

IPX-203 for Parkinson's Disease



August 25, 2021



IPX-203 IS AN INVESTIGATIONAL PRODUCT THAT IS NOT APPROVED BY THE FDA.

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Welcome and Opening Remarks

Chirag Patel

Co-Chief Executive Officer
Amneal Pharmaceuticals, Inc.

Chintu Patel

Co-Chief Executive Officer
Amneal Pharmaceuticals, Inc.



Expanding Our Specialty Business Portfolio and Driving Growth

- Our Specialty strategy is to expand our business through organic growth, advancing our pipeline, and pursuing accretive inorganic opportunities to build our branded product presence in Neurology, Endocrinology and other therapeutic areas, through the following:
 - Leverage commercial expertise in Neurology and Endocrinology to drive growth of RYTARY® and UNITHROID®
 - Advance our key R&D programs, including IPX-203 and K-127, and maximize Kashiv’s proprietary drug delivery technologies to drive long term sustainable organic growth
 - Pursue strategic, accretive transactions that leverage our commercial infrastructure

Advancing our pipeline and accelerating transition to Specialty				
2022	2023	2024	2025	2026
DHE Autoinjector (Migraine and Cluster Headache)				
	IPX-203 (Parkinson’s)			
	K-127 (Myasthenia Gravis)			
		K-114 (Hypothyroidism, T4 sub-indication)		
			K-128 (Sialorrhea & Movement Disorders)	

- Kashiv acquisition brings R&D expertise and proprietary drug delivery technologies (GRANDE and KRONOTEC) for future innovations (e.g., new delivery of existing molecules)
- Additional pipeline not yet disclosed

Expect to launch at least one Specialty product per year starting in 2022

FDA NEW DRUG APPLICATION SUBMISSION PLANNED FOR MID-2022 | PATENTS RUN THROUGH 2034

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Unmet Needs Remain for Parkinson's Disease



Parkinson's Disease is the Fastest Growing Neurological Disorder Worldwide with ~1 Million Patients Currently Diagnosed in the United States



There is a Need for Improved CD/LD Formulations to Help Patients Experience More “Good On” Time

CURRENT TREATMENT OPTIONS

- The combination of CD/LD has been the gold standard of treatment for PD since the 1970s, but it has limitations such as an increase in “Off” time as the disease progresses
- Some treatment strategies can provide patients with more “On” time, but the quality of “On” time can remain inconsistent; furthermore, these therapies may complicate treatment regimens, which can lead to adherence challenges and increased healthcare costs

Improved CD/LD formulations are needed that can help patients function more consistently with an increase in “Good On” time per dose

IPX-203 was Developed to Potentially Help Patients Achieve More “Good On” Time with Less Frequent Dosing

- IPX-203 is a novel, oral formulation of CD/LD extended-release capsules for patients with Parkinson’s disease who have motor fluctuations
- IPX-203 was developed with an innovative formulation that contains immediate-release and extended-release granules, and mucoadhesive polymers, to provide rapid absorption and maximize levodopa absorption
- This formulation is distinct from RYTARY (carbidopa/levodopa) extended-release capsules, Amneal’s extended-release CD/LD treatment for PD approved by the U.S. FDA in 2015

Advancing the Development of IPX-203 for Parkinson's Disease

IPX-203 is a carbidopa-levodopa (CD/LD) treatment for patients with Parkinson's disease and an investigational product not approved by FDA

We are excited about the commercial opportunity that IPX-203 represents



Developed with an innovative formulation that contains immediate-release and extended-release granules, and mucoadhesive polymers, to provide rapid absorption and maximize levodopa absorption

- This formulation and delivery technology is distinct from other forms of long-acting CD/LD



Expect a broader market opportunity for IPX-203 in treating patients with Parkinson's disease

- RYTARY is successful yet represents only ~5% penetration into the broader CD/LD space



Planning to approach market launch differently than prior launches with an enhanced focus on:

- KOL engagement, proper formulary coverage, robust patient support services, and education of dose conversion



Potential to achieve more “Good On” time by delivering fast-acting and longer lasting motor symptom control

- Increased “Good On” time—“on” without troublesome dyskinesia
- More “Good On” time per dose, compared to immediate-release CD/LD



Offers reduced dosing in comparison with immediate-release CD/LD

- In Phase 3 study, IPX-203 demonstrated a statistically significant improvement in efficacy when dosed on average 3 times per day, compared to immediate-release CD/LD dosed on average 5 times per day



Note: The above listed are management's views, and do not reflect a comparison of clinical data from different studies

Experts With Us Today



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SVP, Specialty R&D,
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RISE-PD Trial Overview

Richard D'Souza, PhD

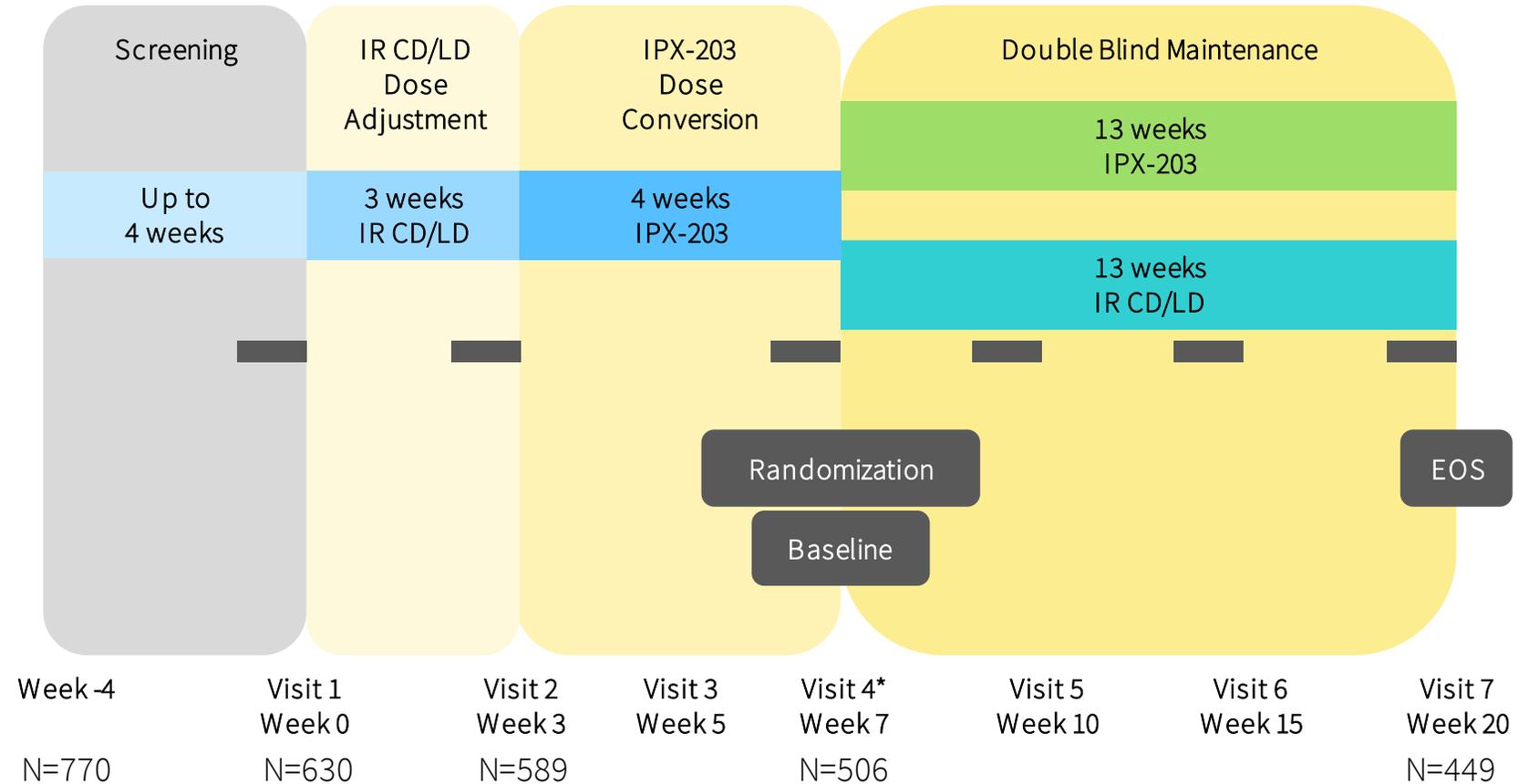
SVP, Specialty R&D

Amneal Pharmaceuticals, Inc.



IPX-203 was Studied in a Pivotal Phase 3 Clinical Trial: RISE-PD

- RISE-PD was designed to evaluate the efficacy and safety of IPX-203 in comparison with immediate-release CD/LD in the treatment of patients with PD who have motor fluctuations
- There were 630 patients enrolled and 506 patients entered randomization
- The study design was reviewed by FDA and conducted pursuant to a Special Protocol Assessment



■ PD diary (3 days)



*Subject must be on a stable dosing regimen of IPX-203 for at least 5 days prior to returning for Visit 4.
 EOS, end of study; IR CD/LD, immediate-release carbidopa/levodopa.
 IPX-203 is an investigational product that is not approved by the FDA.
 Protocol No. IPX-203-B16-02.

RISE-PD was Successful in Demonstrating Statistically Significant Improvement in Efficacy for IPX-203 Compared With Immediate-Release CD/LD

Primary Endpoint:

- IPX-203 treatment resulted in 0.53 more hours of “Good On” time than immediate-release CD/LD ($p=0.0194$), when comparing change from baseline (Week 7) in both study arms
 - IPX-203 was dosed on average 3 times per day and immediate-release CD/LD was dosed on average 5 times per day

Secondary Endpoints:

- IPX-203 resulted in significantly less “Off” time compared with immediate-release CD/LD (-0.48 hr, $p=0.0252$)
- PGI-C scores showed 29.7% of patients treated with IPX-203 were “much improved” or “very much improved” compared with 18.8% of patients treated with immediate-release CD/LD ($p=0.0015$)
- IPX-203 change in baseline scores for MDS-UPDRS Part III or sum of MDS-UPDRS Parts II and III were similar to those of immediate-release CD/LD

Post Hoc Analysis:

- IPX-203 increased “Good On” time by 1.55 more hours per dose compared with immediate-release CD/LD ($p<0.0001$)

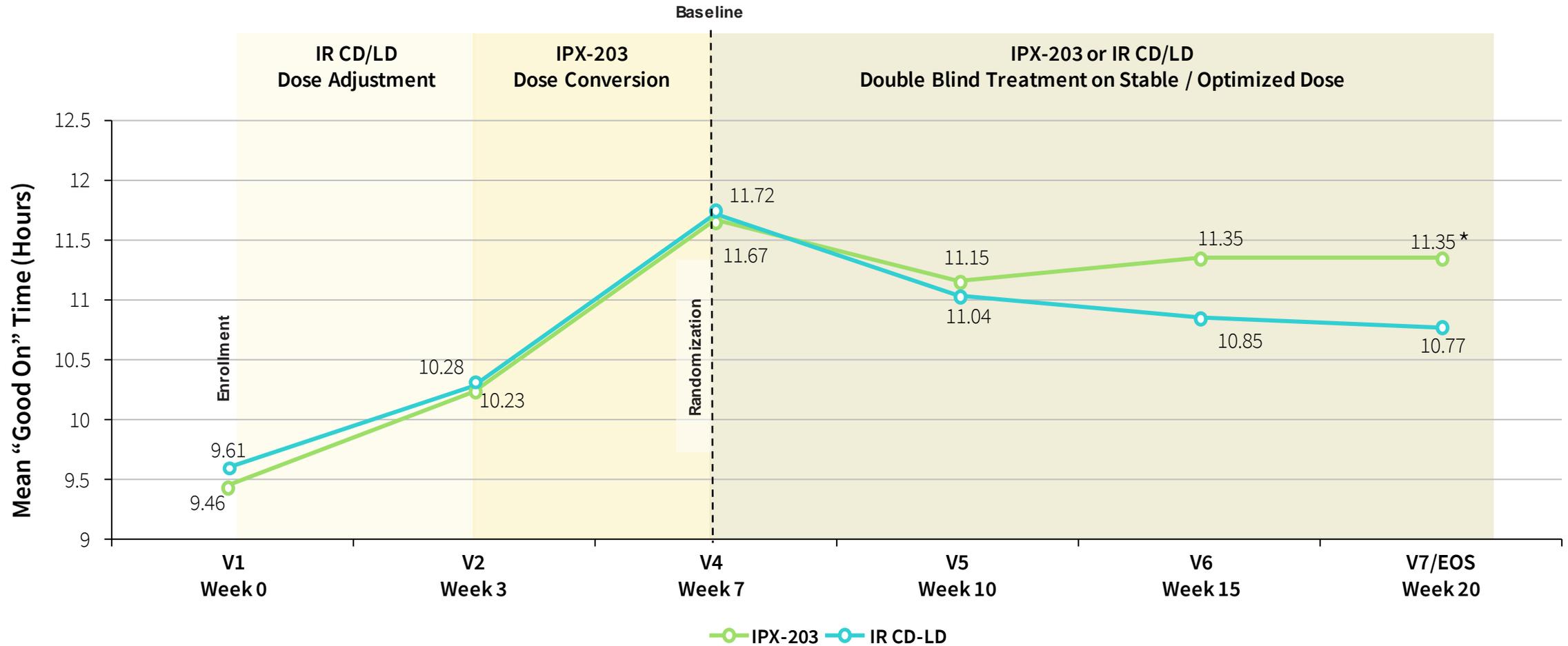
RISE-PD Results

Robert A. Hauser, MD, MBA, FAAN
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University of Cincinnati Academic Health Center



IPX-203 Demonstrated a Statistically Significant Improvement in “Good On” Time From Baseline to End of Study

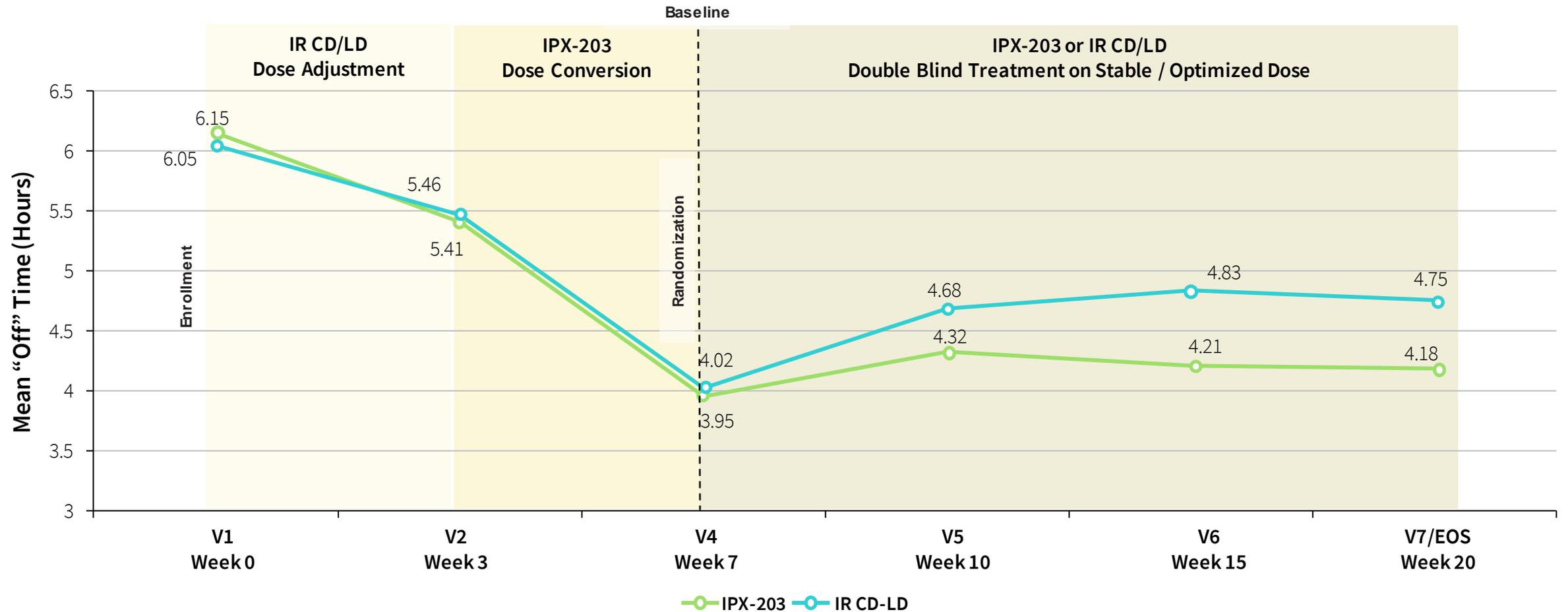


- The change in amount of “Good On” time from baseline to end of study was the primary endpoint of the study.



*p=0.0194 IPX-203 vs. IR CD/LD
 IR CD/LD, immediate-release carbidopa/levodopa.

IPX-203 Demonstrated a Statistically Significant Reduction in “Off” Time From Baseline to End of Study



- The change in amount of “Off” time from baseline to end of study was a secondary endpoint of the study.



*p=0.0252 IPX-203 vs. IR CD/LD
 IR CD/LD, immediate-release carbidopa/levodopa.

RISE-PD Secondary Endpoints

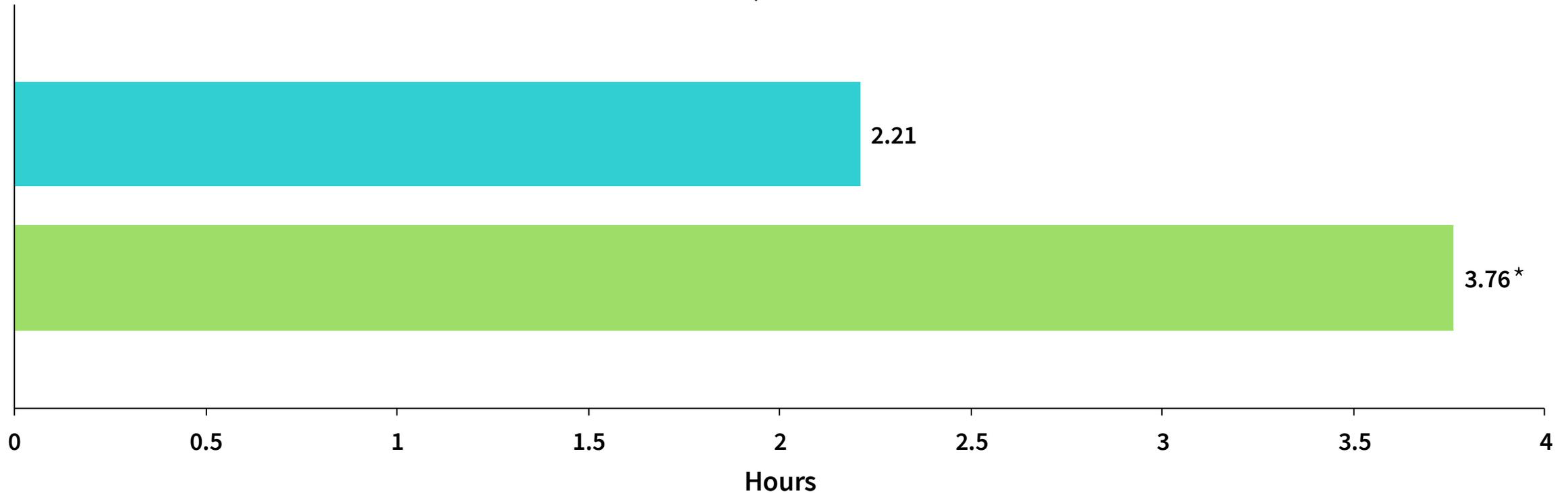
	Enrollment	Week 7 Baseline (Randomization)	Week 20 End of Study (or Early Termination)	p-value
Percent of patients reporting “much improved” or “very much improved” score on PGI-C scale				
IPX-203	N/A	N/A	29.7%	0.0015
IRCD/LD	N/A	N/A	18.8%	
Mean MDS-UPDRS Part III score				
IPX-203	29.6	26.9	27.8	0.9587
IRCD/LD	29.7	27.0	28.0	
Mean MDS-UPDRS Sum of Part II + III score				
IPX-203	42.9	38.9	40.6	0.9668
IRCD/LD	42.9	39.3	41.1	



Post Hoc Analysis: IPX-203 Provided 1.55 More Hours of “Good On” Time Per Dose Compared With Immediate-Release CD/LD

“Good On” time per dose at EOS (Week 20)

■ IR CD/LD ■ IPX-203



*LS Mean difference = 1.55h, p<0.0001.
EOS, end of study; IR CD/LD, immediate-release carbidopa/levodopa; LS, least squares.

Most Common Adverse Events in RISE-PD

Most Common Adverse Events Occurring in $\geq 3\%$ of Patients

	IPX-203		IR CD/LD	
	Dose conversion (N=589)	Maintenance (N=256)	Dose adjustment (N=630)	Maintenance (N=250)
Nausea	4.9%	4.3%	1.1%	0.8%
Dry mouth	4.2%	1.2%	0.3%	0.8%
Urinary tract infection	1.2%	1.6%	0.2%	3.2%
Fall	2.2%	2.0%	1.0%	3.6%

Summary and Next Steps



- Phase 3 study successfully demonstrated a statistically significant improvement in efficacy of IPX-203 compared to immediate-release CD/LD, even when IPX-203 was dosed on average 3 times per day and immediate-release CD/LD was dosed on average 5 times per day
- Based on these topline results plus other supportive data, Amneal plans to submit an NDA for IPX-203 with the U.S. FDA in mid-2022
- Begin market analysis and commercial assessments as we build out our go to market strategy for IPX-203



Q&A

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