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Next-generation psoriasis battle lures AbbVie

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AbbVie's half-billion-dollar-plus payment to secure rights to Boehringer Ingelheim's phase III asset BI 655066 is a sign either of high expectations for a cohort of new antibodies in psoriasis, or of its anxieties about business development.

The Illinois-based group has assembled an arsenal of new agents in cancer and immunological disease, yet consensus forecasts show its revenue and profit growth stalling in 2020 as Humira faces biosimilar competition. Psoriasis might not give AbbVie the answer it is looking for either, as its new project looks like it may be late to a crowded market, after data on more advanced interleukin-blocking agents were released at a US medical meeting.

Spending loads

AbbVie paid the private German company $595m up front for rights to the IL-23-blocking antibody, currently in a 2,100-patient phase III programme with readouts expected next year, along with BI 655064, an anti-CD40 antibody in phase I. The company said the R&D costs that it assumes would reduce earnings per share by 8 cents in 2016.

This is a pretty steep up-front investment in the Boehringer asset, which if successful would trail the very first interleukin-blocking psoriasis drug, Johnson & Johnson's Stelara, by about 10 years, and the most recent, Novartis's Cosentyx, by three. Before BI 655066, the sector also looks likely to see launch of Lilly's ixekizumab and possibly J&J and MorphoSys's guselkumab – the former is expected to get an FDA decision within weeks.

Marketed and late-stage interleukin-blocking antibodies in psoriasis

	Product	Company	Pharmacology class
Marketed	Cosentyx	Novartis	Anti-IL-17A MAb
	Stelara	Johnson & Johnson	Anti-IL-12 & IL-23 MAb
Filed	ixekizumab	Eli Lilly	Anti-IL-17A MAb
Phase III	tildrakizumab	Merck & Co/Sun Pharmaceutical Industries	Anti-IL-23 MAb
	guselkumab	Johnson & Johnson/MorphoSys	Anti-IL-23 MAb
	BI 655066	AbbVie/Boehringer Ingelheim	Anti-IL-23 MAb

AbbVie may reason that there is room for BI 655066 as it acts on a different target from the IL-17A of Cosentyx and ixekizumab. However, the psoriasis pipeline has two IL-23s, one of which is on a timeline similar to or faster than BI 655066 – the aforementioned guselkumab, due pivotal data in mid-2016.

Thus, AbbVie might need some clear evidence that BI 655066 can outperform incumbents by the time it launches to persuade payers that it is worth putting on a formulary. So far, the clinical plan has two trials against Stelara, both initiated in February, and a planned one against Humira, the biggest-selling product in the indication.

Head to head

Novartis has already delivered on this front. At the American Academy of Dermatology meeting over the weekend it detailed data from a Cosentyx versus Stelara trial in which Cosentyx showed statistical superiority on the skin clearance endpoints PASI90 and PASI100.

So far, Novartis has not compared Cosentyx with Humira, perhaps reasoning that Stelara, being an interleukin blocker, is a more relevant comparator. In any case, Humira's psoriasis trials used PASI75 and the physicians' global assessment scale as endpoints, so even a cross-trial comparison is difficult.

Lilly, meanwhile, has also released data at AAD, from three trials showing that ixekizumab has a benefit on work productivity for patients – something in which the US employers who pay for health insurance coverage will be interested.

The data indicate that Novartis and Lilly know they must be able to show how expensive new drugs are superior to established products to earn a place on payer formularies. AbbVie is making a sizable bet that BI 655066 will be able to do the same.

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