



# First Quarter 2019 Financial Results & Business Update

April 25, 2019

# Forward-Looking Statements and Non-GAAP Financial Information

Certain statements set forth in this presentation constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the company’s expectations with respect to its future financial and operating performance, business plans or prospects; expectations with respect to continued revenue growth from the company’s commercial products, including potential VIVITROL® growth driven by state policy initiatives and federal funding and potential ARISTADA® and ARISTADA INITIO® growth driven by expansion of the company’s commercial organization, addition of such products to a key formulary and results from the ALPINE study; the therapeutic and commercial value of the company’s marketed and development products and patient access to such products; expectations concerning the timing and results of clinical development activities relating to the company’s products and product development candidates, including expansion of the ongoing phase 1 study for ALKS 4230, the presentation of data relating to dioximel fumarate (“DRF”) and topline data from the phase 3 elective study for DRF, and submission of a new drug application (“NDA”) for ALKS 3831 and the presentation and publication of data relating to detoxification and induction strategies; the company’s expectations and timelines for regulatory interactions with the U.S. Food and Drug Administration (“FDA”), and actions by the FDA, relating to the company’s NDA submission for DRF and planned NDA submission for ALKS 3831; the potential financial benefits that may be achieved under the license and collaboration agreement between the company and Biogen for DRF; Biogen’s marketing plans for DRF; and expectations concerning the timing and results of commercial activities relating to the company’s products and potential expansion of the company’s commercial portfolio. The company cautions that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks, assumptions and uncertainties include, among others: the unfavorable outcome of litigation, including so-called “Paragraph IV” litigation and other patent litigation, related to any of the company’s products, which may lead to competition from generic drug manufacturers; data from clinical trials may be interpreted by the FDA in different ways than the company interprets it; the FDA may not agree with the company’s regulatory approval strategies or components of the company’s filings for its products, including its clinical trial designs, conduct and methodologies or the sufficiency of the results thereof to support approval; clinical development activities may not be completed on time or at all; the results of the company’s clinical development activities may not be positive, or predictive of real-world results or of results in subsequent clinical trials; regulatory submissions may not occur or be submitted in a timely manner; the company and its licensees may not be able to continue to successfully commercialize their products; there may be a reduction in payment rate or reimbursement for the company’s products or an increase in the company’s financial obligations to governmental payers; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company’s products; the company’s products may prove difficult to manufacture, be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and those risks, assumptions and uncertainties described under the heading “Risk Factors” in the company’s most recent Annual Report on Form 10-K and in subsequent filings made by the company with the U.S. Securities and Exchange Commission (“SEC”), which are available on the SEC’s website at [www.sec.gov](http://www.sec.gov), and on the company’s website at [www.alkermes.com](http://www.alkermes.com) in the ‘Investors – SEC filings’ section. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this presentation.

**Non-GAAP Financial Measures:** This presentation includes information about certain financial measures that are not prepared in accordance with generally accepted accounting principles in the U.S. (GAAP), including non-GAAP net income and non-GAAP earnings per share. These non-GAAP measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similar measures presented by other companies. Reconciliations of these non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in the Alkermes plc Current Report on Form 8-K filed with the SEC on Feb. 14, 2019.

**Note Regarding Trademarks:** The company is the owner of various U.S. federal trademark registrations (®) and other trademarks (™), including ARISTADA®, ARISTADA INITIO®, VIVITROL® and VUMERITY™. Any other trademarks referred to in this presentation are the property of their respective owners. Appearances of such other trademarks herein should not be construed as any indicator that their respective owners will not assert their rights thereto.

# First Quarter Earnings Call Agenda

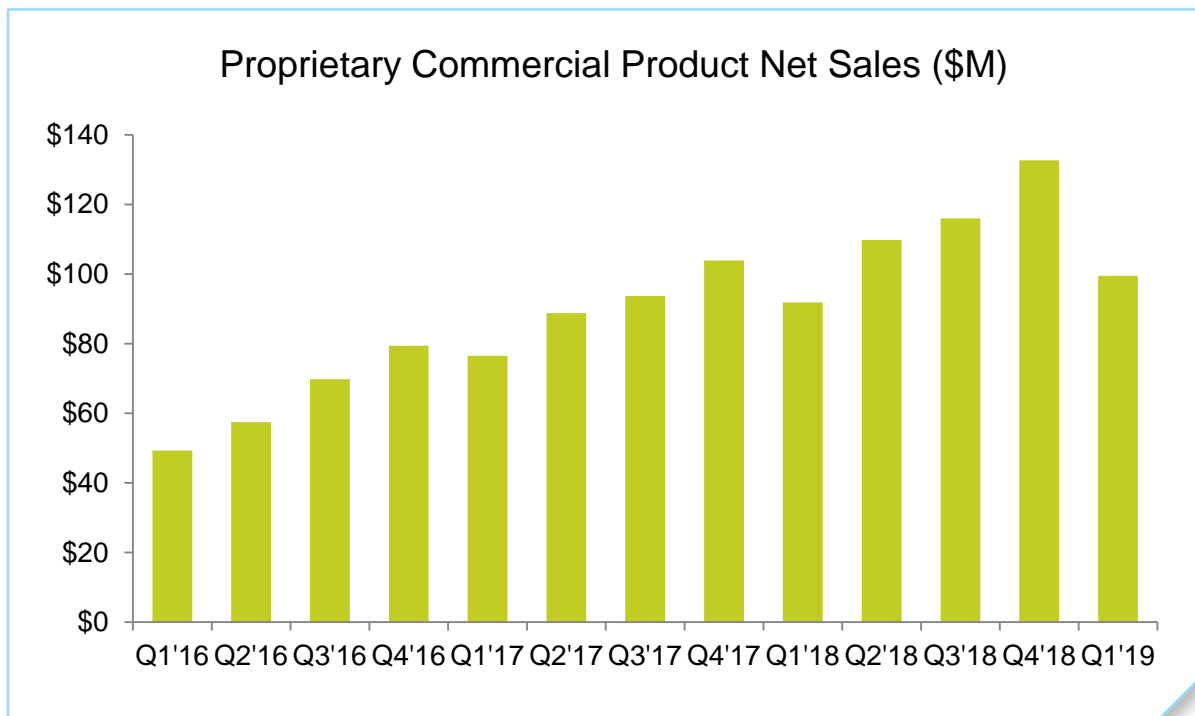
Q1 2019 Financial Results	Jim Frates Chief Financial Officer
Pipeline and R&D Update	Craig Hopkinson Chief Medical Officer
Business Update	Richard Pops Chief Executive Officer

# First Quarter 2019 Revenue Summary

In millions, except %	Q1'19	Q1'18	Δ Q1'19 vs. Q1'18
VIVITROL®	\$69.2	\$62.7	10%
ARISTADA®	\$30.3	\$29.2	4%
Manufacturing & Royalty Revenues	\$108.9*	\$114.6	(5%)
R&D Revenues	\$14.7	\$18.7	(21%)
Total Revenues	\$223.1	\$225.2	(1%)

\*These results reflect a \$17.9 million decline in revenues from AMPYRA® following generic market entry near the end of 2018.

# Revenues From Proprietary Commercial Medicines



**ARISTADA  
INITIO<sup>®</sup>**  
aripiprazole lauroxil  
extended-release injectable suspension

675 mg

**ARISTADA<sup>®</sup>**   
aripiprazole lauroxil  
extended-release injectable suspension

441 mg 662 mg 882 mg 1064 mg

**Vivitrol<sup>®</sup>**  
(naltrexone for extended-release  
injectable suspension)

# VIVITROL® Performance

VIVITROL Quarterly Net Sales (\$M)



- ▶ Q1 year-over-year net sales growth of **10%**, driven by underlying unit growth of **8%**
  - Gross-to-net deductions of 49% in Q1'19, compared to 46% in Q4'18 and 50% in Q1'18
- ▶ Sequential decrease in net sales driven by seasonal inventory fluctuations
  - Inventory drawdown of ~\$5M in quarter
- ▶ 2019 full year net sales expectations of **\$330M - \$350M**

# ARISTADA® Performance

ARISTADA Quarterly Net Sales (\$M)



- ▶ Q1 year-over-year net sales growth of **4%**
  - Gross-to-net deductions of 49%, compared to 44% in Q4'18 and 43% in Q1'18
- ▶ Sequential decrease in net sales driven by seasonal inventory fluctuations
  - Inventory drawdown of ~\$10M in quarter
  - Total prescriptions increased by 5% sequentially during the quarter<sup>1</sup>
- ▶ 2019 full year net sales expectations of **\$210M - \$230M**

1. IMS NPA

# Alkermes: 2019 Financial Expectations†

<i>(in millions, except per share amounts)</i>	Financial Expectations for Year Ending Dec. 31, 2019†
Revenues	\$1,140 – 1,190
COGS	\$180 – 190
R&D Expense	\$450 – 480
SG&A Expense	\$590 – 620
Amortization of Intangible Assets	~\$40
Net Interest Expense	\$5 to \$10
Income Tax Expense	\$10 to \$15
GAAP Net Loss	\$(135) – (165)
GAAP Net Loss Per Share	\$(0.87) – (1.06)
Non-GAAP Net Income‡	\$40 – 70
Non-GAAP Earnings Per Share (Basic)	\$0.26 – 0.45
Non-GAAP Earnings Per Share (Diluted)	\$0.25 – 0.43

## Revenues:

- VIVITROL® net sales of \$330M - \$350M
- ARISTADA® net sales of \$210M - \$230M
- License revenues: \$150M milestone anticipated upon FDA approval of diroximel fumarate (expected Q4'19)

† This financial guidance was initially provided by Alkermes plc (the "Company") in its Current Report on Form 8-K filed with the SEC on Feb. 14, 2019. This financial guidance was reiterated by the Company in its Current Report on Form 8-K filed with the SEC on Apr. 25, 2019 and is effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm this guidance. The Company only provides guidance in a Regulation FD compliant manner.

‡ Non-GAAP net income adjusts for one-time and non-cash charges by excluding from GAAP results: share-based compensation expense; amortization; depreciation; non-cash net interest expense; certain other one-time or non-cash items; and the income tax effect of these reconciling items. Reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure can be found in the Alkermes plc Current Report on Form 8-K filed with the SEC on Feb. 14, 2019.



## VIVITROL®: Opportunities to Increase Utilization and Drive Growth

- ▶ Federal grant dollars related to 21<sup>st</sup> Century Cures and SUPPORT for Patients and Communities Acts continue to be allocated
  - Funding slowly flowing into fragmented treatment system
- ▶ States have adopted more targeted policies in criminal justice and community settings, and have passed legislation to remove certain barriers that limit access to medications
  - California, Texas, Pennsylvania, New Jersey and Kentucky
- ▶ VIVITROL net sales continue to be concentrated geographically
  - Top five states represented 44% of volume during Q1'19
    - Pennsylvania, Ohio, Massachusetts, New York, California

# ARISTADA®: Potential New Growth Drivers

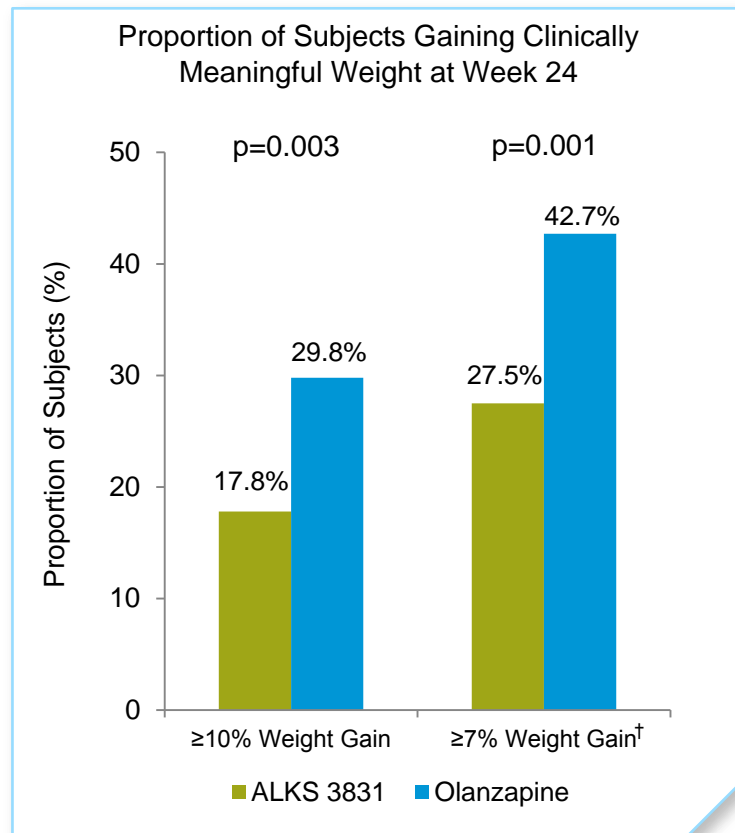
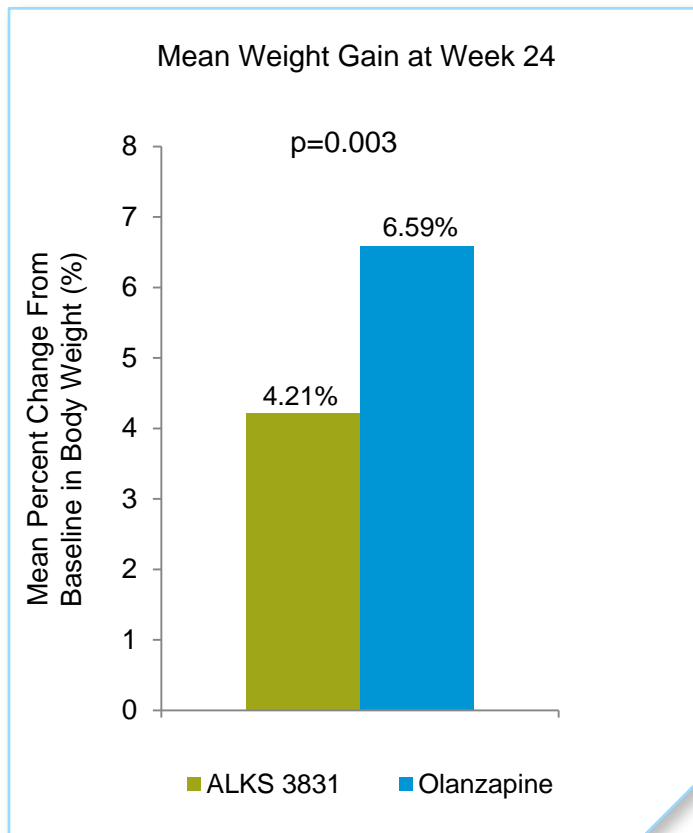
- ✔ Commercial organization expansion completed in Q1'19
  - 60 new community and hospital-based sales representatives recently onboarded
- ✔ Positive topline results from ALPINE study demonstrated efficacy, safety and tolerability of both ARISTADA and the current market-leader, INVEGA SUSTENNA®
  - Plan to publish data in peer-reviewed journal and present at upcoming medical meetings
- ✔ ARISTADA product family, including ARISTADA INITIO®\* recently added to the U.S. Department of Veterans Affairs' National Formulary at parity with other atypical LAIs
- ✔ ARISTADA market share was 29% of new aripiprazole long-acting atypical prescriptions (months of therapy) in March 2019<sup>1</sup>

\*ARISTADA INITIO regimen consists of ARISTADA INITIO + single 30 mg dose of oral aripiprazole. ARISTADA INITIO regimen plus ARISTADA on day 1 of treatment yields relevant levels of aripiprazole concentration in the body within four days.

1. IMS NPA

ALKS 3831: ENLIGHTEN-2 and Interim Results From  
Ongoing ENLIGHTEN-2-EXT Open-Label Safety Study

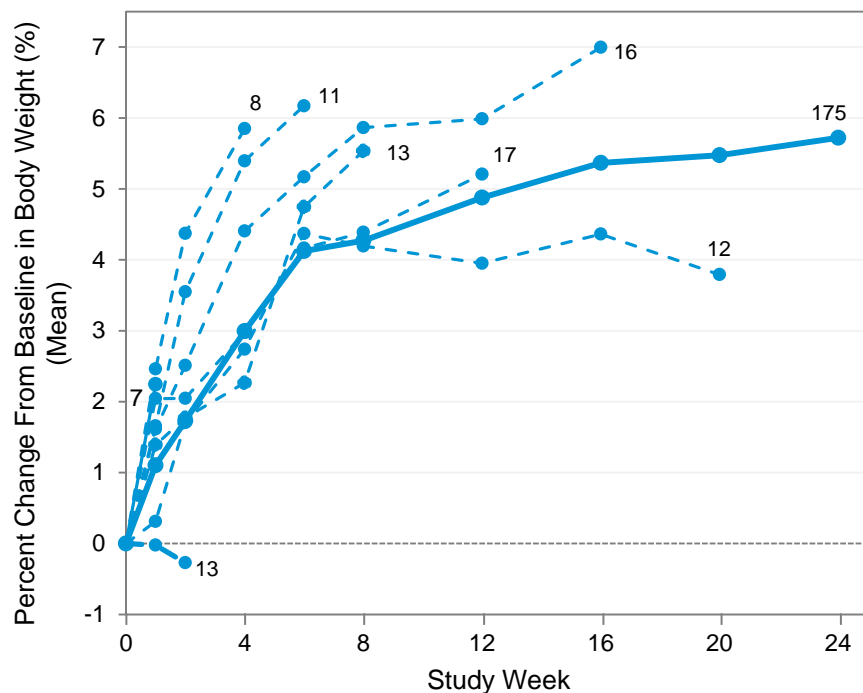
# ENLIGHTEN-2: Achieved Prespecified Co-Primary and Key Secondary Endpoints



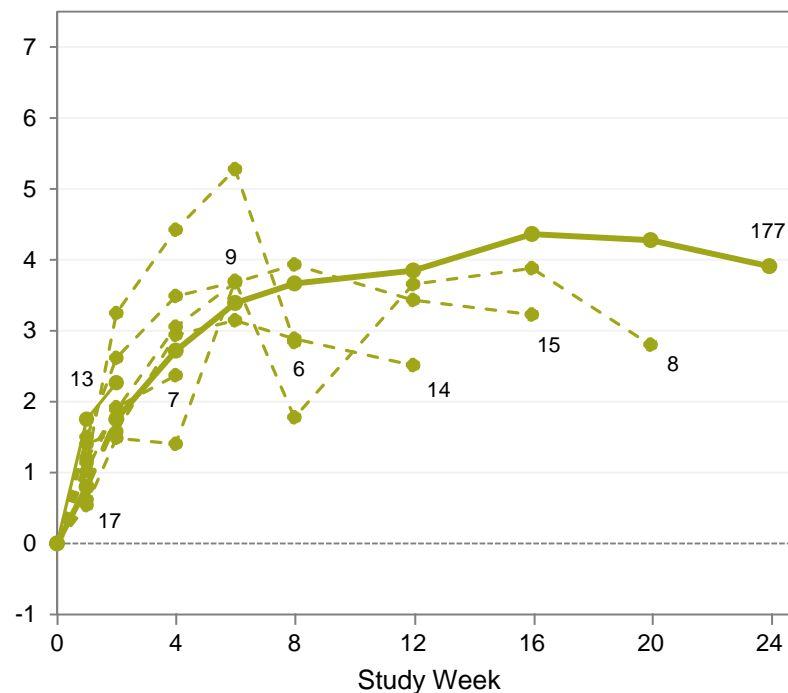
# ENLIGHTEN-2: Weight Gain Trajectory of Early Discontinuations

**Percent Change From Baseline in Body Weight by Treatment**  
Completers vs. Premature Discontinuations

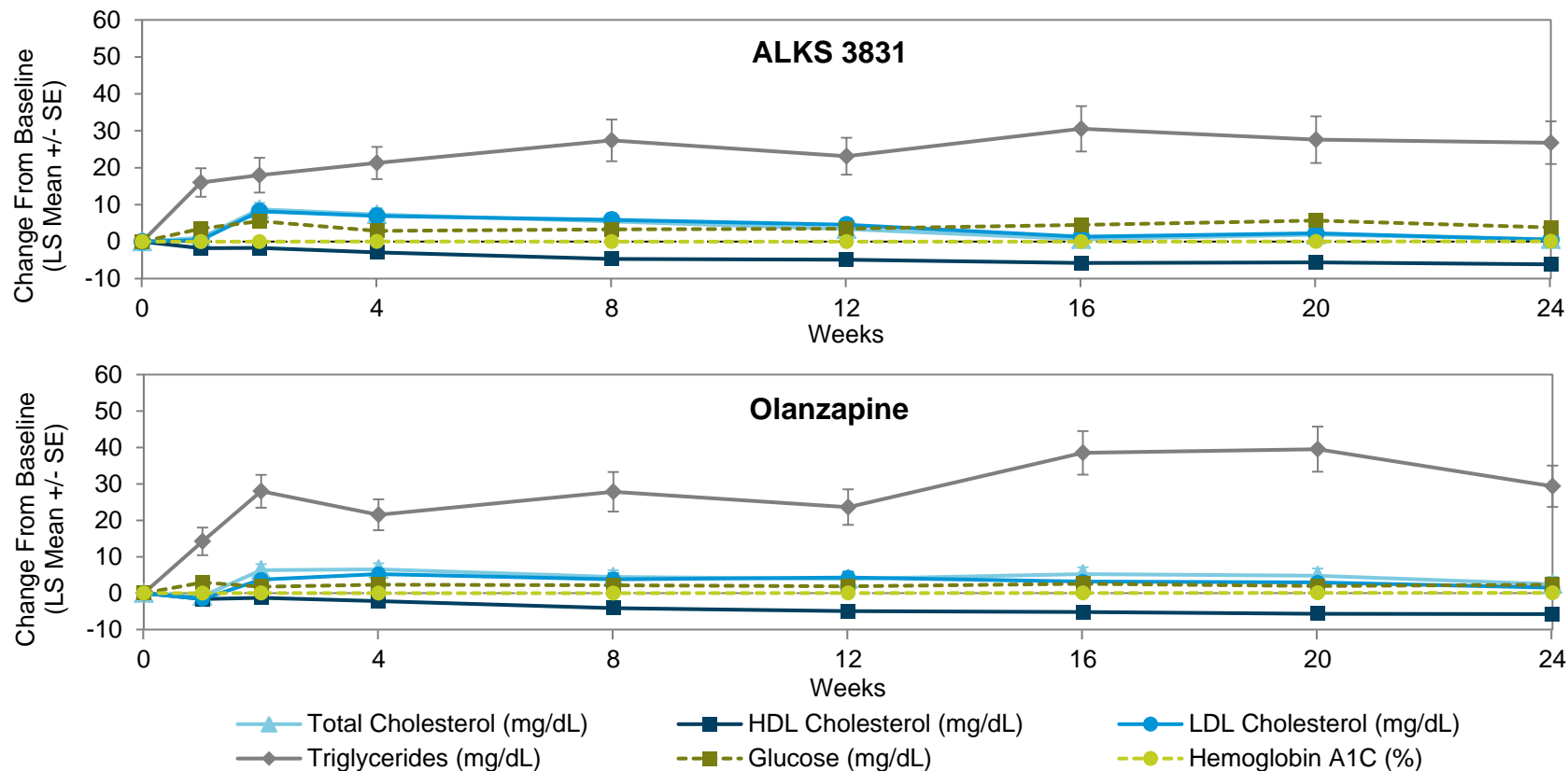
Olanzapine



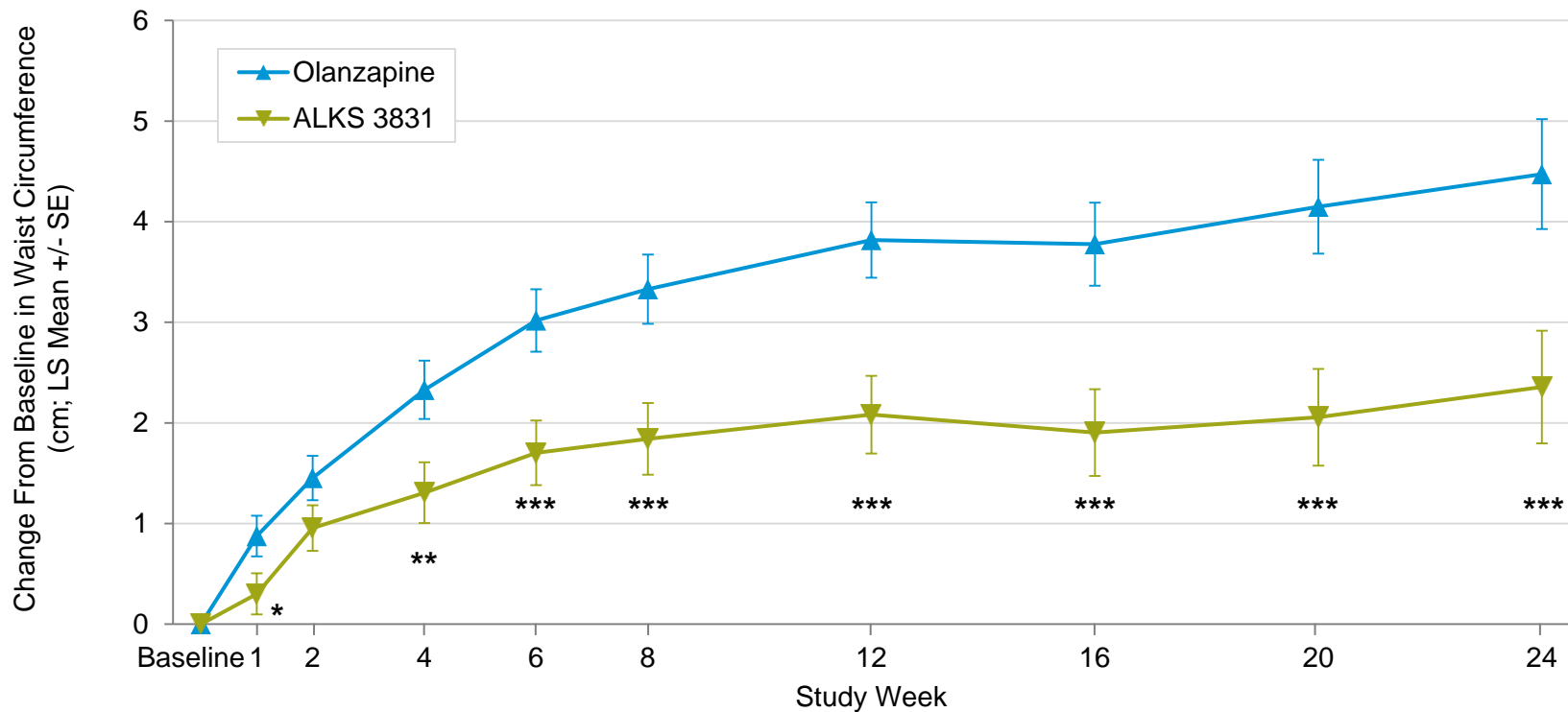
ALKS 3831



# ENLIGHTEN-2 Metabolic Parameters: Changes Were Generally Small for Both ALKS 3831 and Olanzapine

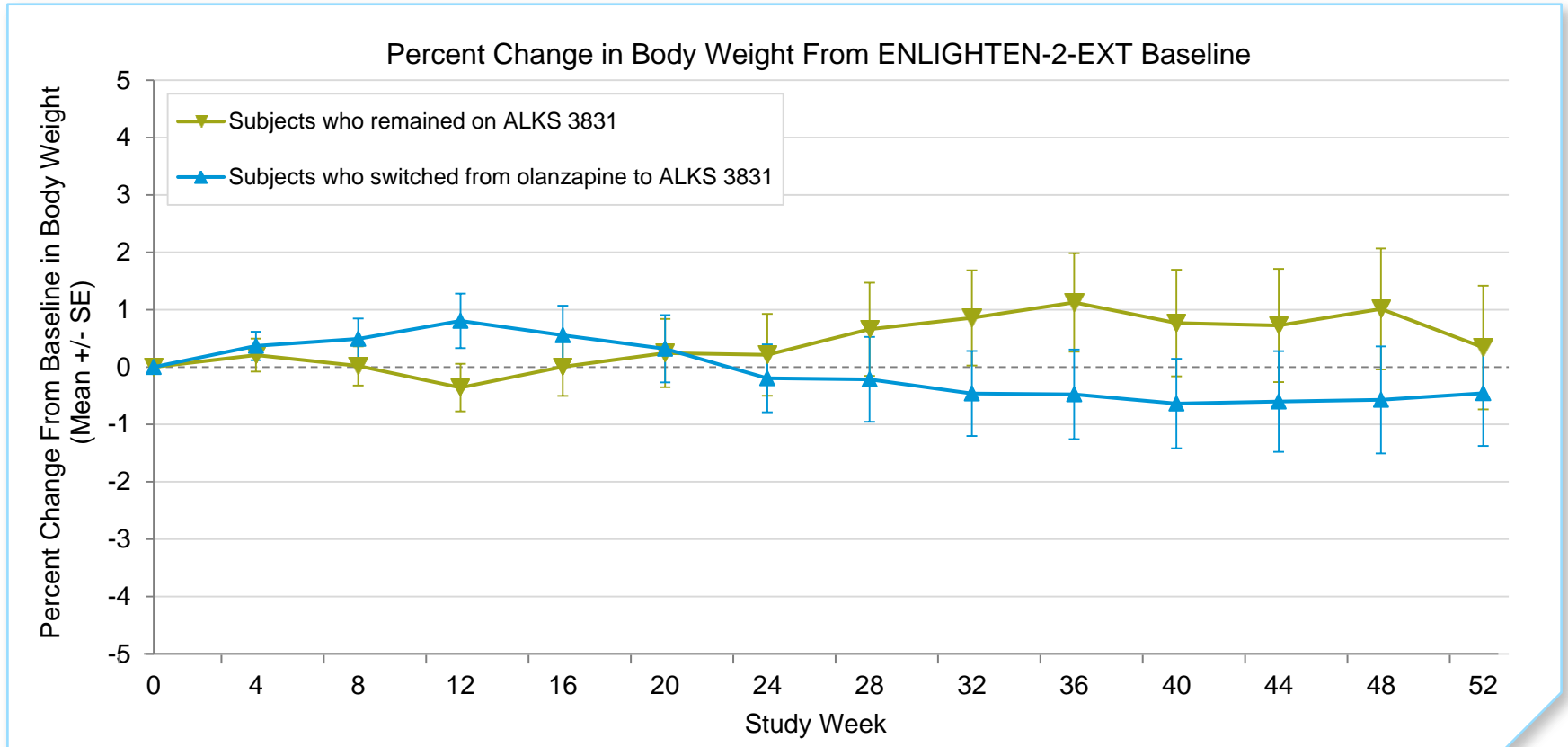


# ENLIGHTEN-2: Early and Significant Impact on Waist Circumference



Note: Waist circumference curve based on ANCOVA approach using MI for missing data  
 \* $p < 0.05$  vs. olanzapine; \*\* $p < 0.01$  vs. olanzapine; \*\*\* $p < 0.001$  vs. olanzapine

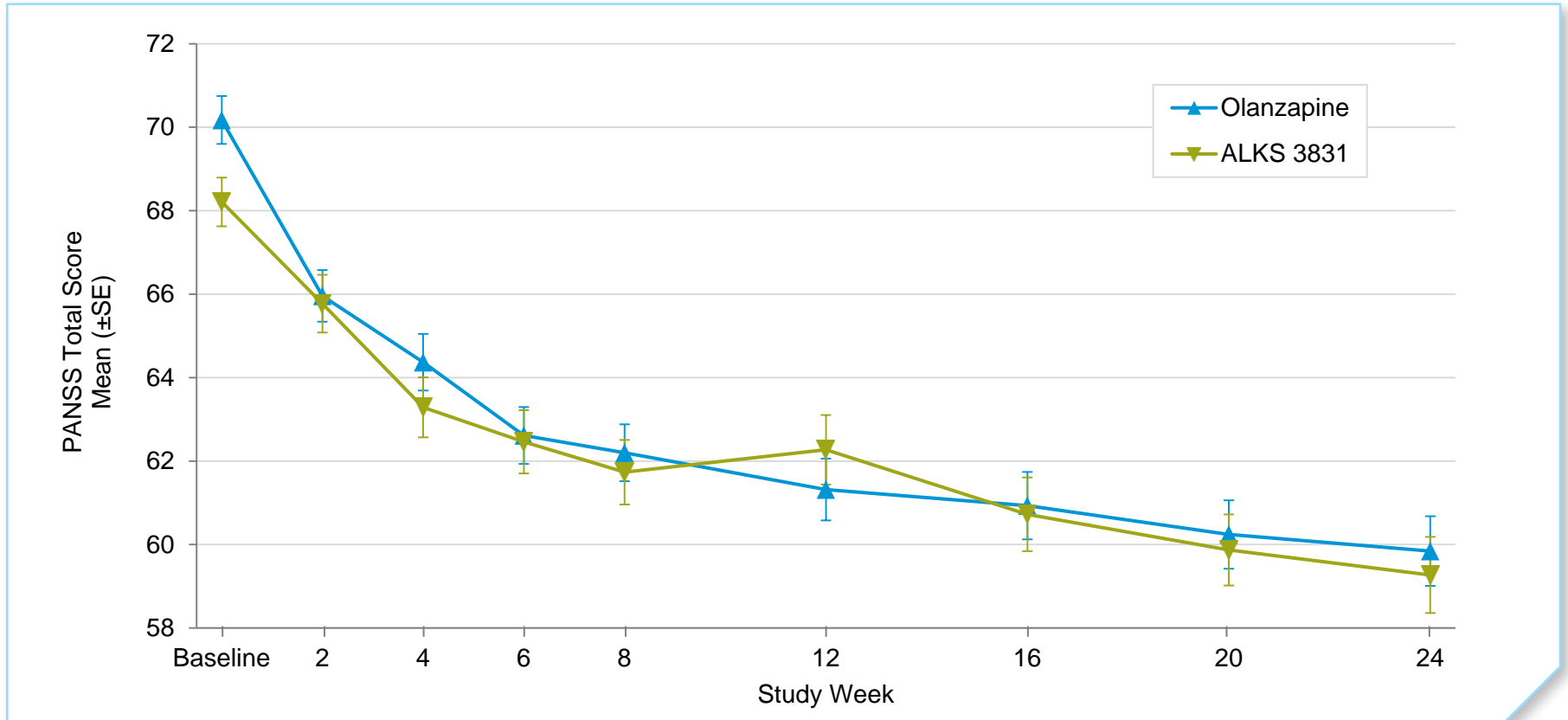
# ENLIGHTEN-2-EXT Open-Label, Safety Extension Study Interim Results: Weight Remains Stable Over 52 Weeks





# ENLIGHTEN-2: Antipsychotic Efficacy

## PANSS Scores Show Continuous Improvement in Stable Patients



## ENLIGHTEN-2: Most Common Adverse Events

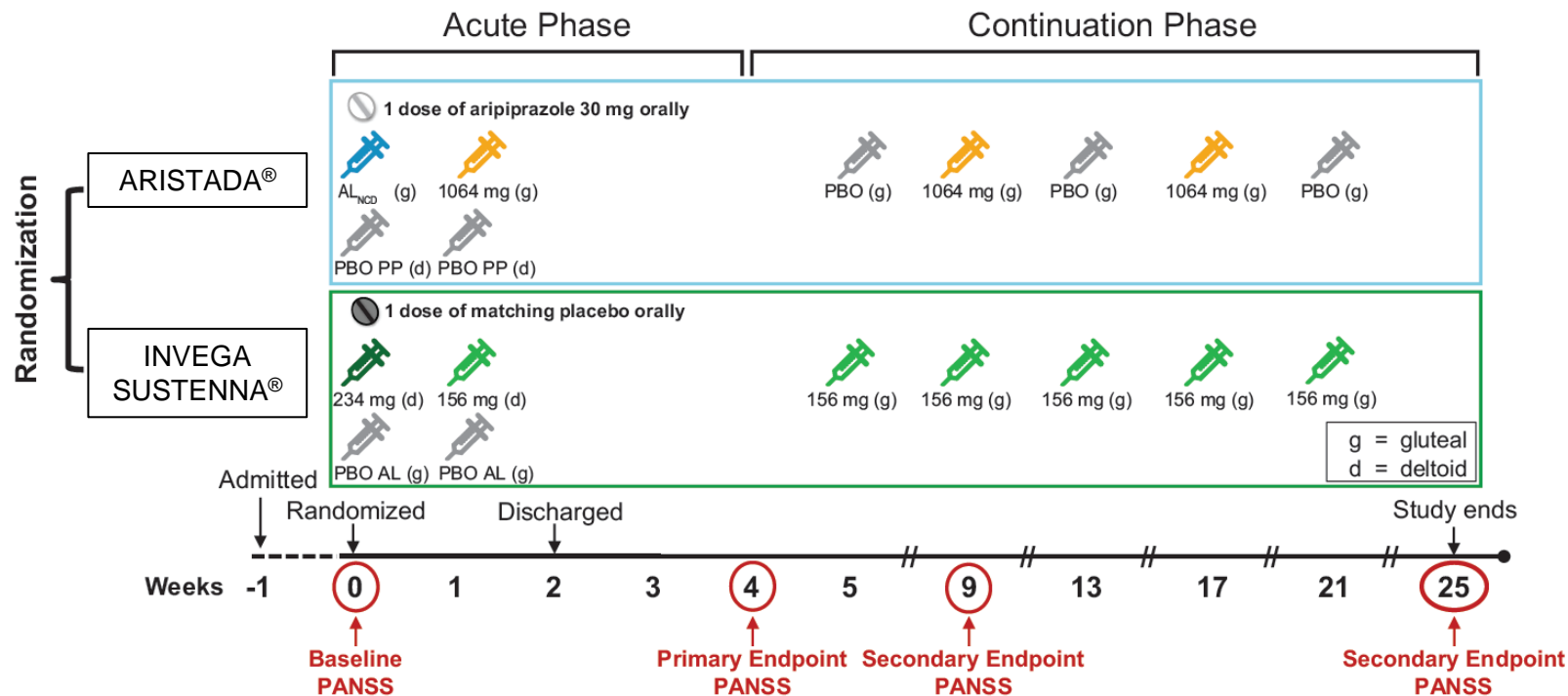
	ALKS 3831 (N=274) n (%)	Olanzapine (N=276) n (%)
<b>Serious Adverse Events†</b>	10 (3.6)	7 (2.5)
<b>Any Adverse Event (≥5%)</b>	203 (74.1)	227 (82.2)
Weight increased	68 (24.8)	100 (36.2)
Somnolence	58 (21.2)	50 (18.1)
Dry mouth	35 (12.8)	22 (8.0)
Increased appetite	30 (10.9)	34 (12.3)
Waist circumference increased	17 (6.2)	22 (8.0)
Blood creatine phosphokinase increased	14 (5.1)	12 (4.3)
Extra dose administered	14 (5.1)	17 (6.2)

- Similar safety profile observed to date in ongoing extension safety study (ENLIGHTEN-2-EXT)

†Only 1 serious adverse event in each group deemed to be study-drug related

▶ ALPINE Study  
Aripiprazole Lauroxil and Paliperidone Palmitate:  
Initiation Effectiveness

# ALPINE: Study Design



AL=aripiprazole lauroxil; NCD=NanoCrystal® Dispersion; PBO=placebo; PP=paliperidone palmitate.

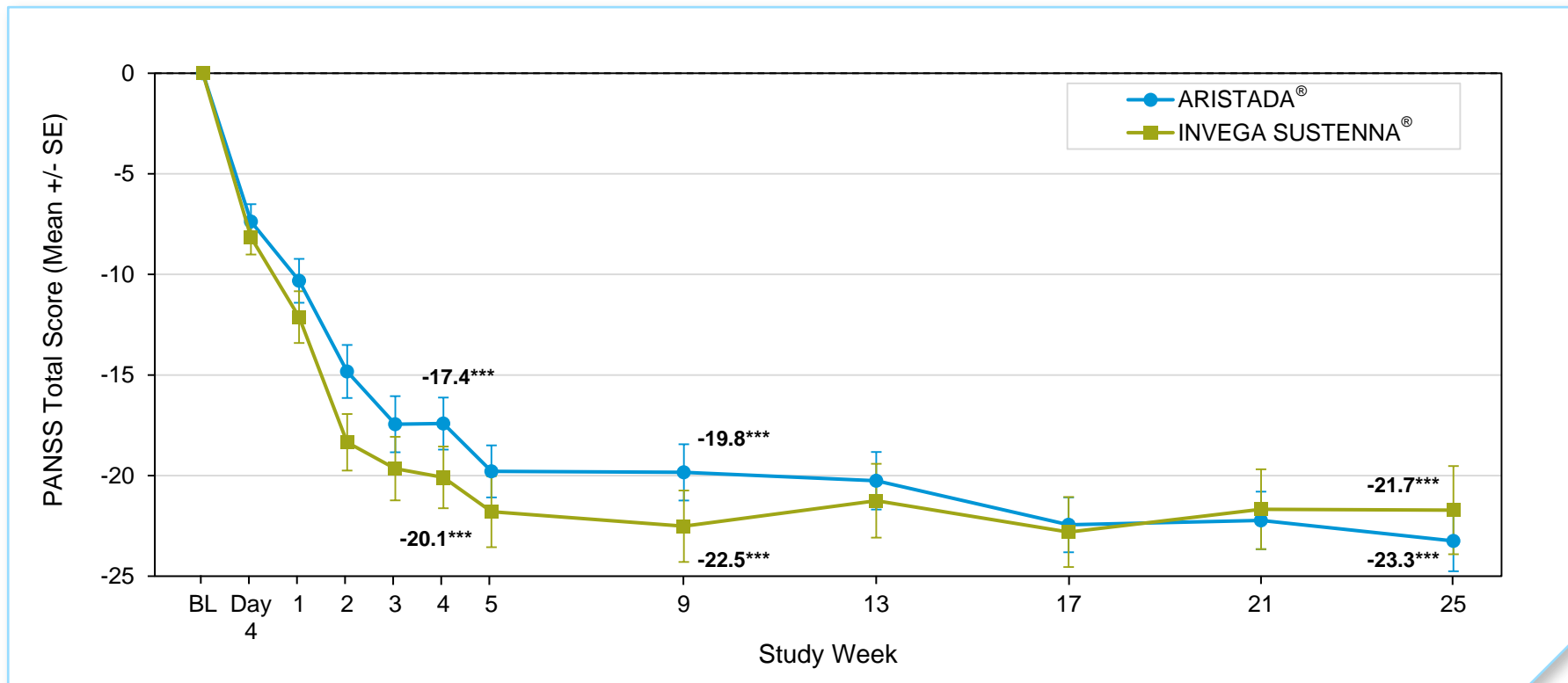
# ALPINE: Demographics and Baseline Characteristics

	ARISTADA® (n=99)	INVEGA SUSTENNA® (n=101)
Age, mean (SD), y	43.5 (9.7)	43.4 (10.8)
Male, n (%)	73.0 (73.7)	76.0 (75.2)
Weight, mean (SD), kg	84.8 (19.8)	85.0 (18.8)
BMI, mean (SD), kg/m <sup>2</sup>	28.2 (5.5)	27.9 (5.1)
PANSS total score, mean (SD) <sup>†</sup>	94.1 (9.0)	94.6 (8.4)
CGI-S score, mean (SD) <sup>†</sup>	4.8 (0.7)	4.9 (0.7)

BMI=body mass index; CGI-S=Clinical Global Impression-Severity; PANSS=Positive and Negative Syndrome Scale

<sup>†</sup>Based on patients who received ≥1 post-baseline PANSS assessment (ARISTADA, n=96; INVEGA SUSTENNA n=99)

# ALPINE: Change From Baseline in PANSS Total Score



# ALPINE: Study Retention

	ARISTADA® (n=99)	INVEGA SUSTENNA® (n=101)
Subjects Who Completed the Treatment Period, n (%)	56 (56.6)	43 (42.6)
Subjects Who Discontinued Study, n (%)	43 (43.4)	58 (57.4)
Most Common Reasons for Discontinuation, n (%)		
Withdrawal by Subject	20 (20.2)	31 (30.7)
Adverse Event	10 (10.1)	11 (10.9)
Lost to Follow-up	8 (8.1)	9 (8.9)

# ALPINE: Most Common Adverse Events

Most Common Adverse Events, n (%)	ARISTADA® (n=99)	INVEGA SUSTENNA® (n=101)
<b>AEs ≥ 5%</b>		
Injection site pain	17 (17.2)	25 (24.8)
Weight increased	9 (9.1)	17 (16.8)
Akathisia	9 (9.1)	11 (10.9)
Headache	8 (8.1)	8 (7.9)
Somnolence	4 (4.0)	7 (6.9)
Dystonia	3 (3.0)	6 (5.9)
Schizophrenia	5 (5.1)	2 (2.0)



# ALKS 3831

## Program

- Investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of schizophrenia
- Designed to provide antipsychotic efficacy of olanzapine with a favorable weight profile

## Status

- Reported positive topline results from ENLIGHTEN-2, a six-month phase 3 study assessing weight gain with olanzapine compared to ALKS 3831, in Q4'18
- Presented data from ENLIGHTEN-2 and ENLIGHTEN-2-EXT at SIRS\* in April 2019

## Priorities

- Anticipated pre-NDA meeting to discuss key FDA requirements including efficacy, safety, weight and metabolic profile
- NDA submission planned for mid-2019

# Diroximel Fumarate (DRF, formerly BIIB098)

## Program

- Investigational product for the treatment of relapsing forms of multiple sclerosis (MS)
- License and collaboration agreement with Biogen announced in Q4'17

## Status

- NDA filed; PDUFA date in Q4'19
- Biogen intends to commercialize under the brand name VUMERITY™, which has been conditionally accepted by the FDA

## Priorities

- Additional data on DRF to be presented at spring medical meetings
- Topline results for EVOLVE-MS-2 head-to-head study of diroximel fumarate compared to TECFIDERA® expected in mid-2019

## Biogen License and Collaboration Agreement

- Granted Biogen exclusive, worldwide license to commercialize DRF
- Mid-teens percentage royalty to Alkermes on worldwide net sales of DRF
- \$150M milestone upon regulatory approval by FDA by 12/31/21
- Biogen responsible for development and commercial expenses (as of 1/1/18)

# ALKS 4230

## Program

- Novel immuno-oncology candidate
- Designed to selectively activate intermediate-affinity IL-2 receptors to enhance tumor-killing immune cells

## Status

- Monotherapy dose-escalation stage of phase 1 study ongoing
- Initiated evaluation of safety and anti-tumor activity of ALKS 4230 in combination with pembrolizumab in Q3'18
- Initiated subcutaneous dosing study in Q1'19
- Announced preclinical research collaboration with Clovis to evaluate ALKS 4230 in combination with rucaparib, Clovis' marketed PARP inhibitor, and lucitanib, Clovis' investigational tyrosine kinase inhibitor, in Q1'19

## Priorities

- Complete monotherapy dose-escalation stage of phase 1 study to identify optimal dose and advance into monotherapy dose-expansion stage

# Significant News Flow Expected in 2019

## Schizophrenia

### ARISTADA®

- ✓ Report topline results for ALPINE phase 3b study (Q2)

### ALKS 3831

- ✓ Present ENLIGHTEN-2 data at medical meeting (Q2)
- ☐ Submit NDA for schizophrenia (mid-year)

## Addiction

### VIVITROL®

- ☐ Present and publish data on detox and induction strategies

## Multiple Sclerosis

### Diroximel fumarate

- ☐ Report topline data for EVOLVE-MS-2 head-to-head vs. TECFIDERA® (mid-year)
- ☐ Expected FDA regulatory action (Q4)

## Immuno-oncology

### ALKS 4230

- ✓ Initiate subcutaneous dosing study (Q1)
- ☐ Complete monotherapy dose-escalation stage of phase 1 study
- ☐ Initiate monotherapy dose-expansion stage of phase 1 study



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