

First monoclonal antibody biosimilars approved by EMA

Alert: Multinational biosimilar risk premium to rise

Summary and Investment Conclusion — Today's announcement of a positive CHMP opinion recommending approval of biosimilars of JNJ/MRK's Remicade on first review will likely come as a modest surprise to investors. While the rationale is clear, given current fiscal pressures in Europe and following development of detailed biosimilar guidelines over the past couple of years, this will likely increase the biosimilar risk premium currently attributed to MNC pharma's blockbuster biologics. All large-cap pharma names have biologic exposures, with sizable contributions in particular for Roche, JNJ (covered by US analyst Matt Dodds) and Abbvie (Not Rated). It will be interesting to note how the dynamics develop around pricing and market share for biosimilars post pending approval by the European Commission. More immediately, we expect this development to dampen pricing environment for other biologics used in RA (esp smaller franchises such as UCB's Cimzia) although use of Remicade is typically reserved for more refractory settings given its IV mode of administration.

What's New? — The CHMP adopted a positive recommendation, recommending approval of two biosimilar versions of Remicade (infliximab). The biosimilars, branded as Remsima by Celltrion and Inflectra by Hospira, are for the same indications as those for Remicade. This is the first approval of biosimilar monoclonal antibodies anywhere in the developed world. We model \$2.2bn Remicade sales in 2013e recorded by Merck (c.5% of group).

Increases biosimilar threat to Roche blockbuster oncology franchise — A softer EMA stance on biosimilar monoclonals will likely increase the perceived biosimilar risk to Roche's blockbuster oncology franchise, in particular Rituxan and Herceptin (combined 26% of 2013e group sales). However, we already anticipate a generic entry in EU for these franchises starting 2016 / 2017 despite uncertainty existing around timing of generic entry and development plans of biosimilars. This also implies investor focus will now increase on Roche's biosimilar defences, notably Kadcyla / Perjeta (Herceptin) and GA101 (Rituxan).

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