Evaluate Vantage

May 05, 2016

Tildrakizumab’s moment in the Sun

Jonathan Gardner

Sun Pharmaceutical Industries’ chances of climbing the pharmaceutical value chain just improved, with positive phase III results for its psoriasis project tildrakizumab.

Showing a benefit against both placebo and Enbrel gives the IL-23-blocking agent a good chance of approval and launch head-to-head against Johnson & Johnson’s competing candidate guselkumab. Since Sun licensed tildrakizumab from Merck & Co two years ago analysts have largely forgotten about it; this will likely change as regulatory milestones approach.

It’s on

India-based Sun reported that the percentage of patients taking either a 200mg or 100mg dose of tildrakizumab who saw an improvement in the psoriasis area sensitivity index (PASI) and a physician assessment was greater than among placebo recipients at week 12. In the separate head-to-head trial 200mg showed superiority against Enbrel on both endpoints, but the 100mg dose missed on physician assessment.

The findings set up Merck & Co to submit an application to the US FDA, potentially before J&J with its rival guselkumab, which is expected to report data from its larger phase III programme this year.

Under the September 2014 agreement in which Sun assumed commercialisation rights to tildrakizumab, Merck is responsible for clinical development, initial FDA submission and manufactured goods to support the launch, funded by Sun, while the Indian partner assumes control thereafter. Merck received $80m up front, and is eligible for undisclosed milestones and sales royalties escalating to the mid-teens.

While guselkumab and a third IL-23 inhibitor, Boehringer Ingelheim’s AbbVie-partnered BI 655066, have forecasts attached to them – $1bn and $144m in 2022 respectively, according to *EvaluatePharma’s* consensus – tildrakizumab has fallen from analysts’ radar since the Sun-Merck deal was signed. The last consensus, in September 2014, posited $343m in sales in 2020, roughly half of what the J&J project is now expected to make.

Here comes the Sun

Analysts will now have to take the Sun candidate more seriously than they have since the deal. But it could be a hard market to gauge, given the number of shifts already under way.

In psoriasis quite a few biologicals are already on the market and several, like J&J’s Remicade, Amgen’s Enbrel and AbbVie’s Humira, are quickly approaching patent expiry, with biosimilars available in some regions and nearing key catalysts in others. Meanwhile, next-generation agents like Novartis’s Cosentyx and Lilly’s Taltz have been launched.

Thus, the need to show some differentiation has never been more important, explaining why so many companies have done head-to-head studies – guselkumab, for example, is being compared with Humira. This could help explain why Merck was reluctant to move tildrakizumab alone.

The choice of Sun as a partner might seem a little curious, but it makes some sense. The group, known more for its generics and dermatology focus, has made no secret about wanting to increase the share of income it derives from innovative, “value-added” products – a deal with Novartis in March permitted entry into the Japanese branded prescription market – and now it looks to be getting close to breaking into the US.

Merck, meanwhile, might be betting that the psoriasis space is maturing, with a combination of new products and off-patent agents competing for insurance coverage. If this is the case it could be a very good choice to have an experienced generics sales and marketing team on its side, and Sun might very well deliver just that.

Study	Trial ID
MK-3222-010	NCT01722331
MK-3222-011	NCT01729754

To contact the writer of this story email Jonathan Gardner in London at jonathang@epvantage.com or follow @ByJonGardner on Twitter