

# **2019 US NOURIANZ™ (Istradefylline) Commercial Update**

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**Kyowa Kirin Co., Ltd.**

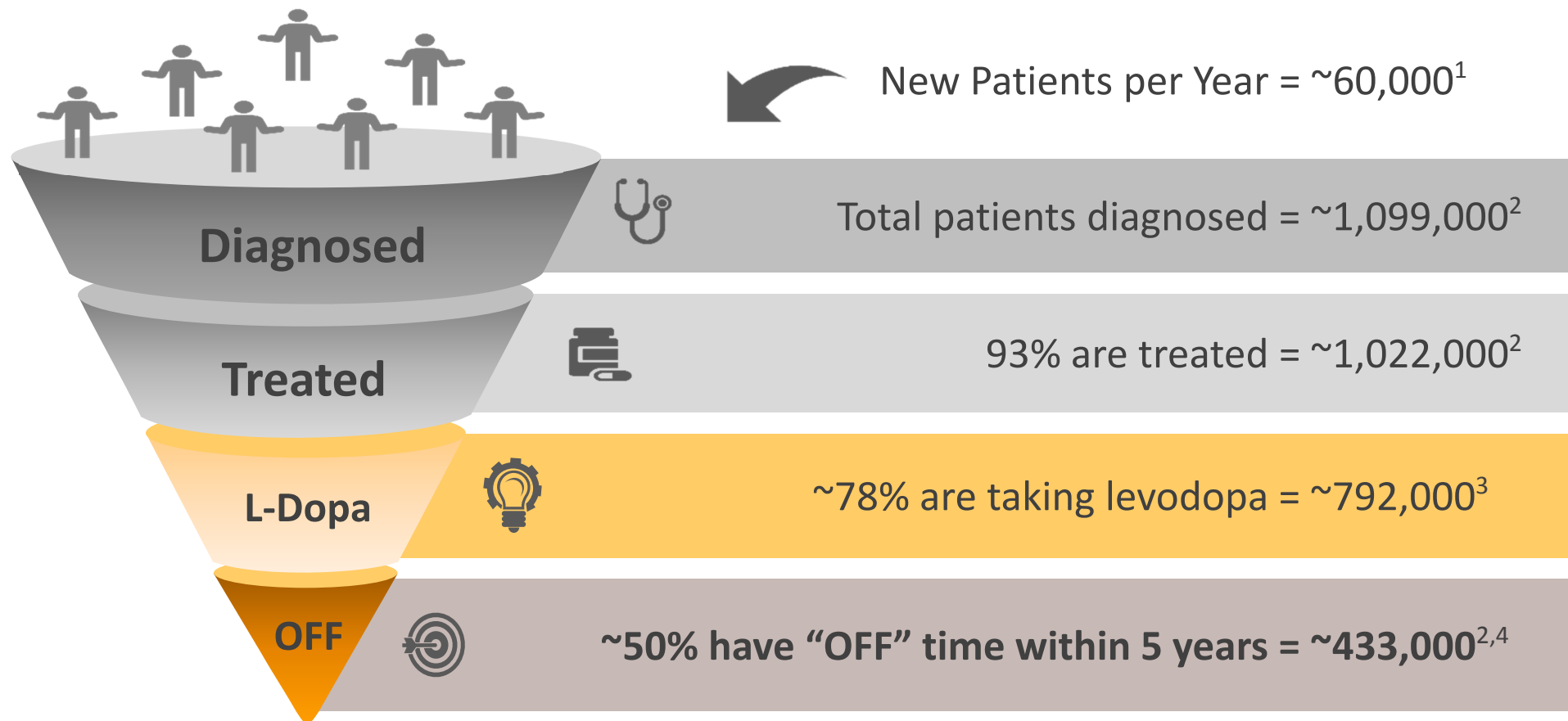
**KYOWA KIRIN**

# Agenda

-  **US Parkinson's Disease Market Dynamics** 01
-  **NOURIANZ Launch Priorities** 02
-  **2020 NOURIANZ Brand Strategy** 03

# Patients with off-time are a subset of the PD population

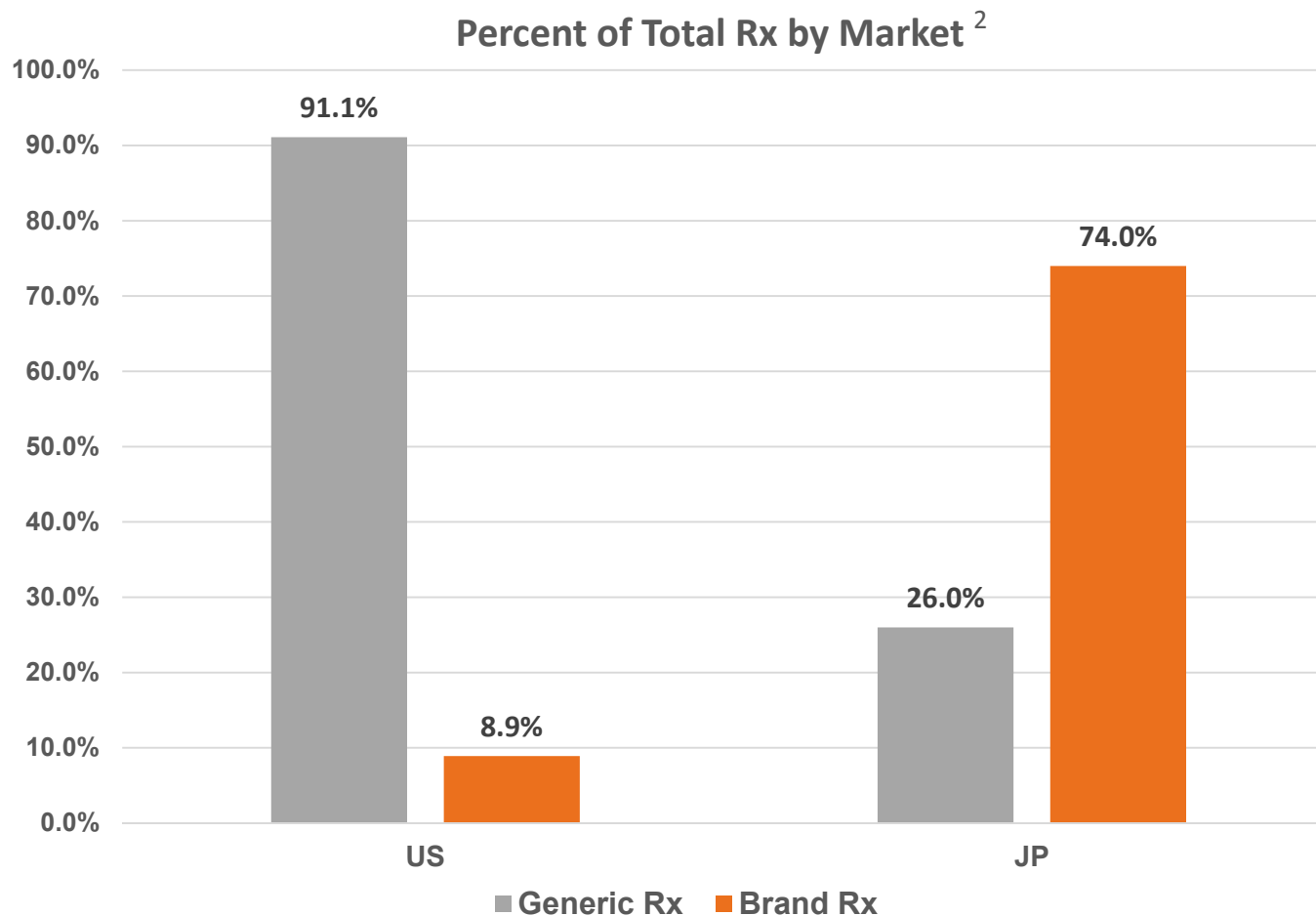
Up to ~433k Patients are on Levodopa therapy and have “OFF” time in the US



1. Parkinson’s Foundation. <https://parkinson.org/Understanding-Parkinsons/Statistics>. Accessed May 16, 2019. 2. Decision Resources Group. Parkinson’s Disease. Epidemiology Mature Markets. 3. Decisions Resource Group – Market Forecast Assumptions March 2019. 4. Hickey P, et al. *Drug Des Devel Ther.* 2011;5:241-254.

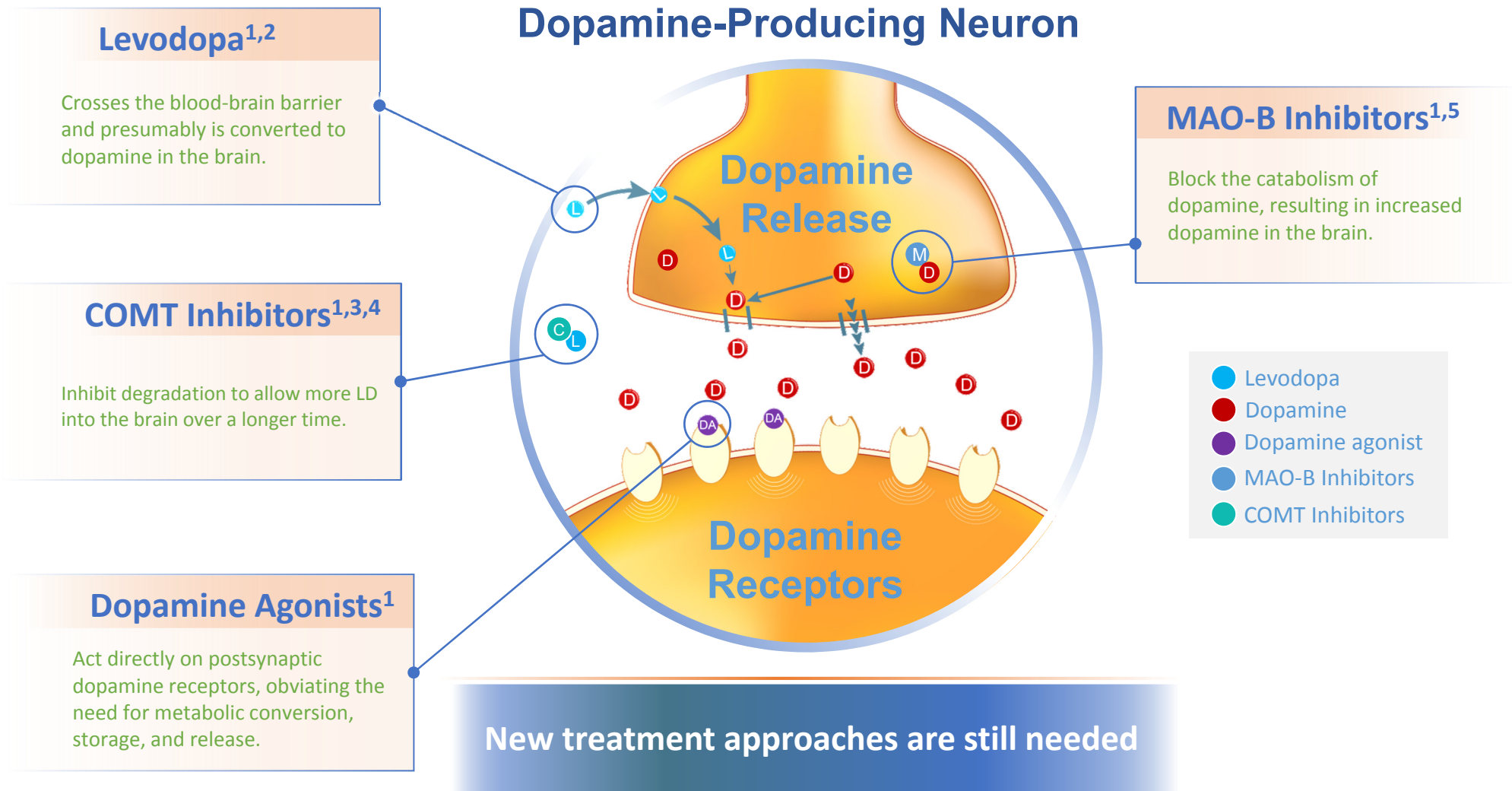
# US PD market is dominated by generic prescriptions

In the U.S., Brand volume accounts for ~8.9% of 3.8M PD prescriptions a year<sup>1</sup>



Sources: Data compiled from Decision Resource Group report: Parkinson’s Disease: Disease Landscape and Forecast, 2017.

# Current treatment options enhance or mimic dopamine to address the symptoms of PD, but wearing off occurs as condition progresses

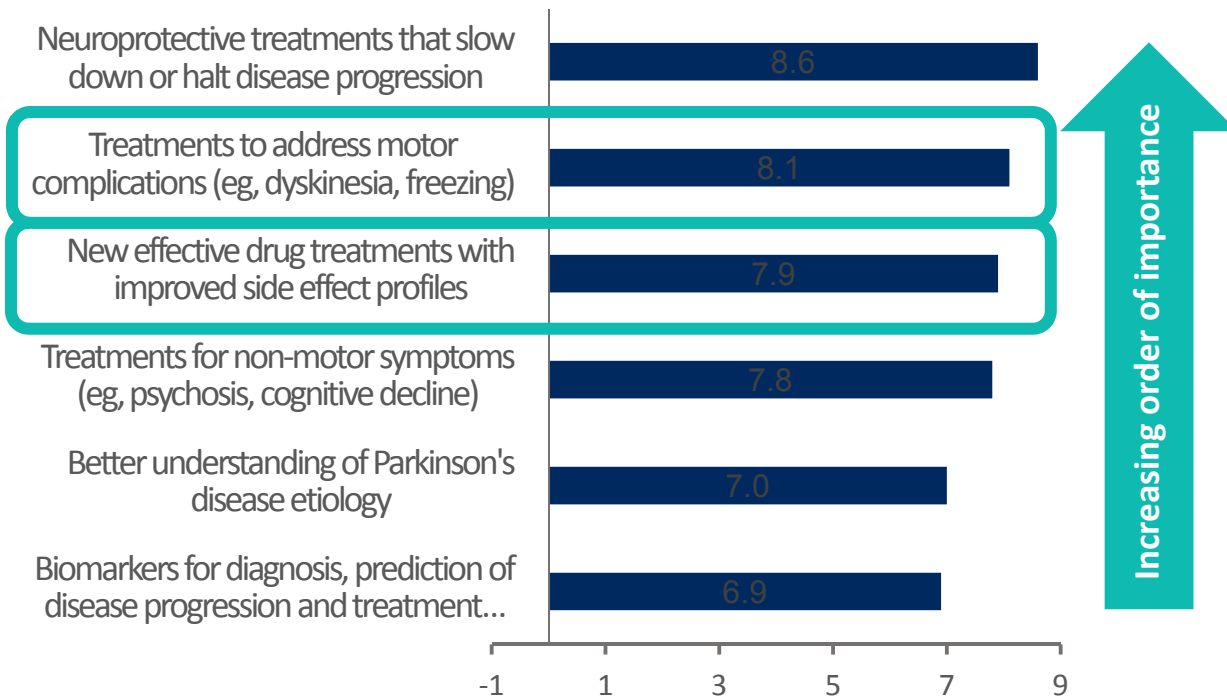


MAO-B, monoamine oxidase type B.

1. Hauser RA. Medscape. <https://emedicine.medscape.com/article/1831191-overview>. Accessed June 24, 2019. 2. Gandhi KR, et al. <https://www.ncbi.nlm.nih.gov/books/NBK482140/>. Accessed June 24, 2019. 3. COMT Inhibitors. <https://parkinsonsdisease.net/medications/comt-inhibitors>. Accessed June 24, 2019. 4. NICE. Parkinson's disease in adults. <https://www.nice.org.uk/guidance/ng71/resources/parkinsons-disease-in-adults-pdf-1837629189061>. Accessed June 24, 2019. 5. Mayo Clinic. <https://www.mayoclinic.org/diseases-conditions/depression/in-depth/maois/art-20043992>. Accessed June 24, 2019.

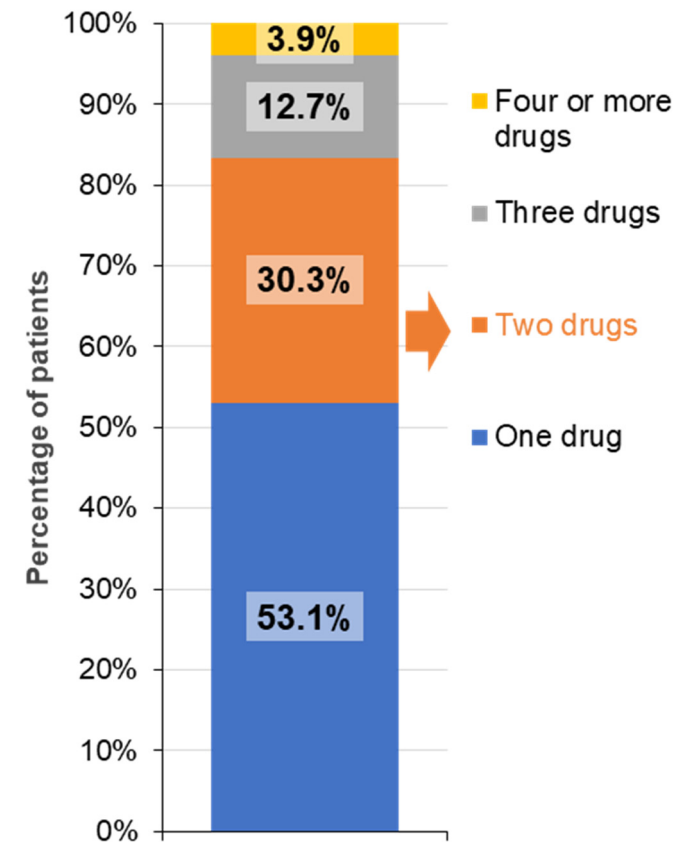
# Surveys indicate off-time remains an unmet need, yet many patients are only treated with 1-2 PD medications

Survey Unmet Needs in Parkinson's Disease<sup>1</sup>



**Note:** Respondents were asked how drug developers should prioritize addressing each of the treatment challenges listed above. They rated the treatment challenges using a scale of 1 to 10, where 1 is very low priority and 10 is very high priority. The bar chart displays the mean rating attributed to each treatment challenge across the seven surveyed markets.

Drug Burden for Parkinson's Disease<sup>2</sup>



Source: 1. Datamonitor Healthcare's Treatment: Parkinson's disease proprietary survey, June 2016, p. 60

2. Decisions Resource Group – Landscape and Market Forecast Apr 2019

# 2020 NOURIANZ™ Launch Success Factors

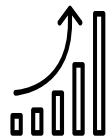
NOURIANZ is an adenosine receptor antagonist indicated as adjunctive treatment with levodopa/carbidopa in adult patients with Parkinson’s Disease (PD) experiencing “off” episodes

- 1 • Raise awareness of NOURIANZ novel MOA
- 2 • Achieve market access with Medicare and Commercial plans
- 3 • Increase awareness and advocacy among Movement Disorder Specialists and Patient Advocacy Groups

[Click here to see Important Safety Information and full US Prescribing Information](#)

# Aim to position NOURIANZ™ to be the **FIRST ADJUNCT** tx

Build understanding of new Mechanism of Action (MOA) and product profile



Mechanism of Action	Safety & Tolerability	Improved OFF Time	Simple Dosing	Manageable DDI
<ul style="list-style-type: none"> <li>• A novel MOA</li> <li>• First and only Adenosine A<sub>2A</sub> receptor antagonist approved as adjunctive treatment for “off” episodes in U.S.</li> </ul>	<ul style="list-style-type: none"> <li>• Well characterized safety and tolerability in clinical trials</li> </ul>	<ul style="list-style-type: none"> <li>• A non-dopaminergic product that reduces off-time</li> </ul>	<ul style="list-style-type: none"> <li>• Once daily dosing</li> </ul>	<ul style="list-style-type: none"> <li>• Can be used in combination with common medications used by PD patients</li> </ul>

Source: Summary of Full Prescribing Information available at <https://www.nourianzhcp.com/assets/pdf/nourianz-full-prescribing-information.pdf>



# Launch Campaign Materials – “Pathways”

## EXPLORE A DIFFERENT PATH

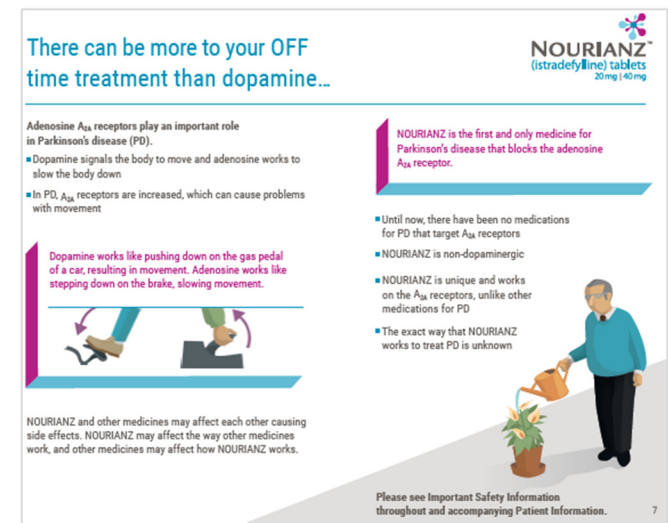
The first and only adenosine  
A<sub>2A</sub> receptor antagonist  
in Parkinson’s disease (PD)

  
**NOURIANZ™**  
(istradefylline) tablets  
20 mg | 40 mg

- Educate physicians and patients on the alternative to dopaminergic adjunct treatments



Online ads



Brochures

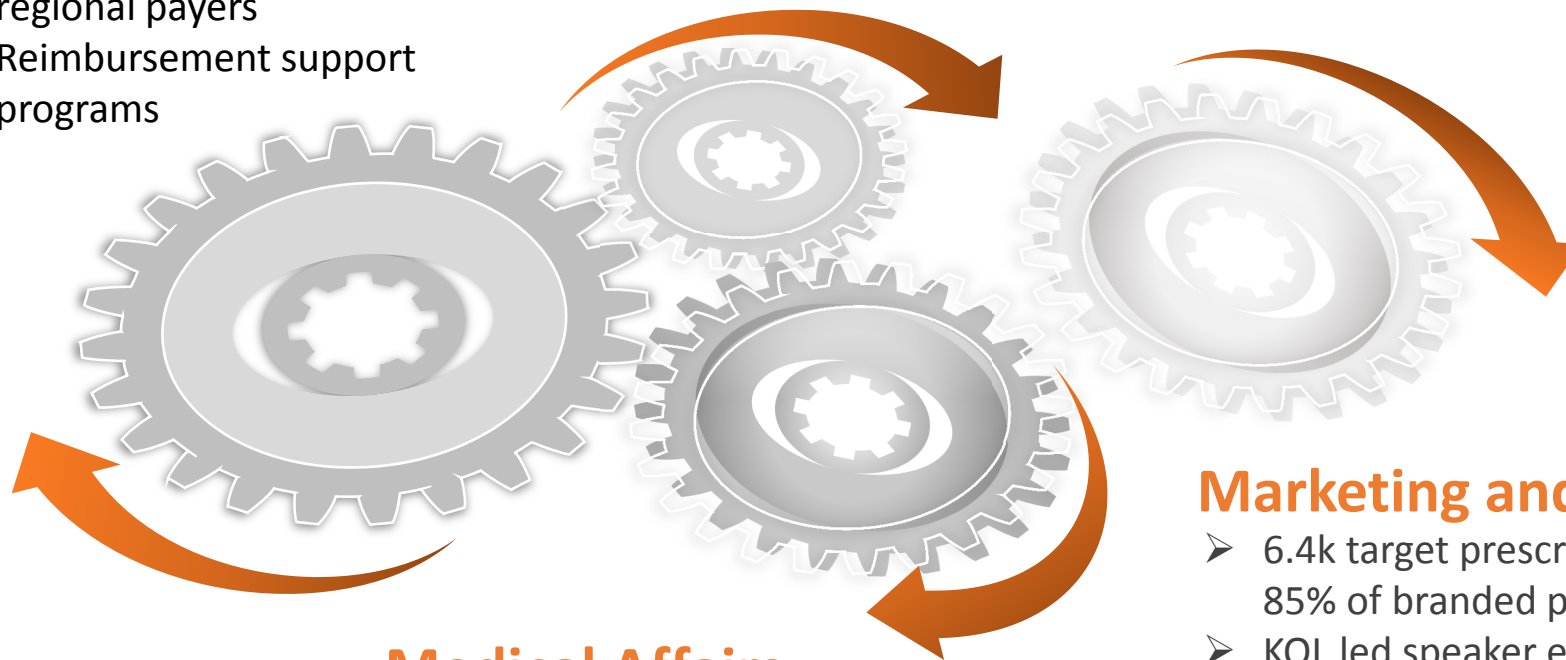
# Cross-Functional Execution for Launch Success

## Market Access

- Kyowa Kirin is engaged with key PBM's as well as national and regional payers
- Reimbursement support programs

## Corporate Communications

- Patient Advocacy Group collaboration
- Patient events and education



## Medical Affairs

- Publication of key Nourianz clinical data
- Scientific Exchange

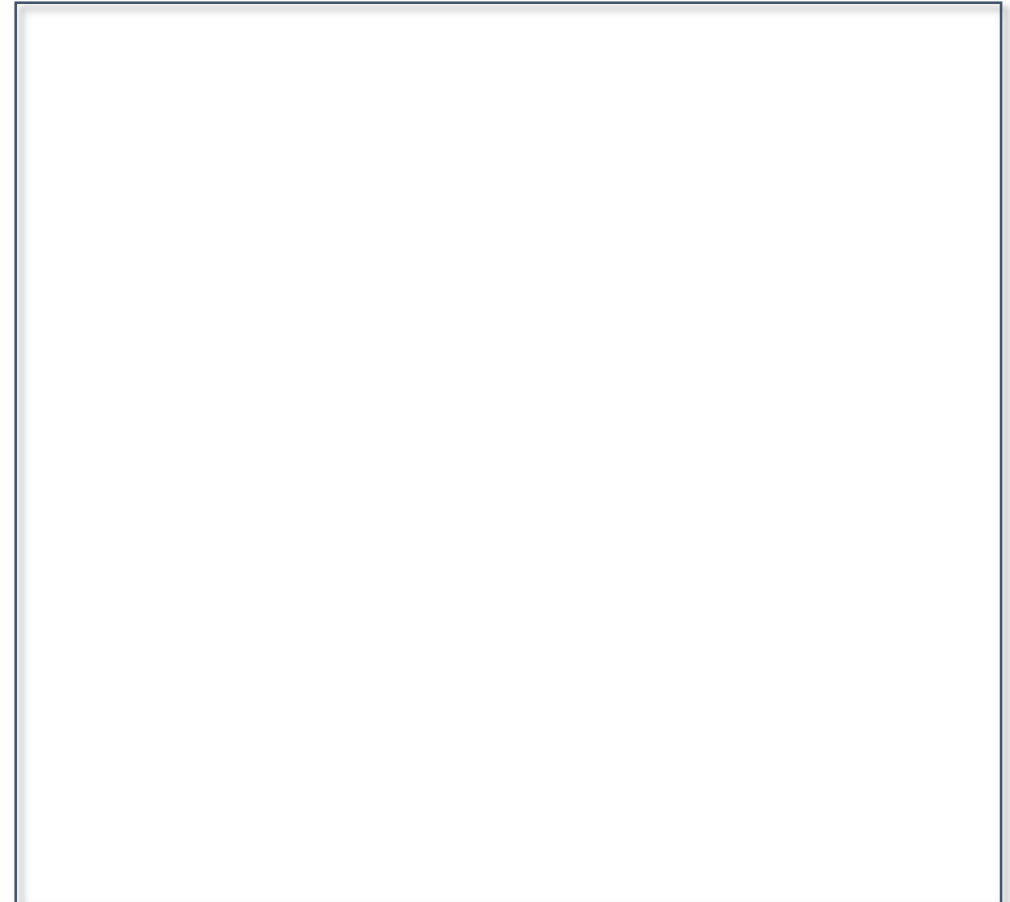
## Marketing and Field sales

- 6.4k target prescribers covering 85% of branded prescriptions
- KOL led speaker events
- Digital education for physicians, patients and caregivers
- Sample Program

## Direct to patient education- empowering people affected by Parkinson's disease

*“It has to be patient-led in order to get a change in treatment. Neurologists don't offer treatment switch, **it's up to the patient to ask.**”*

- Neurologist



Source: Final Mile Consulting. (2017). DRIVE – Research to understand the Behavioural Drivers and the Subconscious Influences of Treatment Decisions in Parkinson's Disease. Retrieved from [https://ucb-cms.krankikom.de/\\_up/ucb\\_com\\_patients/documents/DRIVE%20Report%20EXT%20use-GCCapproved%20as%20HQ-1017-NU-0079-04DEC2017.pdf](https://ucb-cms.krankikom.de/_up/ucb_com_patients/documents/DRIVE%20Report%20EXT%20use-GCCapproved%20as%20HQ-1017-NU-0079-04DEC2017.pdf).

## Wide Coverage of NOURIANZ™ news

*“In my clinical practice, I see patients who experience the troublesome effects of Parkinson’s disease and ‘off’ episodes that interfere with activities of daily living. **NOURIANZ represents an important milestone** – providing U.S. patients and their caregivers with a nondopaminergic, once-a-day oral treatment option to significantly decrease the amount of ‘off’ time.”*

Peter A. LeWitt, M.D.,  
 Professor of Neurology, Wayne State University School of Medicine and Director,  
 Parkinson's Disease and Movement Disorders Program, Henry Ford Hospital.

Press releases received **72M** total impressions and **412** NOURIANZ mentions on social media

*“Options such as NOURIANZ are a step forward in treating ‘off’ episodes... **We encourage patients to speak with their healthcare providers** if they are experiencing ‘off’ episodes.”*

Rachel Dolhun, M.D.,  
 Vice President, Medical Communications at The Michael J. Fox Foundation.

# Summary

- US PD market is competitive, however NOURIANZ provides a novel MOA
- Launch readiness activity was robust and well executed, providing foundation for launch
- KOL support will continue to grow with clinical experience
- Field teams are built, trained and now calling on physicians
- Patient education initiatives are being executed
- Negotiations with key payers are ongoing

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*These uncertain factors include, but are not limited to, potential risks of the business activities in the pharmaceutical industry in Japan and overseas, intellectual property risks, risk of side effects, regulatory risks, product defect risks, risks of changes to the prices for raw materials, risks of changes to market prices, as well as risks of changes to foreign exchange rates and financial markets.*

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