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Safety concerns delay launch of Pfizer's arthritis drug Xeljanz

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Singapore: Pfizer's high hopes for its JAK3 (Janus kinase) inhibitor, tofacitinib (tasocitinib, CP-690550), now branded as Xeljanz, may not be fully realized until safety and efficacy is proven to that of current biologics, according to new analysis released by GlobalData.

"While Pfizer has high hopes that Xeljanz will compete with tumor necrosis factor (TNF) inhibitors as first-line biologic therapies for rheumatoid arthirits (RA), experts interviewed by GlobalData have suggested that safety concerns may temper this enthusiasm and make it a case of 'wait-and-see'," says Ms Dina S Rufo, therapy area analyst, GlobalData.

The US FDA approved Pfizer's JAK3 (Janus kinase) inhibitor, tofacitinib (tasocitinib, CP-690550), now branded as Xeljanz. Xeljanz is an oral drug approved for administration at 5mg twice daily for the treatment of patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to methotrexate (MTX). GlobalData expected the lower dose of 5mg dose to gain approval in Q4 2012 with a launch in early 2013 as the higher dose of 10mg generated more serious adverse effects.

"While this is an exciting time for RA patients, particularly those who do not enjoy needle-based therapy, Xeljanz may have slow uptake due to its safety profile," continues Ms Rufo. "As an oral therapy, we believe (as do the physician experts we have interviewed) that Xeljanz will play a third-line therapy role until safety and efficacy is proven to that of the current biologics.'

"While physicians have indicated they will not openly prescribe Xeljanz, they do recognize that patient requests may be high due to its oral formulation. The lower price in comparison to current biologics gives Xeljanz an additional selling point as it may be placed higher on the list of acceptable therapies. Overall, however, the uncertain safety profile and lack of post-market surveillance data make it unlikely that physicians will prescribe Xeljanz before proven biologics."