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PharmaPoint

**SAFINAMIDE (PARKINSON'S DISEASE) -
FORECAST AND MARKET ANALYSIS TO 2022**

Executive Summary

The table below summarizes the key metrics for Safinamide in the 8MM Parkinson's disease (PD) pharmaceutical markets in 2022.

Safinamide: Key Metrics in the 8 MM Parkinson's Disease Market	
Launch of Newron's safinamide between 2014–2015	↑↑↑
2022 Market Sales	
US	\$296.9m
5EU	\$103.6m
Japan	N/A
Brazil	\$22.7.0m
Total	\$423.2m
5EU = France, Germany, Italy, Spain, and UK; 8MM = US, 5EU, Japan, and Canada	
Source: GlobalData: N/A = not available	

Sales for Safinamide in Parkinson's Disease Market

Newron is expected to first launch Safinamide in the 5EU in 2014. In its first year, sales of Safinamide in the Parkinson's disease market are projected to reach \$4 million. By 2022, global sales are projected to increase to \$423.2 million.

Major growth drivers for Safinamide in the PD market over the forecast period include:

- Provides symptomatic benefit in both early- and advanced-stage patients
- Selectivity for MAO-B better than others in class, may eliminate the need to adhere to a low tyramine diet
- New mechanism of action, with additional activity in the glutamate pathway

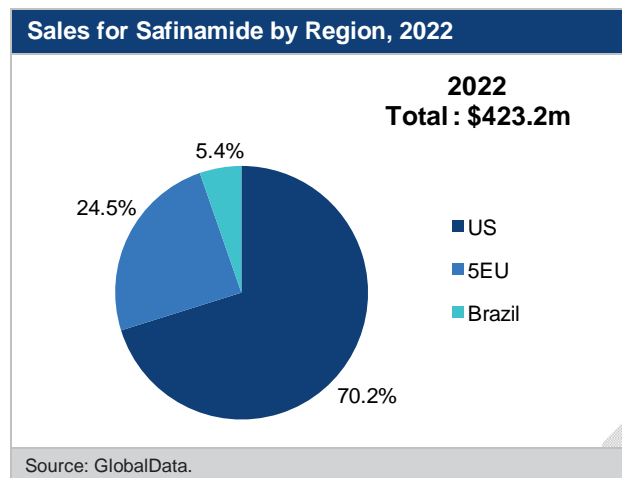
- Good safety profile makes safinamide an option for treatment in most patients, including in older patients or in more advanced stages.
- Establishing marketing deals with Zambon (worldwide) and Meiji Seika (Japan) was a strategic move on behalf of the young and inexperienced biopharmaceutical company, Newron, established in 1999. The partnerships will bring experience in filing for regulatory approval, drug manufacturing, sales, and marketing, allowing Newron to expand its company under the successes of safinamide.

Major barriers of growth for Safinamide in the PD market over the forecast period include:

- Similar to other MAO-B inhibitors, symptomatic benefit is mild
- Activity as a glutamate release inhibitor appears weak and has not been effectively proven.

Executive Summary

The figure below presents the global Safinamide sales by region in 2022.



What Do the Physicians Think?

Physicians state that motor complications remain a major unmet need and stress the impact that an anti-dyskinetic medication would have on the treatment of Parkinson's disease.

"Let's say if we do not consider what is untreatable today [balance, falls, dementia], then the main challenge is probably treating dyskinesia."

[EU] KOL, November 2013

"Wearing-off wouldn't be a problem, if the patients do not develop severe dyskinesia. Because if you can control dyskinesia, then you can use the drug [at a] high enough [dose] to control any motor fluctuation. So wearing-off itself, it's easier to treat. The problem is most patients with wearing-off, they do have dyskinesia too, and when you try to adjust the dose in order to control wearing-off, then the patient may develop dyskinesia, or a worsening form of dyskinesia."

[EU] KOL, November 2013

"I think sometimes we're a bit dismissive in saying we don't see the motor complications that we used to see, and I think that's true, because we've got a range of different drugs. But, some people are really still struggling. Twenty percent of the day they're OFF, [while] twenty percent of the day they're dyskinetic. That's forty percent of the day that's bad for them, and we say, 'well, it's not as bad as the bad ol' days,' but it's still pretty bad for them... We still don't really have an oral drug that is anti-dyskinetic."

[EU] KOL, October 2013

Executive Summary

"The most challenging [unmet need]... Every day I see a few patients for whom treatment is very challenging to me, particularly patients with marked wearing-off, with dyskinesia during ON, it's very difficult to treat with the current medication. If they are eligible for deep brain stimulation, it's okay, but patients over [age] 75, with marked wearing-off, dyskinesia, falling down, and freezing, it's very difficult to treat. And it's very challenging."

[OUS] KOL, November 2013

Physicians believe that the introduction of slow-release levodopa will have a significant impact on the market and be preferred over immediate-release formulations.

"Extended-release levodopa will take the place of regular drugs [immediate-release levodopa]. Even in the early phase of the disease, they are better for patients and will reduce the amount of fluctuations in later disease, as they progress. If they [slow-release levodopa therapies] were available, I would prescribe them over the immediate-release formulations [in early stage]."

[OUS] KOL, November 2013

"If extended release of levodopa are available we may choose such agents as initial therapies, not only in advanced cases but as initial therapy."

[OUS] KOL, November 2013

Current therapeutic options are limited to symptomatic control and do not treat the underlying disease. Although there are no late-stage therapies that will be launched to meet this need during the forecast period, physicians believe that early pipeline agents hold the promise of becoming one of the most significant advancements for PD in recent history.

"At this point, it's not [enough] to show that you can have an improvement of one hour of time. It's interesting, and it should be the first step. But we [are] wait[ing] for the next step; we [are] wait[ing] for drugs that have disease-modifying properties. Meaning that if we take [these drugs], we can have a better fate than not having these drugs for six month[s] or one year... I'm afraid that if a drug could arrive on the market, it will not have a huge impact if it just [demonstrates] symptomatic improvement of one hour of time."

[EU] KOL, November 2013

"Current treatment options are all symptomatic treatments, therefore many people want to discover disease-modifying treatments for Parkinson's disease, but none have been successful yet."

[OUS] KOL, November 2013

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Introduction

2 Introduction

2.1 Catalyst

The Parkinson's disease market is expected to grow from \$3.6 billion to \$5.3 billion over the 10-year forecast period. A major driving force behind this is the increase in the global population and advancements in healthcare that contribute to an aging population at increased risk for Parkinson's disease. The population of Parkinson's disease patients is expected to increase from 3.2 million people in 2012 to 4.3 million in 2022 in the eight major markets covered. The market for Parkinson's disease is expected to grow as it is the second most common neurological disorder, with an increased prevalence in the elderly.

Parkinson's disease has had a history of successful drugs that are highly effective; however, unmet needs remain. Advancements in technology and drug delivery systems have driven growth in this market during the forecast period and made it a less risky market than other neurological conditions, while still holding potential for a big payout. While all products to this point have treated the signs and symptoms of Parkinson's disease rather than the underlying condition, the growing understanding of the nervous system holds promise for a breakthrough in the development of disease-modifying agents. Ample opportunity in the Parkinson's disease market remains. As most products have been launched by collaborative efforts of at least two companies, we expect such strategic partnerships to continue during the coming decade in the market for Parkinson's disease.

2.2 Related Reports

- GlobalData (2013) EpiCast: Parkinson's Disease – Epidemiology Forecast to 2022, November 2013, GDHCER043
- GlobalData (2012) PharmaPoint: Alzheimer's Disease – Global Drug Forecast and Market Analysis to 2022, July 2013 GDHC016PIDR.
- GlobalData (2014). PharmaPoint: Parkinson's Disease – Global Drug Forecast and Market Analysis to 2022, March 2014, GDHC82PIDR
- GlobalData (2014). Parkinson's Disease – US Drug Forecast and Market Analysis to 2022, March 2014, GDHC235CFR

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- GlobalData (2014). Parkinson's Disease – 5EU Drug Forecast and Market Analysis to 2022, March 2014, GDHC236CFR
- GlobalData (2014). Parkinson's Disease – Japan Drug Forecast and Market Analysis to 2022, March 2014, GDHC237CFR
- GlobalData (2014). Parkinson's Disease – Brazil Drug Forecast and Market Analysis to 2022, March 2014, GDHC238CFR
- GlobalData (2014). Madopar (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC389DFR
- GlobalData (2014). Sinemet (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC390DFR
- GlobalData (2014). Duodopa (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC391DFR
- GlobalData (2014). Stalevo/Comtan (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC392DFR
- GlobalData (2014). Neupro (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC393DFR
- GlobalData (2014). Requip/Requip XL (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC394DFR
- GlobalData (2014). Apokyn (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC395DFR
- GlobalData (2014). Azilect (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC396DFR
- GlobalData (2014). Nourias (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC397DFR
- GlobalData (2014). Tozadenant (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC399DFR

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- GlobalData (2014). CVT-301 (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC400DFR
- GlobalData (2014). Rytary/IPX066 (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC401DFR
- GlobalData (2014). Opicapone (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC402DFR
- GlobalData (2014). Mavoglurant/AFQ056 (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC403DFR
- GlobalData (2014). CD/LD-GR (Parkinson's Disease) – Forecast and Market Analysis to 2022, March 2014, GDHC404DFR
- GlobalData (2014). Parkinson's Disease – Current and Future Players, March 2014, GDHC1033FPR

Appendix

9.7 About GlobalData

GlobalData is a leading global provider of business intelligence in the Healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

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