PD IS A COMPLEX, PROGRESSIVE DISORDER THAT PLACES A SIGNIFICANTLY INCREASING BURDEN ON PATIENTS AND CARE PARTNERS

The course of PD does not follow a clear trajectory. Each patient experiences his or her own individualized journey.[1-4]

PRODROMAL | **ADVANCED STAGE** | **LATE STAGE**

Gradual Development
A range of symptoms appear slowly, with nonmotor symptoms often preceding motor symptoms[1-3]

Motor and Nonmotor Symptoms

Diagnosis
Fear, shock, sadness, or denial[4]

Sustaining Control
Symptom relief during the first few years of dopaminergic treatment[5,6]

Wearing-off and Dyskinesia
Decline in the duration of benefit from each dose[5,6]

Striving for Control
Introduction of various treatments, mainly adjunct, to control motor fluctuations[5]

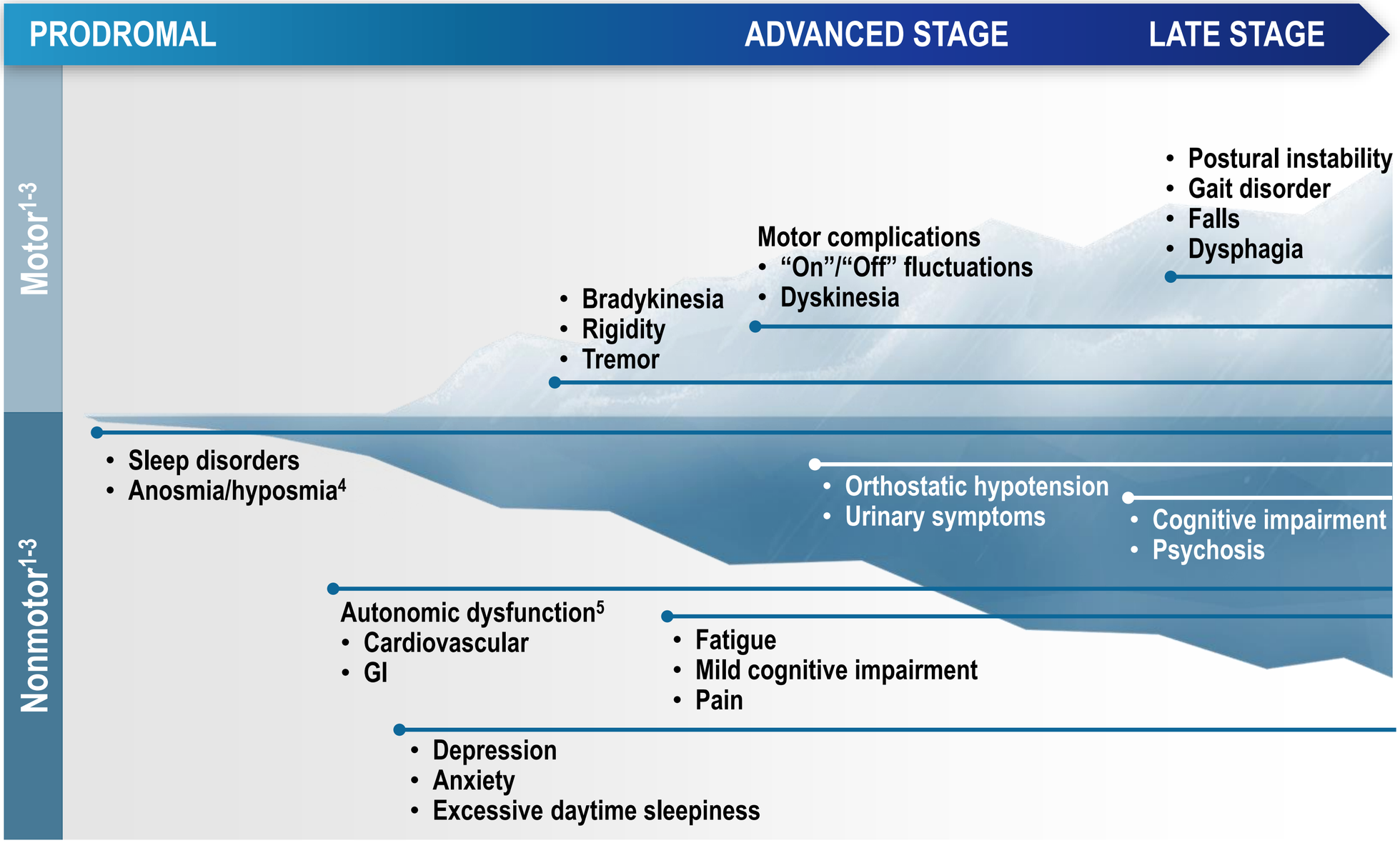
Loss of Independence
Worsening disability requires increasing support from a care partner; disruption of work and daily tasks (eg, driving)[3,7]

PSYCHOSOCIAL IMPACTS WORSEN THROUGHOUT THE COURSE OF PD[3,7,8]

- Lower self-esteem
- Loss of identity
- Living in uncertainty

- Changes in relationships
- Social withdrawal
- Increased burden for care partner

PD IS A PROGRESSIVE MULTISYSTEM DISORDER CHARACTERIZED BY MOTOR AND NONMOTOR SYMPTOMS



GI=gastrointestinal.

1. Poewe W, et al. *Nat Rev Dis Primers.* 2017;3:17013. 2. Kalia LV, et al. *Lancet.* 2015;386(9996):896-912. 3. Reichmann H, et al. *Eur Neurol Rev.* 2015;10(2):182-188. 4. Tarakad A, et al. *Int Rev Neurobiol.* 2017;133:541-556. 5. Merola A, et al. *Mov Disord.* 2018;33(3):391-397.

THE THERAPEUTIC WINDOW OF LEVODOPA RESPONSE DIMINISHES WITH DISEASE PROGRESSION[1-8]

Pulsatile Stimulation | **Continuous Stimulation**

EARLY STAGE

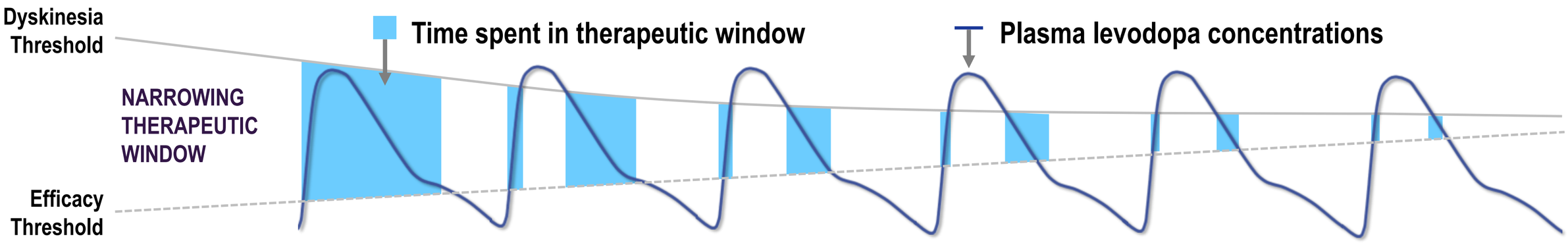
- Smooth, extended response
- Absent or infrequent dyskinesia

ADVANCED STAGE

- Diminished duration of response
- Increased “Off” fluctuations between doses
- Increased incidence of dyskinesia

LATE STAGE

- Shorter, unpredictable “On” time with increased dyskinesia



Effect of GI Dysfunction on Levodopa Availability

Remaining DA neurons maintain relatively constant DA levels

DA TERMINALS IN THE STRIATUM

As DA neurons degenerate, intrasynaptic concentrations reflect drug levels

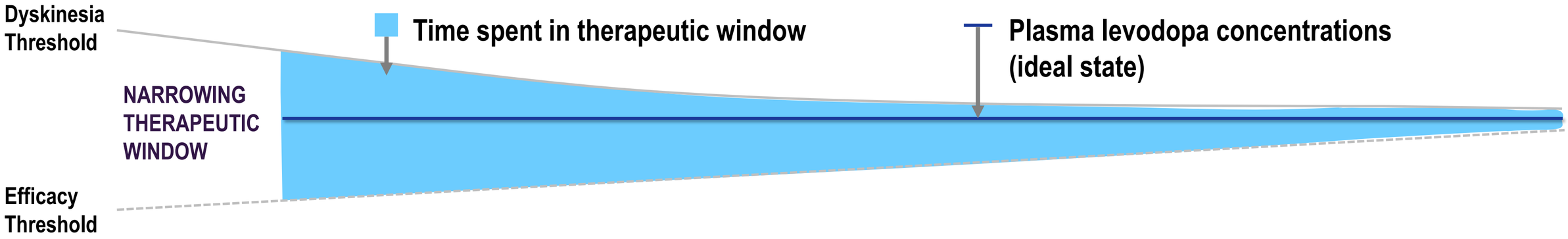
CONTINUOUS LEVODOPA DELIVERY MAY HELP PATIENTS STAY WITHIN THE NARROWING THERAPEUTIC WINDOW[1-7]

Pulsatile Stimulation | **Continuous Stimulation**

EARLY STAGE → ADVANCED STAGE → LATE STAGE

Goal of continuous therapy is to promote stable levels of dopamine in an effort to:

- Reduce “Off” fluctuations and dyskinesia
- Increase “On” time without dyskinesia



Effect of GI Symptoms on Levodopa Availability +

Remaining DA neurons maintain relatively constant DA levels

As DA neurons degenerate, intrasynaptic concentrations reflect drug levels

DA TERMINALS IN THE STRIATUM

LEVODOPA AVAILABILITY IS AFFECTED BY GI DYSFUNCTION

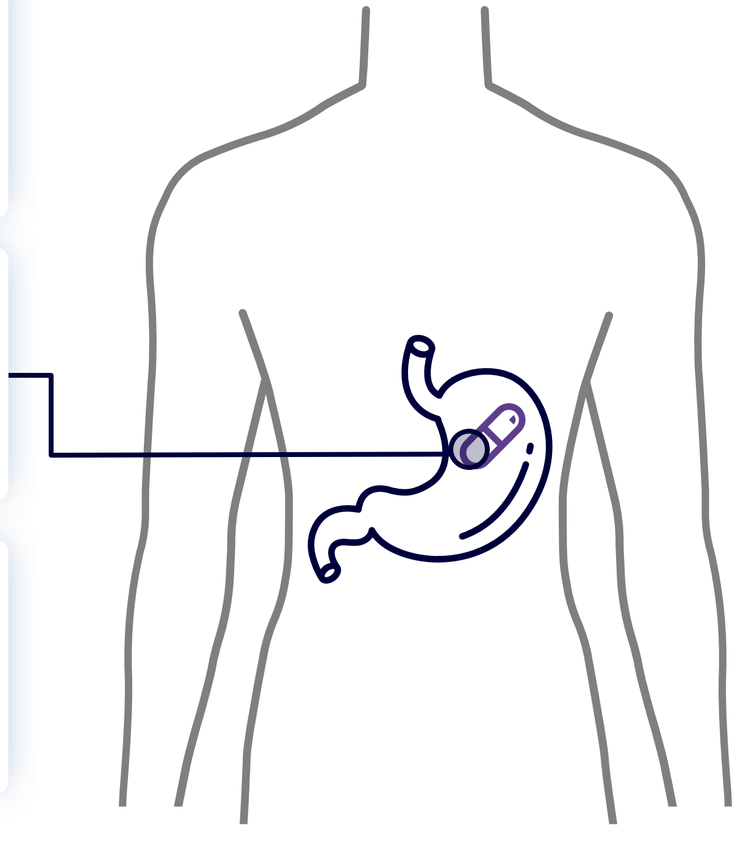
Approximately 70-100% of patients with PD are affected by gastroparesis[1,2]

Impaired gastric emptying contributes to fluctuations and delays in clinical response among patients on long-term oral LD therapy[1]

LD is mainly absorbed in the proximal small intestine[3]

Oral LD may be trapped in the stomach and degraded by gastric secretions, reducing drug availability[2,4]

CD/LD tablets can remain intact in the stomach 1.5 hours after ingestion[5]



CD=carbidopa; GI=gastrointestinal; LD=levodopa; PD=Parkinson's disease.

1. Marrinan S, et al. *Mov Disord.* 2014;29(1):23-32. 2. Heetun ZS, et al. *Parkinsonism Relat Disord*. 2012;18(5):433-440. 3. Varanese F, et al. *Parkinsons Dis*. 2011;2010:480260.
4. Stocchi F. *Parkinsonism Relat Disord*. 2009;15(Suppl 3):S68-S71. 5. Fasano A, et al. *Lancet Neurol.* 2015;14(6):625-639.

INTRODUCTION TO FOSCARBIDOPA/FOSLEVODOPA CONTINUOUS SUBCUTANEOUS INFUSION SYSTEM

CDp/LDp INDICATION AND IMPORTANT SAFETY CONSIDERATIONS[1]

INDICATION

CDp/LDp is indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease.

SELECT IMPORTANT SAFETY INFORMATION

CDp/LDp is **contraindicated** in patients who currently taking a nonselective monoamine oxidase [MAO] inhibitor or have recently (within 2 weeks) taken a nonselective MAO inhibitor.

CDp/LDp may cause:

- **sudden falling asleep** during daily activities. Some patients perceived that they had no warning signs, such as excessive drowsiness. Consider discontinuing CDp/LDp in patients who report significant daytime sleepiness or episodes of falling asleep during activities that require active participation (e.g., conversations, eating).
- **hallucinations and psychosis**. There is an increased risk for hallucinations and psychosis in patients taking CDp/LDp. Patients with a major psychotic disorder should not be treated with CDp/LDp. Hallucinations may be responsive to dose reduction of CDp/LDp or other concomitantly administered medications.
- **impulse control disorders** or compulsive behavior. Consider reducing the dose or discontinuing CDp/LDp if a patient develops such urges.
- **infusion site reactions and infections**. If an infection is suspected at the infusion site, the cannula should be removed from the infusion site. If the cannula is removed for an infection, either a new cannula should be placed at a new infusion site or, in the event of a prolonged interruption, prescribe the patient oral carbidopa/levodopa until they are able to resume CDp/LDp.
- **withdrawal-emergent hyperpyrexia** and confusion. Avoid sudden discontinuation or rapid dose reduction in patients taking CDp/LDp.
- **dyskinesia or exacerbation of dyskinesia**. The occurrence of dyskinesias may require a dosage reduction of CDp/LDp or other medications used to treat PD.

Monitor patients for cardiovascular ischemic events and glaucoma.

The **most common adverse reactions (CDp/LDp incidence at least 10% and greater than oral CD/LD incidence)** were infusion/catheter site reactions, infusion/catheter site infections, hallucinations, and dyskinesia.

Review CDp/LDp full Prescribing Information for additional information; visit www.rxabbvie.com or contact AbbVie Medical Information at 1-800-633-9110.

1. CDp/LDp [package insert]. North Chicago, IL: AbbVie Inc.

THE CDp/LDp SYSTEM ALLOWS FOR CONTINUOUS TREATMENT THROUGH A PORTABLE INFUSION PUMP[1-3]

Delivery

- **24 hours/day** continuous infusion of LD-based therapy
  - Replaces LD-containing medications and COMT inhibitors*
  - Can temporarily disconnect for water-based activities†

Formulation

- **CDp/LDp is converted** to CD/LD by alkaline phosphatases
- **Bypasses the gut**
  - Absorption or systemic exposure of CD/LD not affected by food or iron salts[3]

Dosing

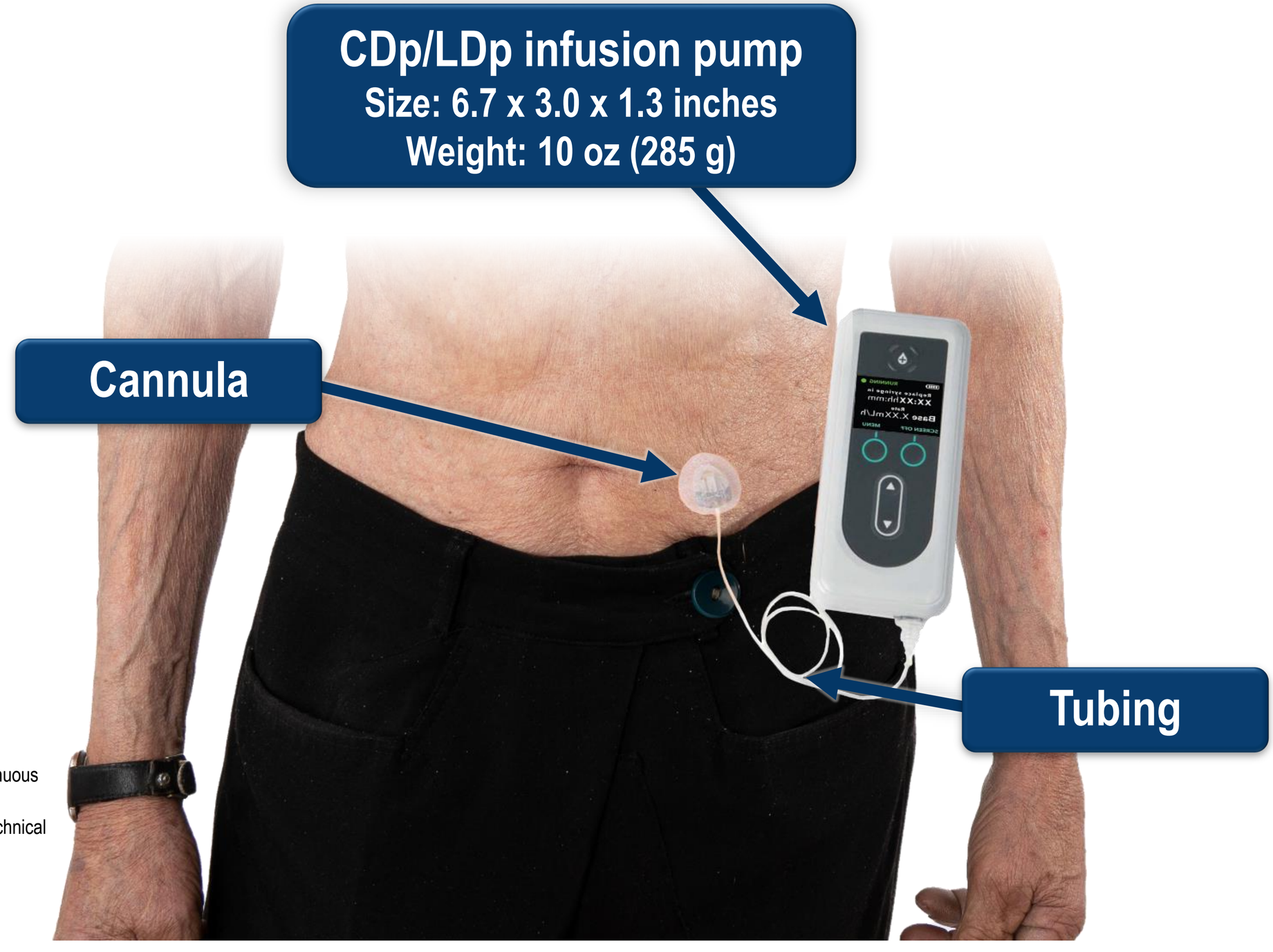
- **Individualized dosing** to address clinical needs of patients‡
  - **Precise** adjustments to hourly infusion rate by **1.7 mg LE/hr**
  - Account for changes in functional demand with alternative **low/high flow rates**§
  - Self-administered **optional loading dose** and **extra dose** functions§
  - Maximum recommended daily dose of CDp/LDp is ~2500 mg LE (3525 mg LDp)

Components of the CDp/LDp CSCI System

PK Study in PD Patients

*Prescribing a backup oral carbidopa and levodopa product is recommended in the event that delivery of CDp/LDp is interrupted, which may result in underdosing. The maximum recommended daily dosage of CDp/LDp is ~2500 mg LE (3525 mg of LDp). †Can disconnect for <1 hour without the need for replacing cannula and/or infusion-set tubing. ‡In the pivotal trial, doses ranged from ~600 to 4250 mg LE (864-6000 mg LDp). §If enabled by their healthcare professional.

COMPONENTS OF THE CDp/LDp CSCI SYSTEM[1,2]

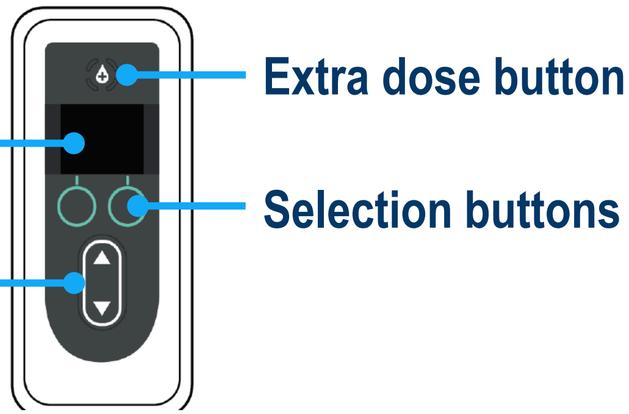


CDp/LDp=foscarbidopa/foslevodopa; CSCI=continuous subcutaneous infusion.

1. VYAFUSER™ HCP Technical Manual. Struer, Denmark.
2. VYAFUSER™ Patient Technical Manual. Struer, Denmark.

PUMP COMPONENTS[1,2]

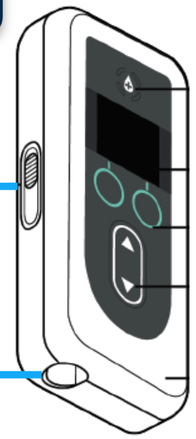
Front view



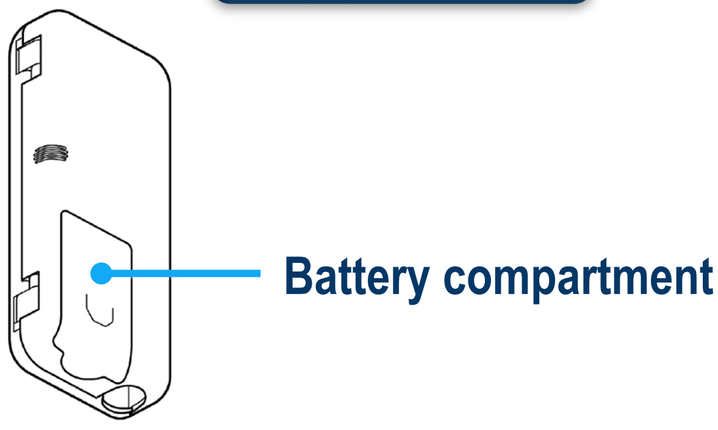
Side view (closed)

Sliding button (lid latch)
to release the lock and open the casing longitudinally

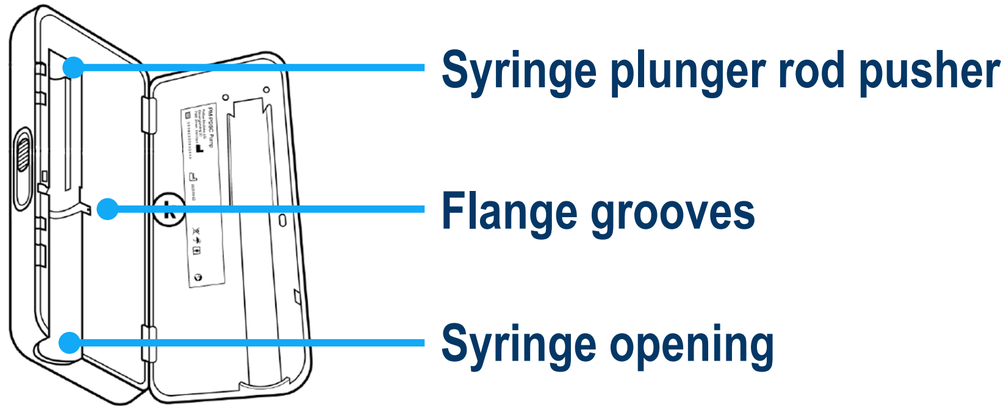
Opening
to allow the syringe tip to protrude so it can be connected to the infusion tubing



Back side view



Open view



1. VYAFUSER™ HCP Technical Manual. Struer, Denmark. 2. VYAFUSER™ Patient Technical Manual. Struer, Denmark.

Pump Delivery Methods

INDIVIDUAL COMPONENTS OF THE CDp/LDp CSCI SYSTEM[1-3]

Replaced at least once per day

Medication vial

Vial adapter

Syringe

Battery

Replaced at least once every 3 days

Tubing

Cannula insertion device with cannula

CDp/LDp=foscarbidopa/foslevodopa; CSCI=continuous subcutaneous infusion.

1. CDp/LDp [package insert]. North Chicago, IL: AbbVie Inc. 2. VYAFUSER™ HCP Technical Manual. Struer, Denmark. 3. VYAFUSER™ Patient Technical Manual. Struer, Denmark.

FOSCARBIDOPA/FOSLEVODOPA PIVOTAL TRIAL

CHANGE FROM BL TO WEEK 12 IN "ON" TIME WITHOUT TROUBLESOME DYSKINESIA AND "OFF" TIME FOR CDp/LDp VS ORAL IR CD/LD[1,2]

Select Inclusion Criteria

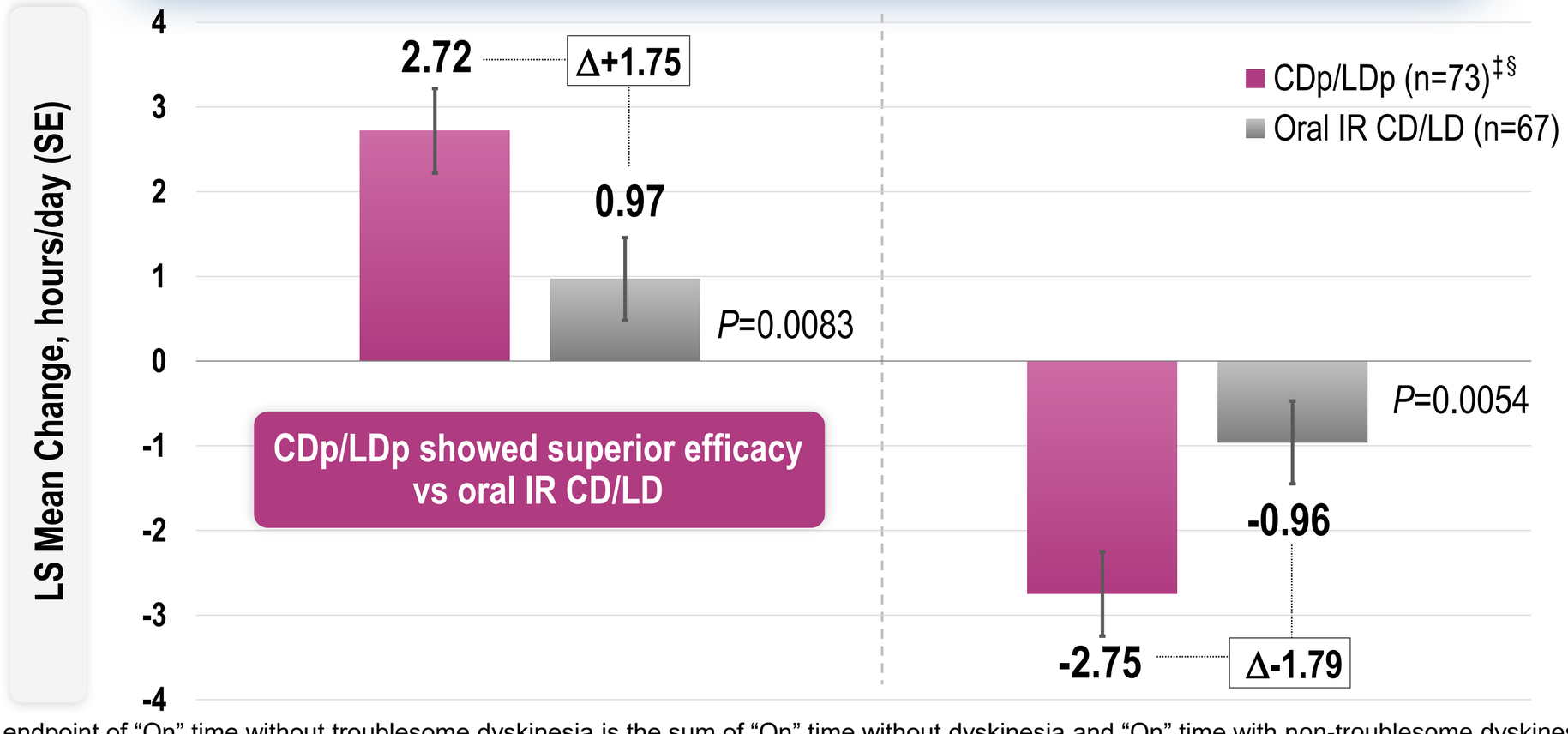
- ≥30 years of age and LD-responsive idiopathic PD
- Motor fluctuations inadequately controlled by current therapy with minimum daily average "Off" time of 2.5 hours per day

Select Exclusion Criteria

- History of significant skin conditions or disorders
- History of DBS, CLES, apomorphine, or any PD medication as continuous infusion

Primary Endpoint*
"On" Time Without Troublesome Dyskinesia

Ranked Secondary Endpoint†
"Off" Time



*Primary endpoint of "On" time without troublesome dyskinesia is the sum of "On" time without dyskinesia and "On" time with non-troublesome dyskinesia, normalized to a daily 16-hour waking day. †"Off" time as assessed using the PD diary. ‡There were 74 patients in the CDp/LDp cohort, and 1 patient did not have PD diary data. §Daily normalized "Off" and "On" times are averaged over valid PD diary days for each visit to obtain the average daily normalized times.

Study Overview
Baseline Characteristics
PD Diary
Data Visualizations

PIVOTAL TRIAL—CDp/LDp IN PATIENTS WITH ADVANCED PD[1,2]

Study

12-week randomized, double-blind, double-dummy, active-controlled, multicenter study

Primary Objective

Evaluate efficacy and safety of CDp/LDp CSCI vs oral IR CD/LD

CD/LD=carbidopa/levodopa; CDp/LDp=foscarbidopa/foslevodopa; CSCI=continuous subcutaneous infusion; IR=immediate release; PD=Parkinson's disease.

1. CDp/LDp [package insert]. North Chicago, IL: AbbVie Inc. 2. Soileau MJ, et al. *Lancet Neurol*. 2022;21(12):1099-1109.

KEY ELIGIBILITY CRITERIA[1-4]

Inclusion Criteria

- ☑ Adult patients ≥30 years of age
- ☑ Levodopa-responsive idiopathic PD*
- ☑ Motor fluctuations inadequately controlled by current therapy
- ☑ MMSE score ≥24
- ☑ Minimum daily average "Off" time of 2.5 hours per day
- ☑ Currently taking at least 400 mg of LE per day†

Exclusion Criteria

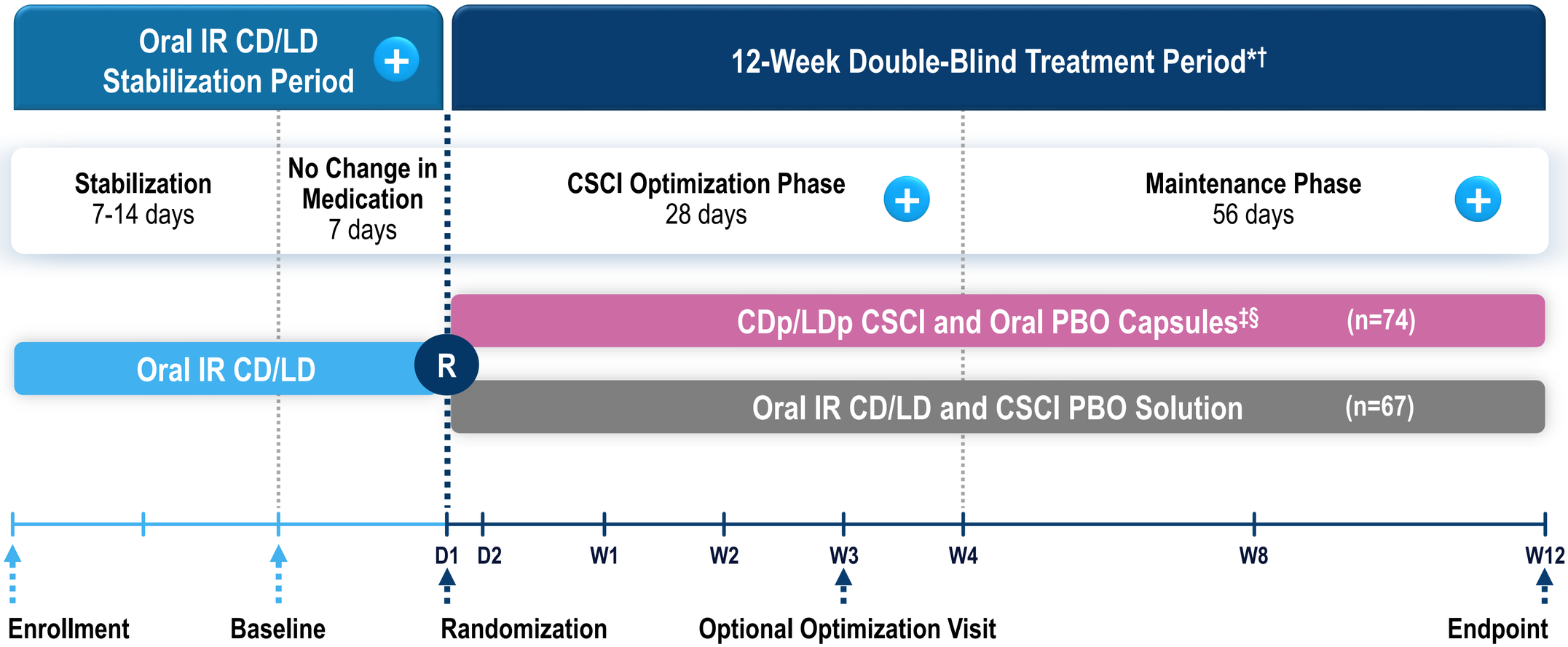
- ☒ Low vitamin B_{12} level[3‡]
- ☒ History of significant skin conditions or disorders
- ☒ History of deep brain stimulation
- ☒ Prior CLES, apomorphine, or other continuous daily infusion of PD medication
- ☒ Previous exposure to foscarbidopa/foslevodopa

*With recognizable/identifiable "Off" and "On" states. †From LD-containing medications and COMT inhibitors. ‡Patients were allowed to be rescreened if vitamin B_{12} level <200 pg/mL or low-normal level (<300 pg/mL) with elevated methylmalonic acid (>0.41 mmol/L) at the first visit.[4]

CLES=carbidopa/levodopa enteral suspension; COMT=catechol-O-methyltransferase; LD=levodopa; LE=levodopa equivalents; MMSE=Mini-Mental State Examination; PD=Parkinson's disease.

1. CDp/LDp [package insert]. North Chicago, IL: AbbVie Inc. 2. Soileau MJ, et al. *Lancet Neurol*. 2022;21(12):1099-1109. 3. Soileau MJ, et al. Supplement to: *Lancet Neurol*. 2022;21(12):1099-1109. 4. Facheris MF, et al. Poster presented at: Movement Disorder Society Virtual Annual Meeting; September 12-16, 2020.

STUDY DESIGN[1-3]



All LD-containing medications and COMT inhibitors converted to equivalent oral IR CD/LD‖

No changes in concomitant PD medications. Rescue oral IR CD/LD was allowed.

*All participants were eligible to receive open-label oral IR CD/LD as rescue medication in the event of rapid deterioration of motor symptoms. †Extra dose functions and low/high rates of the CSCI pump were disabled to maintain blinding. ‡Doses in trial ranged from 600 mg to 4250 mg LE. §The maximum recommended daily dosage of CDp/LDp is 3525 mg of the LDp component (equivalent to approximately 2500 mg LE). ‖Concomitant PD medications (with the exception of COMT inhibitors) that were non–LD-containing were not included; these were allowed in the study but had to remain unchanged until study completion.

CD/LD=carbidopa/levodopa; CDp/LDp=foscarbidopa/foslevodopa; COMT=catechol-O-methyltransferase; CSCI=continuous subcutaneous infusion; D=day; IR=immediate release; LE=levodopa equivalents; PBO=placebo; PD=Parkinson's disease; R=randomization; W=week.

1. CDp/LDp [package insert]. North Chicago, IL: AbbVie Inc. 2. Soileau MJ, et al. *Lancet Neurol*. 2022;21(12):1099-1109. 3. Soileau MJ, et al. Supplement to: *Lancet Neurol*. 2022;21(12):1099-1109.

All Patients Overview | By Treatment Group

DEMOGRAPHICS AND CLINICAL CHARACTERISTICS OF ALL PARTICIPANTS[1,2]

Min | Mean | Max | N=141

Age, years

39 | 66.4 | 85

Duration Since Onset of Motor Fluctuations, years

0.3 | 5.6 | 19.3

"On" Time Without Troublesome Dyskinesia, hours

0 | 9.3 | 13.6

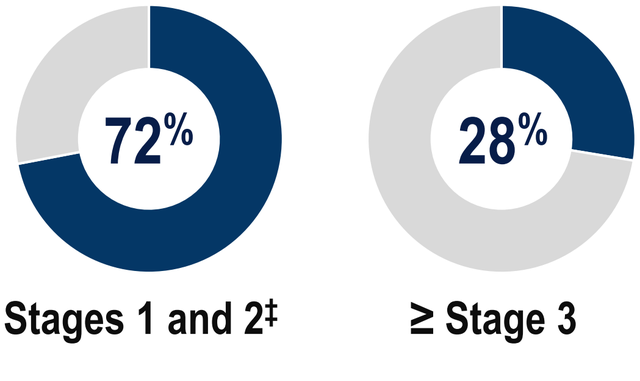
"Off" Time, hours

2.5 | 6.1 | 14.0

Daily Levodopa Dose at Baseline, mg*

400 | 1170 | 3200

Hoehn and Yahr, %†



Stages 1 and 2‡ | ≥ Stage 3

Mean Oral IR CD/LD Frequency

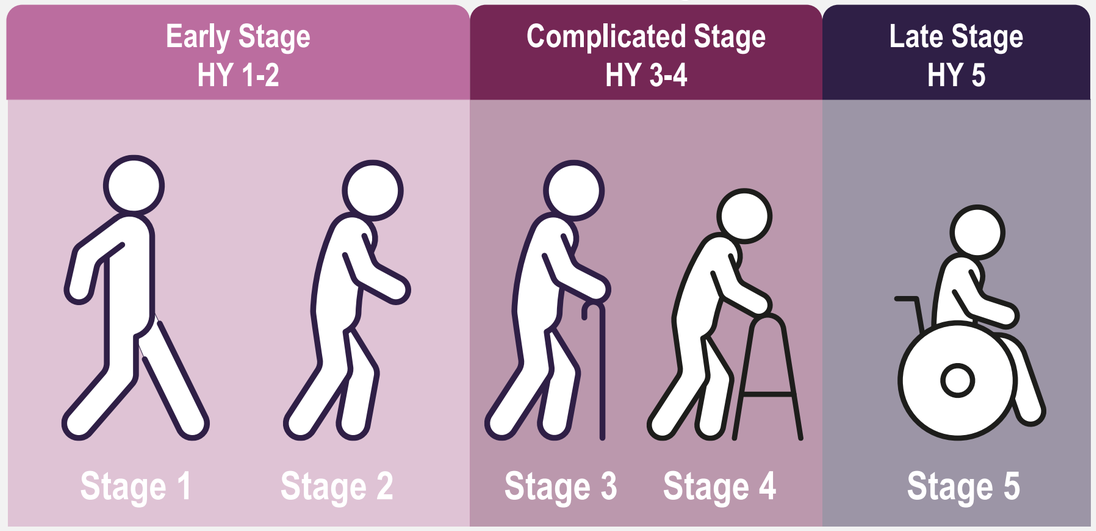
Concomitant Medications and Dosing

*Inclusive of medications containing LD and COMT. †Hoehn and Yahr stages captured in PD patients in the "On" state or on medication. ‡One patient in the oral IR CD/LD arm had a reported H & Y of stage 0.

1. Soileau MJ, et al. *Lancet Neurol*. 2022;21(12):1099-1109. 2. Data on File, AbbVie Inc. ABVRRTI75558.

HOEHN AND YAHR SCALE FOR PIVOTAL TRIAL PATIENTS[1,2]

Criteria for H&Y Stages[1*]



1 Unilateral involvement only, usually with minimal or no functional disability

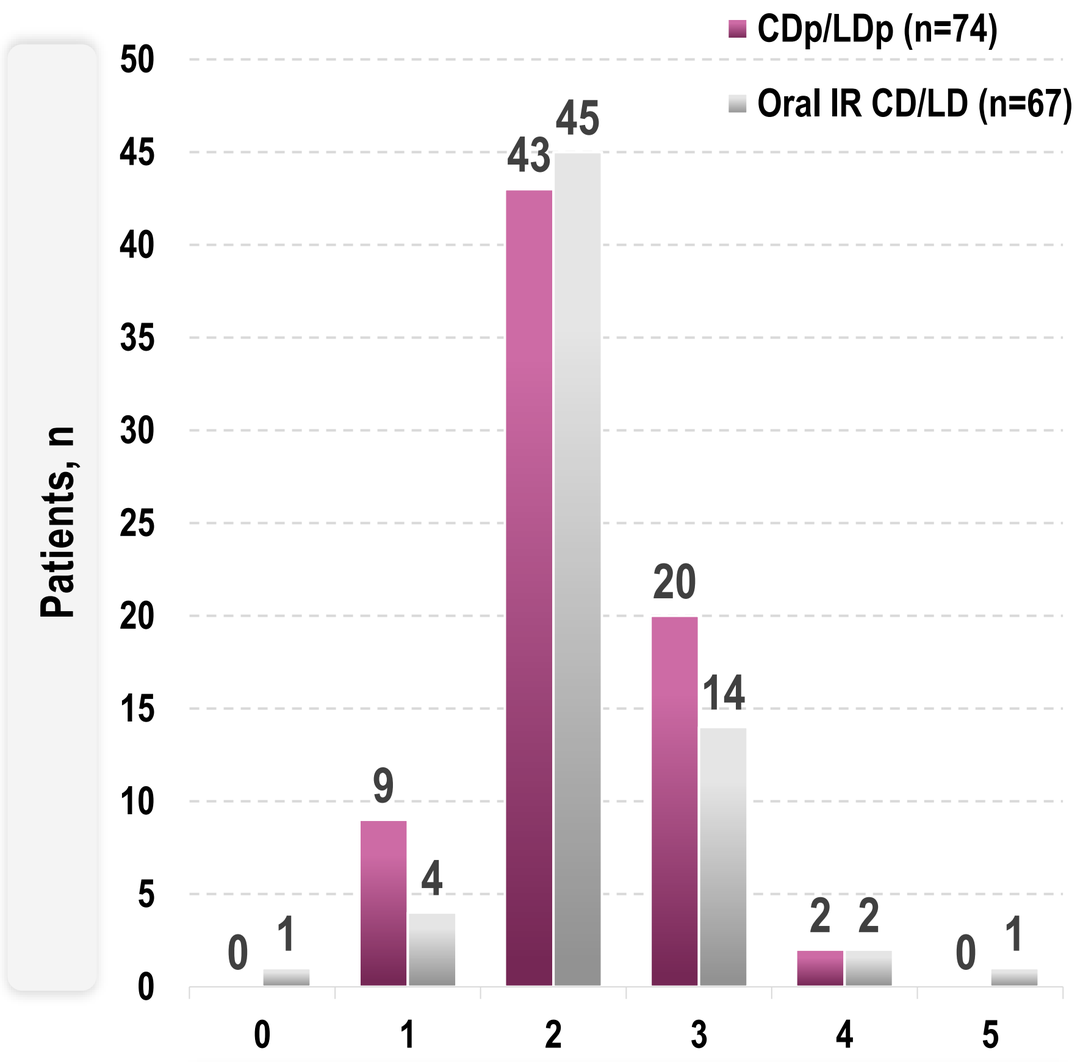
2 Bilateral or midline involvement without impairment of balance

3 Bilateral disease: mild to moderate disability with impaired postural reflexes; physically independent

4 Severely disabling disease; still able to walk or stand unassisted

5 Confinement to bed or wheelchair unless aided

Baseline H&Y Stages[2†]



*0=no signs of disease present. †One patient in the oral IR CD/LD arm had a reported H & Y of stage 0.

CD/LD=carbidopa/levodopa; CDp/LDp=foscarbidopa/foslevodopa; H&Y=Hoehn and Yahr; IR=immediate release.

1. Goetz CG, et al. *Mov Disord*. 2004;19(8):1020-1028. 2. Soileau MJ, et al. *Lancet Neurol*. 2022;21(12):1099-1109.

CONCOMITANT MEDICATION[1*†]

n (%)	CDp/LDp (n=74)	Oral IR CD/LD (n=67)	Total (N=141)
No Other PD Medication	19 (25.7)	23 (34.3)	42 (29.8)
1 Additional Class of PD Medication	34 (45.9)	26 (38.8)	60 (42.6)
2 Additional Classes of PD Medications	19 (25.7)	14 (20.9)	33 (23.4)
3 Additional Classes of PD Medications	2 (2.7)	4 (6.0)	6 (4.3)
>3 Additional Classes of PD Medications	0	0	0
Dopamine agonists	34 (45.9)	25 (37.3)	59 (41.8)
MAO-B inhibitors	26 (35.1)	21 (31.3)	47 (33.3)
Amantadine	14 (18.9)	15 (22.4)	29 (20.6)
COMT inhibitors	0	0	0
Istradefylline	2 (2.7)	3 (4.5)	5 (3.5)
Benztropine	0	1 (1.5)	1 (0.7)
Trihexyphenidyl	1 (1.4)	2 (3.0)	3 (2.1)

*Concomitant medication after converting LD-containing medications and COMT inhibitors to oral IR CD/LD in the oral CD/LD stabilization period.[1,2] †Concomitant PD medications that were non–LD-containing medication were allowed in the study but had to remain unchanged until study completion.[2]

CD/LD=carbidopa/levodopa; CDp/LDp=foscarbidopa/foslevodopa; COMT=catechol-O-methyltransferase; IR=immediate release; MAO-B=monoamine oxidase type B; PD=Parkinson's disease.

1. Data on File, AbbVie Inc. ABVRRTI75558. 2. Soileau MJ, et al. *Lancet Neurol*. 2022;21(12):1099-1109.

ADVERSE EVENTS IN THE PIVOTAL TRIAL[1,2]

Arranged by Frequency | **Arranged by Type** | Severity of AEs | AEs by Study Phase

	Adverse Events[2*]	CDp/LDp n=74 (%)	Oral IR CD/LD n=67 (%)
Infusion/Catheter Site	Erythema	27	1
	Pain	26	1
	Cellulitis	19	0
	Edema	12	0
	Bruising	8	3
	Hemorrhage	8	0
	Nodule	8	0
	Induration	5	0
	Infection	5	0
	Pruritis	5	0

	Adverse Events[1†]	CDp/LDp n=74 (%)	Oral IR CD/LD n=67 (%)
Motor Symptom	Dyskinesia	11	6
	"On" and "Off" phenomenon	8	0
	Balance disorder	5	0
	Hallucinations	12	2.5
Neurocognitive	Agitation	4	2
	Insomnia	4	2
	Psychotic disorder[‡]	4	2
GI	Constipation	5	0
Other	Peripheral swelling	5	0
	Dyspnea	4	0

- Majority of AEs were nonserious and mild to moderate in severity
- Two participants in the CDp/LDp arm were hospitalized with serious infusion/catheter site infections requiring treatment with antibiotics
- No infusion/catheter site AEs resulted in systemic complications

Falls occurred at a greater rate in patients who received oral IR CD/LD (18%) versus CDp/LDp (8%).

*AEs that occurred in ≥5% of patients. Data available in Soileau, et al. publication. †AEs that occurred in ≥3% of patients in the CDp/LDp arm and with a difference of >2% between the CDp/LDp arm and the oral IR CD/LD arm. Data available in package insert. ‡Psychotic disorder included psychotic disorder, delusion, and paranoia.

PRIMARY REASON FOR DISCONTINUATION[1*]

	CDp/LDp N=74, n (%)	Oral IR CD/LD N=67, n (%)
Discontinued Study Drug	26 (35.1)	5 (7.5)
Adverse event	14 (18.9)	1 (1.5)
Infusion site cellulitis	4 (5.4)	0
Infusion site hemorrhage	2 (2.7)	0
Infusion site pain	2 (2.7)	0
Infusion site edema	1 (1.4)	0
Infusion site bruising	1 (1.4)	0
Dizziness, postural	1 (1.4)	0
Asthenia	1 (1.4)	0
Diaphragm muscle weakness	1 (1.4)	0
Hallucination	1 (1.4)	0
Cellulitis	0	1 (1.5)
Withdrew consent	5 (6.8)	3 (4.5)
Lack of efficacy	1 (1.4)	0
Difficulty with drug delivery system	4 (5.4)	1 (1.5)
Other	2 (2.7)	0

*Patients may have had >1 reason for discontinuation; however, listed here is the primary reason for discontinuation.

CDp/LDp FOR THE TREATMENT OF MOTOR FLUCTUATIONS IN ADULT PATIENTS WITH ADVANCED PD[1,2]

CDp/LDp is a nonsurgical, subcutaneous option for 24-hour continuous, LD-based therapy titratable for individualized treatment

Increase in mean "On" time without troublesome dyskinesia at Week 12 (primary endpoint)*

2.72 hours

Reduction in mean "Off" time at Week 12 (secondary endpoint)*

2.75 hours

Most common adverse reactions for CDp/LDp at an incidence of at least 10% greater than oral IR CD/LD incidence were:

- Infusion/Catheter site reactions
- Infusion/Catheter site infections
- Hallucinations
- Dyskinesia

The majority of AEs were nonserious and mild to moderate in severity

*Data are LS means.

REFERENCES

1. Poewe W, et al. *Nat Rev Dis Primers*. 2017;3:17013. doi:10.1038/nrdp.2017.13
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