

J&J readies even longer-acting Sustenna for a growing market



[Amy Brown](#)

As generics gradually erode the market for oral anti-psychotic drugs, long-acting injectables remain a growth area. Currently taking only around 5-7% of prescriptions for these medicines in the US, this share is expected to expand rapidly in coming years (see table).

The market leader, Johnson & Johnson, last week stopped a phase III trial of its even-longer acting formulation of Invega Sustenna early for efficacy. While few will be surprised that the established product managed to beat placebo, the study represents manufacturers' latest attempt to convince doctors, patients and payers of these drugs' benefits.

On track to grow

J&J said independent reviewers stopped a 509-patient trial of the three-monthly version of Sustenna – which has yet to be approved – after a planned interim analysis found that it significantly delayed time to first occurrence of relapse of symptoms of schizophrenia, compared with a sham injection. It will seek approval later this year.

The once-monthly version of Sustenna was approved back in 2009 based on, among other measures, its ability to delay time to relapse. So unless the full results from the three-monthly version, when they become available, reveal substantially improved clinical outcomes this trial in itself does not break new ground.

However, J&J will no doubt hope that the study will help dispel many concerns about these injected medicines. It is widely accepted that an infrequently injected anti-psychotic can improve compliance considerably, and as such improve the overall effectiveness. But an aversion to injections and the stigma of such a route of administration, in so much as it implies a fair degree of severity of illness, deters many patients.

This, plus the fact that with patent expiries they are ever more expensive than their oral equivalents, means that long-acting injectables accounted for only a few percentage points of the US antipsychotic market in 2013. This is expected to grow, following other regions of the world – in some European countries about a third of marketed products are estimated to be injectable.

Cowen analysts recently wrote that physicians believe the share could double to more than 10% in five years.

Proof of benefit

The table below shows that analysts expect long-acting injectables to dominate the branded market for schizophrenia meds by 2018, although this has more to do with the loss of patent protection for their oral equivalents than their own commercial triumphs.

J&J, which has long been a trailblazer with the launch of Risperdal Consta in 2002, is set to remain market leader, although Otsuka's injected version of Abilify is seen as a strong contender. And, however the market shakes out, another big player promoting the class can only help.

More entrants are likely. Alkermes, which supplies the extended-release technology for both Invega Sustenna and Risperdal Consta, will report phase III data on its version of an injectable Abilify, ALKS 9070, later this year.

However, not all have been successful. Lilly tried to get into this market with an injectable, once-monthly formulation of Zyprexa called Relprevv, but this has flopped commercially. It has been linked with post-injection delirium and last year the FDA started an investigation into two patient deaths. And, perhaps surprisingly, AstraZeneca has not tried to add to its hugely successful Seroquel franchise with an injected formulation.

By promising better compliance and therefore reduced relapse rates and, ultimately, lower costs to healthcare systems, these products do seem to present a more valuable proposition than other lifecycle extension strategies that pharma has employed. However, few rigorous clinical studies have been conducted to prove their advantages over the original pills.

As the oral anti-psychotics fall to generics and the price difference between these options becomes more apparent, J&J and its competitors will have to work even harder to convince sceptical physicians and patients that these products are really worth the extra cost.

Injected products are forecast to dominate branded atypical anti-psychotic market							
Rank	Product	Route of Admin	Company	Patent Expiry	Global sales (\$m)		
					2008	2013	2018e
1	Invega Sustenna	Injection	Johnson & Johnson	May 2019	-	1,248	2,081
2	Abilify Maintena	Injection	Otsuka Holdings	Oct 2024	-	95	1,201
6	Latuda	Oral	Dainippon Sumitomo/Takeda	Jul 2018	-	366	849
3	Risperdal Consta	Injection	Johnson & Johnson	May 2014	1,309	1,318	845
7	Invega	Oral	Johnson & Johnson	Apr 2012	326	583	767
4	Abilify	Oral	Otsuka Holdings	Apr 2015	2,967	5,501	706
5	Brexpiprazole	Oral	Otsuka Holdings	Dec 2026	-	-	636
8	Zyprexa	Oral	Eli Lilly	Oct 2011	4,696	1,195	429
9	Seroquel XR	Oral	AstraZeneca	Mar 2012	-	1,337	390
10	Seroquel	Oral	AstraZeneca	Mar 2012	4,452	345	250
				Total	17,735	13,532	11,629

To contact the writer of this story email Amy Brown in London at AmyB@epvantage.com or follow [@AmyEPVantage](https://twitter.com/AmyEPVantage) on Twitter