market competition will put downward pressure on Humira sales and pricing.

Japanese firms Kyowa Hakko Co. and Fujifilm Corp. are already working on biosimilars to Abbott's Humira. In order to stymie these efforts, Abbott has asked the FDA to block adalimumab biosimilars, arguing that trade secrets from the Biologics License Application (BLA) would be involved for their development. Given the success of Amgen's patent extension for

Enbrel, there is a real possibility that Abbott could succeed in this strategy. However, it remains to be seen whether the pressure to bring biosimilars to market will simply be too great for their emergence to be forestalled.

Abbott's marketing strength and reputation in the immunology space strongly support the drug's high status in the RA market, and Humira's first-line biologic status demands that new therapies prove superior results in order to effectively take Humira's market share. Humira may even gain an expanded patient pool, if guidelines change to include biologic usage for early RA.

Nevertheless, this market giant is not without its flaws. Humira's safety profile is similar to those of other TNF inhibitors, requiring vaccinations for pneumococcal disease and influenza in defence of immunosuppressive complications that RA biologics can provoke. However, Humira also carries a black box warning noting an increased risk of cancer, tuberculosis, and other opportunistic infections. Humira's subcutaneous administration also means that injection-site infections are common, and so the emergence of an oral RA therapy could severely threaten Humira's standing in the RA treatment market.

GlobalData predict that RA drug sales for Humira will reach over $4.2 billion in 2012, across the US, the UK, France, Germany, Italy, Spain, Japan and Australia. However, sales are anticipated to decline to a mere $2.3 billion by 2022, at a negative CAGR of 5.6%.

* Humira (Rheumatoid Arthritis) - Forecast and Market Analysis