

Alkermes' approval injects new life into antipsychotic market



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Yesterday's approval of Alkermes' once-monthly antipsychotic Aristada not only hands the Ireland-domiciled company its biggest growth driver over the next five years, but it also extends the presence of injectables in this highly competitive market.

After a scare in August, when Alkermes said FDA approval would be delayed by "weeks", Aristada, a prodrug of Abilify's active ingredient, has been given the green light. What is more, the FDA has included a few positive announcements on the label, which might help it carve out a niche in a market dominated by two other long-acting injectables.

Chief among the label information is that Aristada was approved in all three of its tested doses, despite negligible differences in efficacy between the highest and lowest quantities in clinical trials.

Speaking on a conference call today Richard Pops, Alkermes' chief executive, said this would give the drug more flexibility than the market rival Abilify Maintena, which has only been approved in one dose, limiting the amount of titration to achieve an optimum dose.

Aristada's label also includes switching data for oral Abilify, which could help with physician adoption, something that will be key if Aristada is to achieve decent sales.

Pricing

In a time when pricing is one of the sensitive push points for the industry, Alkermes gave a hint at what it might charge for Aristada. Mr Pops said that the midpoint for similar antipsychotic drugs was \$15,000 a year, and Alkermes wants to "position itself around the midpoint".

However, in a possible nod to payer sensibilities, he added that owing to the drug's efficacy at lower doses, and the fact it would be reimbursed on a per-mg basis, there could be opportunities for savings.

Aristada might also make some gains against its competition because at the highest 882mg dose it only has to be administered every six weeks, compared with every four weeks for most other long-acting injectable antipsychotics.

Analysts are forecasting sales of \$344m for Aristada in 2020, though the market leader, Invega Sustenna/Trinza, is expected to have \$2.25bn of revenue in the same year.

Growing point for injectables

Although Aristada expectations have lagged significantly behind Invega Sustenna/Trinza, the approval now means that four of the top 10 atypical anti-psychotics are injectable. The table below also shows that while many oral antipsychotics are succumbing to generic competition one area of growth appears to be long-acting injectables.

About 7% of the whole market is long-acting injectables, and this could increase as companies continue to extend the time needed between injections. In May Johnson & Johnson managed to gain FDA approval for Invega Trinza, a product dosed once every three months.

How much of the market long-acting injections could take from oral products is debatable, as the savings from many of these either being or becoming generics will be compelling. What the makers of long-acting injections will have to hammer home is their value in improving compliance, and therefore the associated cost savings of patients remaining stable.

Alkermes has made it very clear that it will be targeting the vast number of schizophrenia patients still on oral drugs and new patients. The coming quarters will tell just how successful this ambition has been.

Injected products to dominate branded atypical anti-psychotic market

Product	Route of Admin.	Company	Patent expiry	Global sales (\$m)		Status
				2014	2020	
Invega Sustenna	Injection	Johnson & Johnson	May 2019	1,588	2,254	Marketed
Abilify Maintena	Injection	Otsuka Holdings	Oct 2024	148	1,436	Marketed
Rexulti	Oral	Otsuka Holdings	Feb 2027	-	752	Approved
Risperdal Consta	Injection	Johnson & Johnson	May 2014	1,190	646	Marketed
ITI-007	Oral	Intra-Cellular Therapies	Dec 2031	-	435	Phase III
Cariprazine	Oral	Allergan	Dec 2027	-	411	Filed
Invega	Oral	Johnson & Johnson	Apr 2012	640	359	Marketed
Zyprexa	Oral	Eli Lilly	Oct 2011	1,037	350	Marketed
Aristada	Injection	Alkermes	Jun 2030	-	334	Filed
Abilify	Oral	Otsuka Holdings	Apr 2015	4,638	331	Marketed

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