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Pivotal Phase 3 Trial: Topline Results

April 27, 2020

Safe Harbor

This presentation may include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words “will,” “may,” “believe,” “expect,” “anticipate,” “estimate,” “project” and similar expressions, and the negatives thereof, identify forward-looking statements, each of which speaks only as of the date the statement is made. Although we believe our forward-looking statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks, and, as a result, there can be no assurance that actual results of our research, development and commercialization activities and our results of operations will not differ materially from the results contemplated in such forward-looking statements. These risks include: (a) risk relating to potential negative impacts resulting from public health epidemics, such as the current coronavirus, on our employees, contractors, customers, and supply chain, as well as the global economy; (b) risks relating to our recent cost-saving actions, including risks that (i) such actions may not result in the amount of cost savings we anticipate, and (ii) such cost-saving actions may cause us to incur one-time costs in amounts greater than we anticipate; (c) risks relating to the development of our investigational “FT218” sodium oxybate product, including risks that (i) we may not have adequate capital to complete the development of FT218, we may need to obtain additional capital for such purpose, and such additional capital may not be available on attractive terms or at all, (ii) we could experience delay or failure in completing the remaining data compilation and processing steps of the Phase 3 REST-ON clinical trial, (iii) we may encounter challenges in the remaining development efforts for FT218, (iv) the FDA may determine there are deficiencies in the NDA for FT218 or may never approve the NDA for FT218, (v) FT218 may not have the therapeutic benefits we anticipate, (vi) the commercial launch of FT218 could be delayed, (vii) FT218 may not achieve commercial acceptance, and (viii) other companies may develop competing products that may receive FDA approval before FT218; (d) risks related to the commercialization of Nouress™, including risks that (i) we delay the commercial launch Nouress or do not commercially launch Nouress at all, (ii) the current patent infringement suit alleging that Nouress infringes the intellectual property of a third party may prevent or delay our commercial launch of Nouress, (iii) we may be required to pay royalties to a third party if we commercially launch Nouress, and (iv) third parties may infringe our intellectual property covering Nouress and we may incur substantial costs to defend our intellectual property; and (e) the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2019, and our subsequent filings with the U.S. Securities and Exchange Commission. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made and are not guarantees of future performance. We do not undertake any obligation to publicly update or revise these forward-looking statements.

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Gregory Divis

Chief Executive Officer

REST-ON Phase 3 Study – Positive Topline Results

Once-nightly FT218 demonstrated highly statistically significant (p<0.001), clinically meaningful improvement compared to placebo at all three doses for all three co-primary endpoints

Once-nightly FT218 was generally well-tolerated at the highest dose with commonly known sodium oxybate adverse reactions occurring at low rates

Overall, once-nightly FT218 demonstrated statistically significant and clinically meaningful improvement within 3 weeks of treatment initiation (p<0.001)

Once-nightly FT218 offers an exciting opportunity targeting the estimated $1.7 billion[1] twice nightly sodium oxybate market

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[1]Annualized Xyrem revenues from the Jazz Pharmaceuticals Full Year and Fourth Quarter 2019 Financial Results press release, February 25, 2020

Characteristics of Narcolepsy – Serious Disease with Large Unmet Need

- Under-diagnosed, chronic, disabling neurological disease
- Characterized by excessive daytime sleepiness (EDS), cataplexy, disrupted nocturnal sleep, hypnagogic hallucinations, and sleep paralysis
- Twice-nightly sodium oxybate is the only medication that is approved for both cardinal symptoms of narcolepsy – EDS and cataplexy
- Market expected to grow significantly over period to 2027[1]

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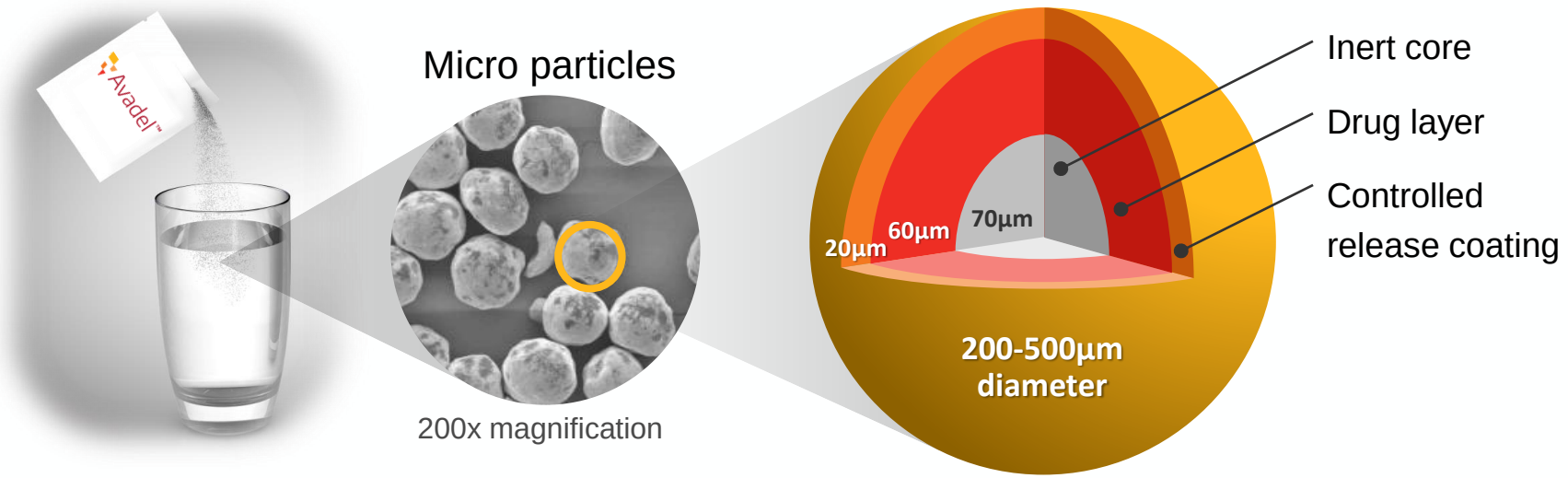
Note: 1 Narcolepsy Drugs Market by Type, Application, and Drug Formulation: Global Opportunity Analysis and Industry Forecast, 2019 - 2026 Source: Research and Markets Syndicated Report – October 2019

Leveraging Our Proprietary Micropump™ Technology – Delivering Sodium Oxybate Once Nightly

The Technology



- **Technology contains thousands of micro particles**
  - Each is a miniature delivery system
- **Microparticulate design can be adapted to each drug's specific challenges**
  - Modify coatings / thickness

The Advantages

- Delayed delivery of small molecule drugs taken orally
- Potential to: improve efficacy, reduce toxicity, improve compliance

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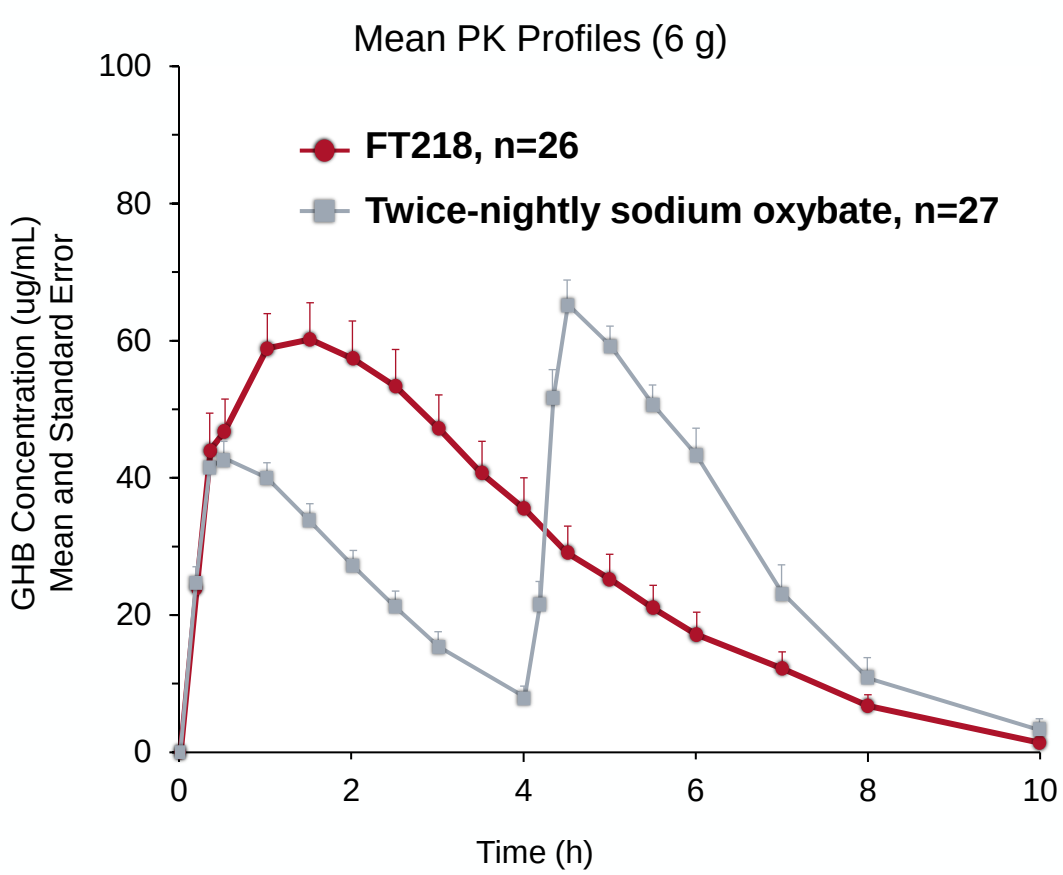
Initial Pharmacokinetic (PK) Studies Indicated Potential Advantages of Once-Nightly FT218

The Results



The Comparison to 2X Nightly

Single dose	Advantage
No middle of the night dosing	Advantage
Overall Peak concentration (Cmax) - lower	Advantage
Overall exposure (AUC) - bioequivalent to SoC	Similar
Onset time	Similar
Morning blood levels (C8H)	Similar

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Jordan Dubow, MD

Chief Medical Officer

Positive Topline Phase 3 Results Across All Doses Studied For All Co-Primary Endpoints

Once-Nightly FT218 at 9 g demonstrated a high degree of statistical significance, compared to placebo, for each of the three co-primary endpoints:

- Maintenance of Wakefulness Test (MWT) ($p<0.001$)
- Clinical Global Impression-Improvement (CGI-I) ($p<0.001$)
- Mean weekly reduction in cataplexy attacks ($p<0.001$)

FT218 7.5 g and 6 g also demonstrated statistical significance for the three co-primary endpoints, compared to placebo

FT218 was generally well-tolerated; commonly known sodium oxybate adverse reactions occurred at low rates at the highest dose (9 g)

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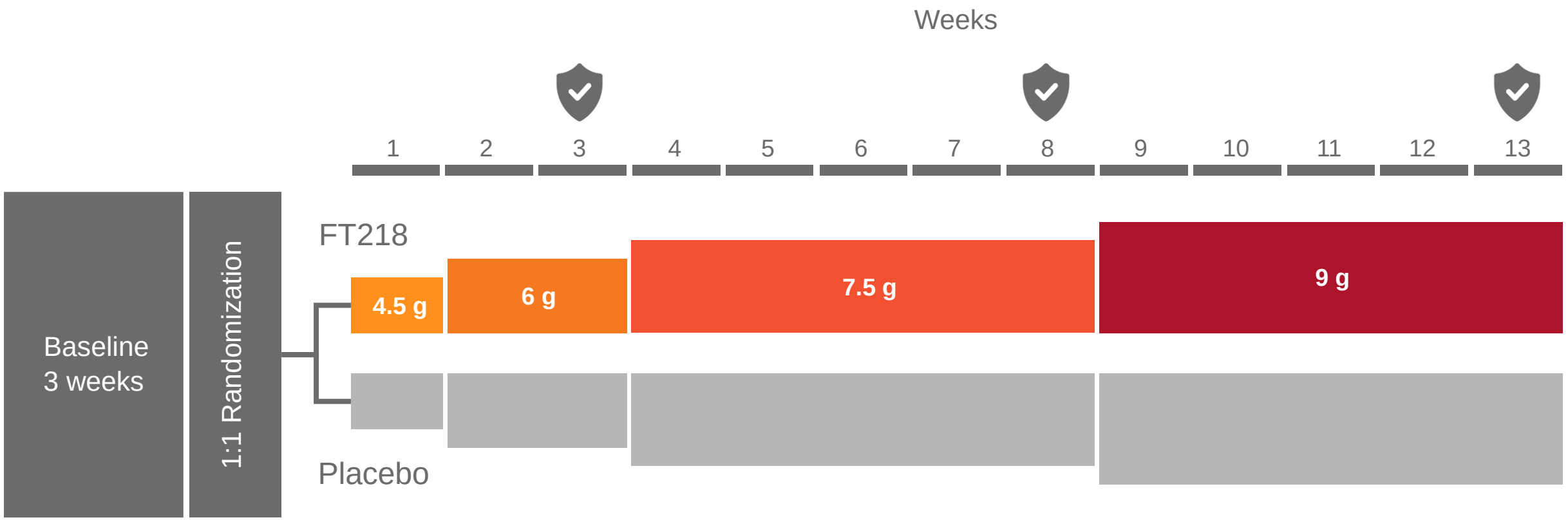
REST-ON Phase 3 Study Design



safety and efficacy assessments

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REST-ON Phase 3 Study – Key Inclusion and Exclusion Criteria

Key Inclusion Criteria

- Age: 16 and over
- Documented diagnosis of narcolepsy (NT1 or NT2) as defined by the International Classification of Sleep Disorders-3 criteria
- Epworth Sleepiness Score (ESS): >10
- May be on stimulants, as long as stable for three weeks prior to entry
- Prior to randomization
  - Maintenance of Wakefulness Test (MWT): < 11 minutes
  - A mean of at least 8 cataplexy attacks per week during the Baseline Period

Key Exclusion Criteria

- Prior use of sodium oxybate
  - In 2018, protocol amended to allow prior use of sodium oxybate of 4.5 g or less, for less than 2 weeks and at least 1 year prior to study entry
- Current use of sodium oxybate
- Must be tapered off any medications for the treatment of cataplexy – SSRIs, SNRIs, TCAs, MAO inhibitors

REST-ON Study – Three Co-Primary Endpoints and Statistical Analysis Plan

Change from baseline to endpoint for FT218 compared to placebo at 9 g for:

1. Maintenance of Wakefulness Test
2. Clinical Global Impression-Improvement (% of patients “much” or “very much” improved)
3. Mean weekly cataplexy attacks

If 9 g dose was positive, then each of the three endpoints will be assessed at the 7.5 g dose level in the same hierarchical manner

If 7.5 g dose was positive, then each of the three endpoints will be assessed at the 6 g dose level in the same hierarchical manner

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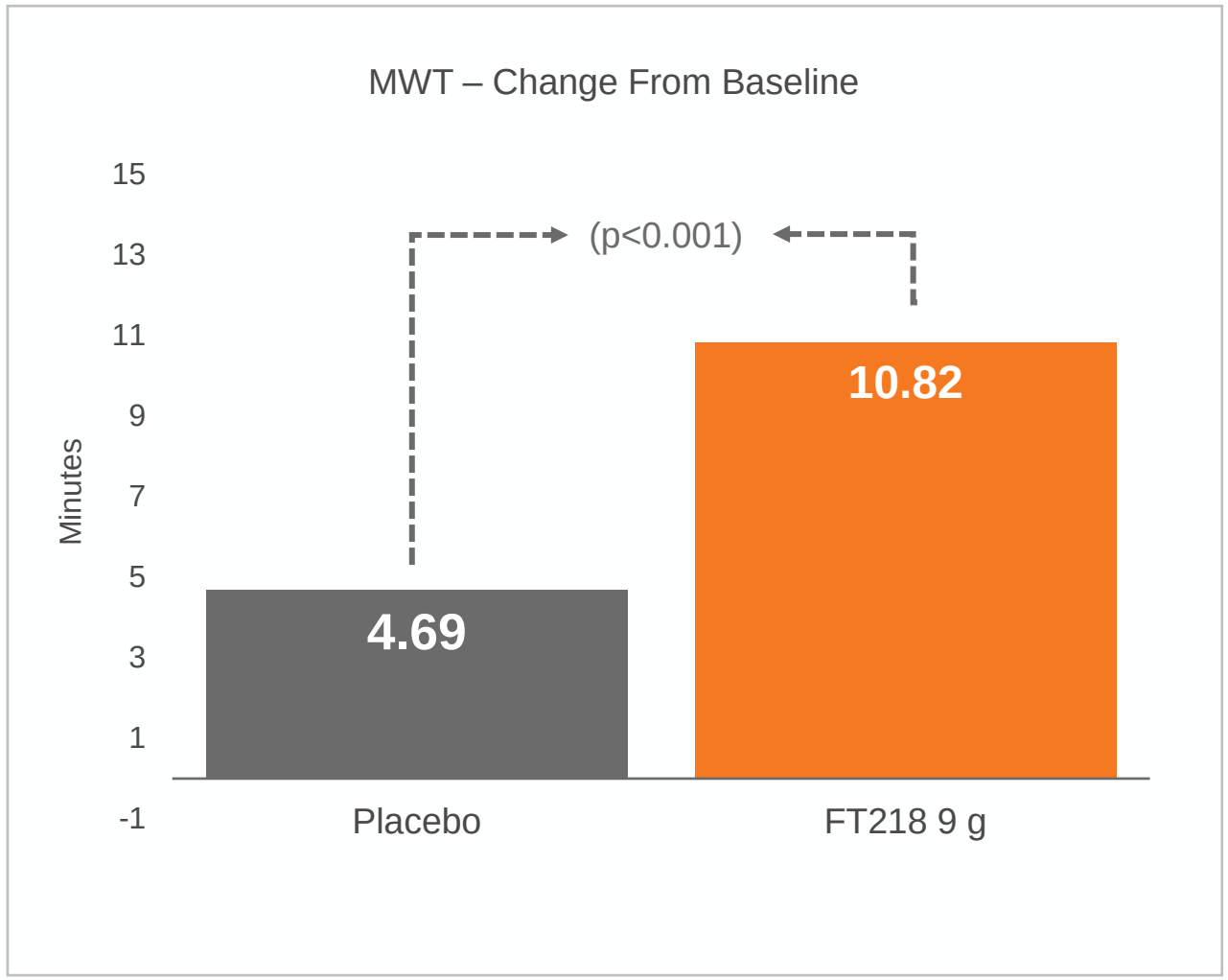
FT218 9 g was Significant on the MWT Compared to Placebo



Change From Baseline in MWT

Change from Baseline to Week 13 for FT218 was 10.82

Change from Baseline to Week 13 for Placebo was 4.69

LS Mean difference between FT218 and Placebo was 6.13 (*p<0.001)*

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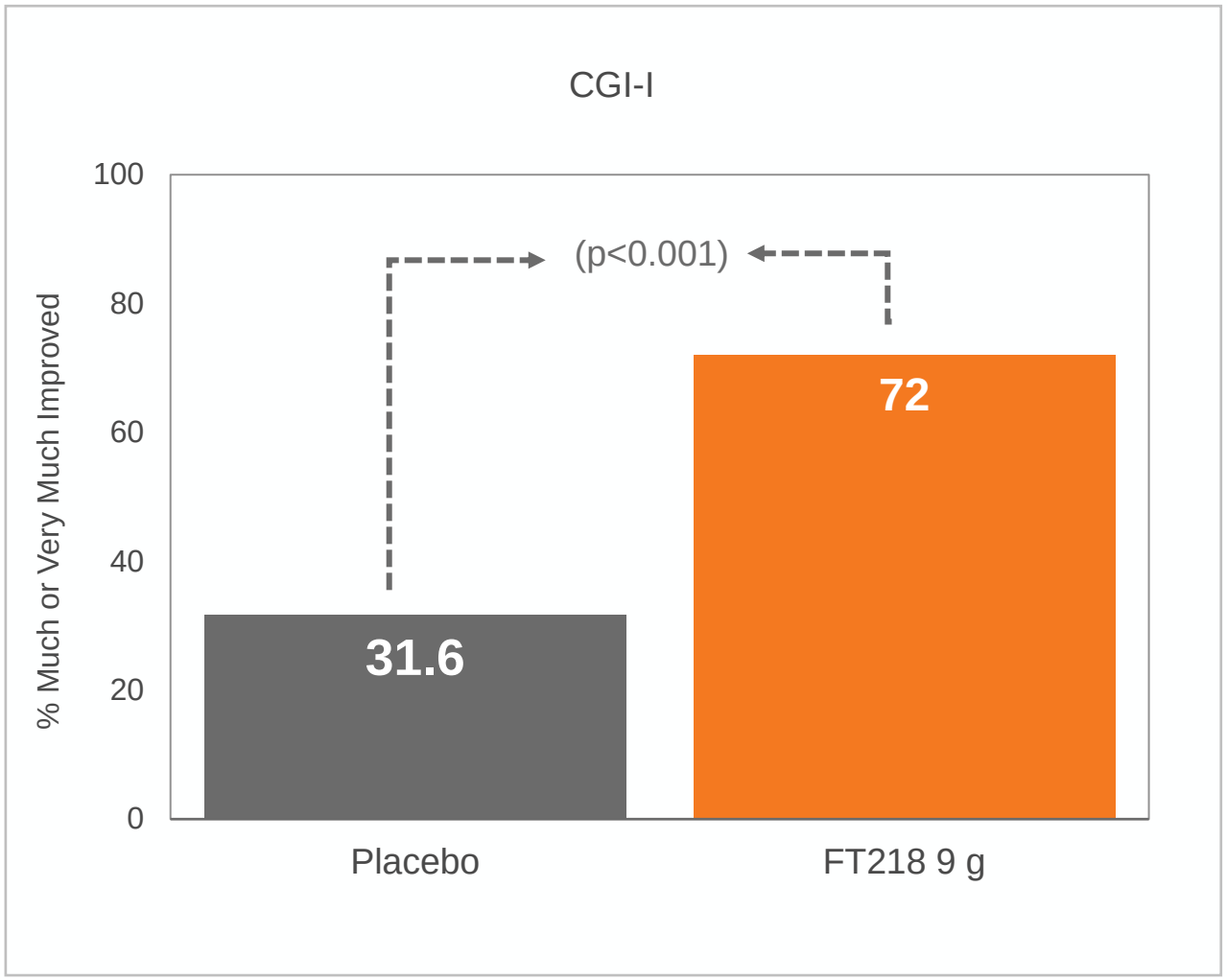
FT218 9 g Had Significant Improvement on the Clinical Global Impression-Improvement (CGI-I) Compared to Placebo



CGI-I - Percent Much or Very Much Improved at Week 13

72.0% of patients on FT218 compared to 31.6% of patients on placebo were rated as much or very much improved at Week 13; odds ratio 5.56 *(p<0.001)*

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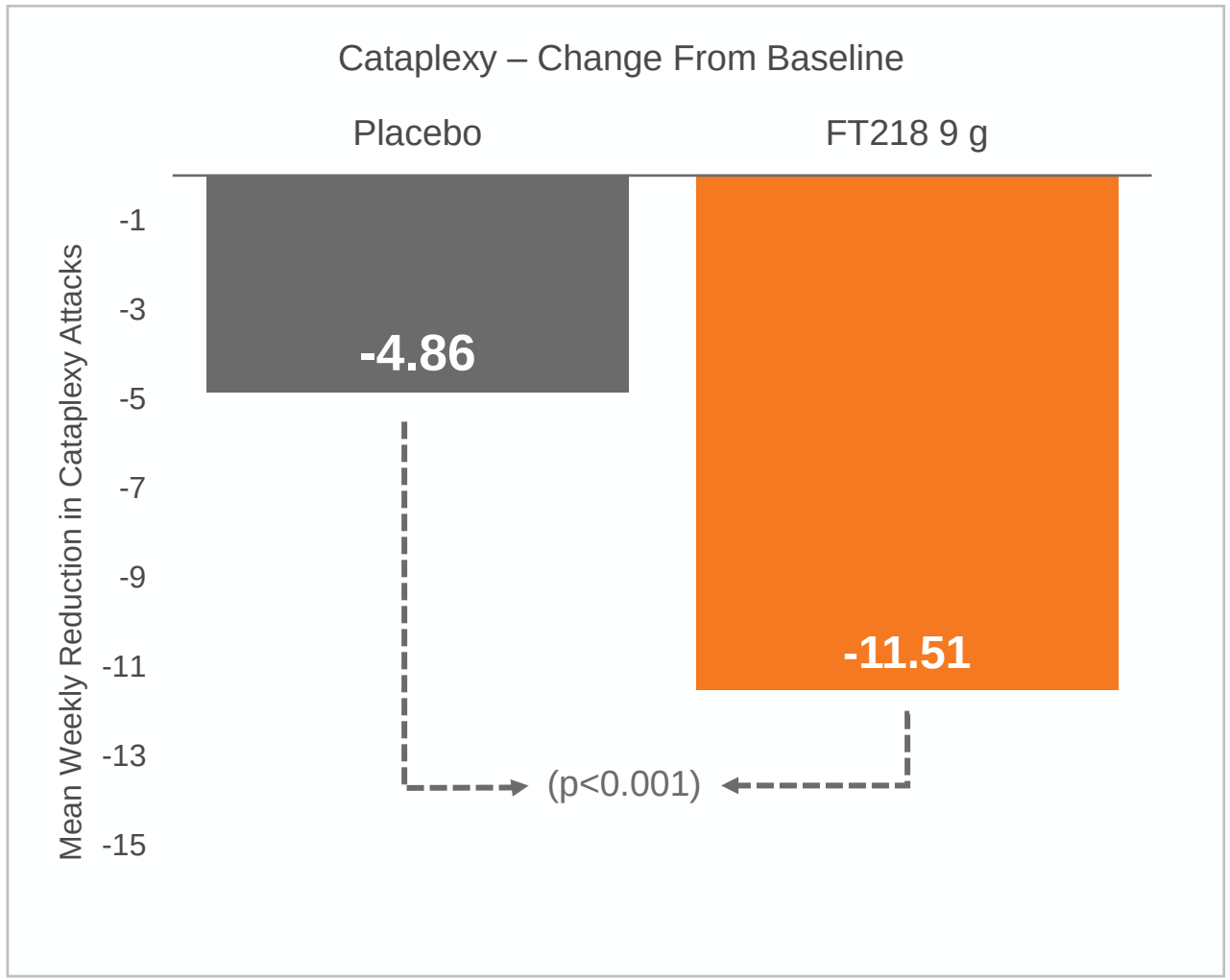
FT218 9 g Had Significant Reduction in Mean Weekly Cataplexy Attacks Compared to Placebo



Change From Baseline in Weekly Cataplexy Attacks

Change from Baseline to Week 13 for FT218 was -11.51

Change from Baseline to Week 13 for Placebo was -4.86

LS Mean difference between FT218 and Placebo was -6.65 *(p<0.001)*

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FT218 9 g was Generally Well Tolerated with Low Rates of Commonly Reported Sodium Oxybate Adverse Reactions

	FT218 (%)	Placebo (%)
Any Adverse Drug Reaction (ADR)	35.1	5.0
Any Serious ADR	1.3	0.0
ADR Leading To Discontinuation	3.9	0.0
Common ADRs		
Nausea	1.3	1.3
Vomiting	5.2	0.0
Decreased Appetite	2.6	0
Dizziness	5.2	0.0
Somnolence	3.9	1.3
Tremor	1.3	0.0
Enuresis	9.1	0.0

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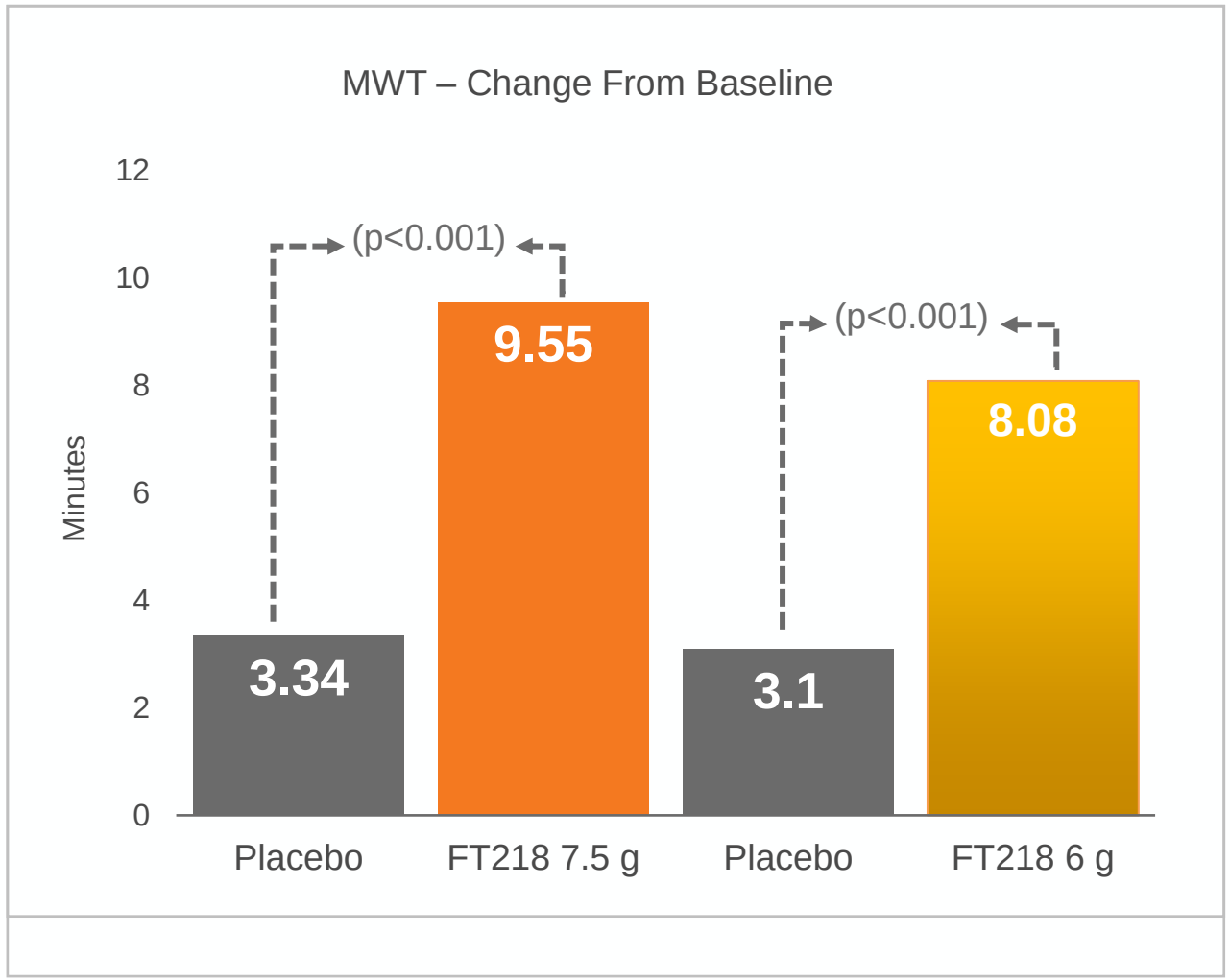
FT218 7.5 g and 6 g was Significant on the MWT Compared to Placebo



Change From Baseline in MWT

Change from Baseline to Week 8 for FT218 7.5 g was 9.55, compared to 3.34 for placebo

LS Mean difference between FT218 7.5 g and Placebo was 6.21 ($p<0.001$)

Change from Baseline to Week 3 for FT218 6 g was 8.08, compared to 3.1 for placebo

LS Mean difference between FT218 6 g and Placebo was 4.98 ($p<0.001$)

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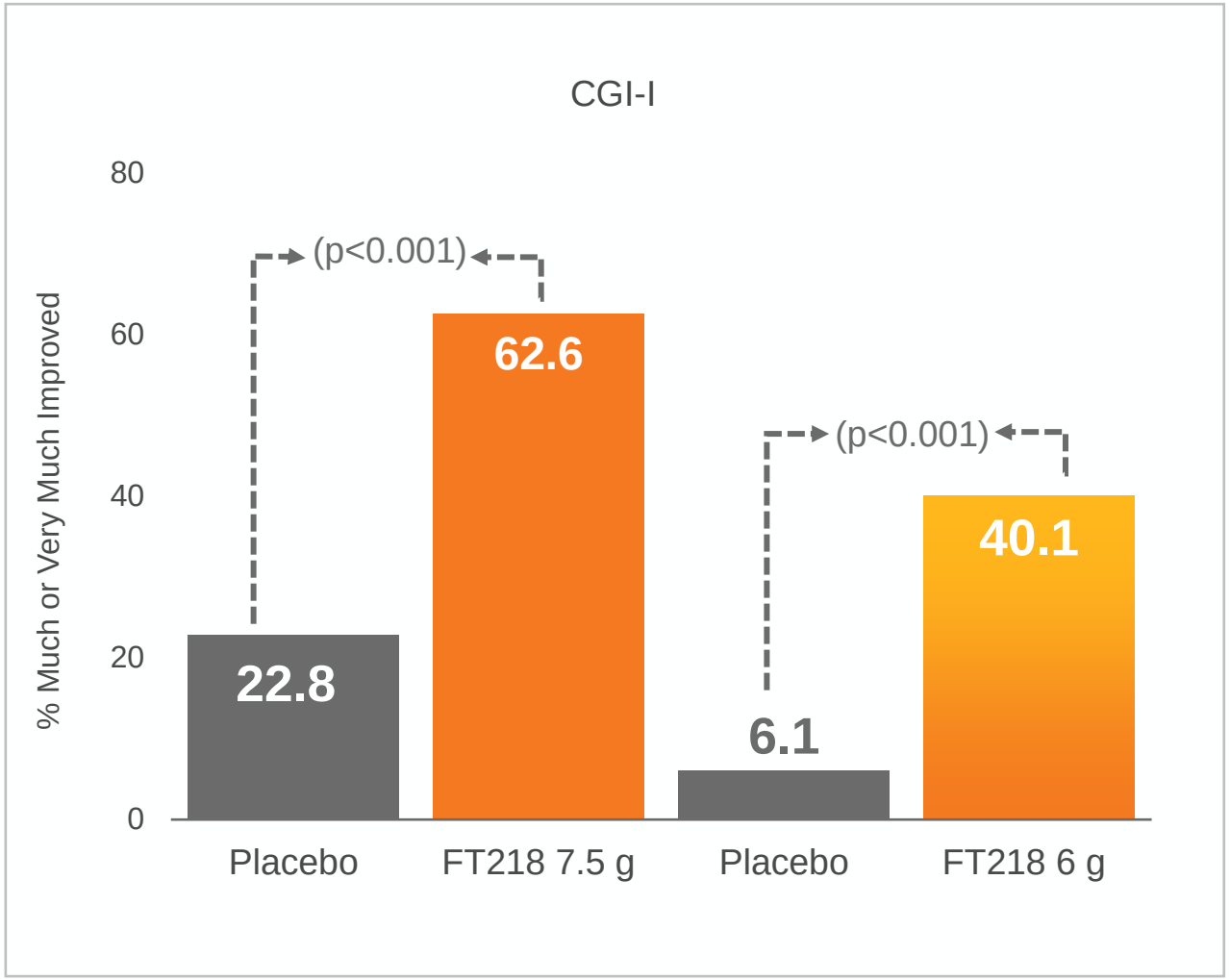
FT218 7.5 g and 6 g Had Significant Improvements on the CGI-I Compared to Placebo



CGI-I - Percent Much or Very Much Improved

62.6% of patients on FT218 7.5 g compared to 22.8% of patients on placebo were rated as much or very much improved at Week 8; Odds Ratio 5.67 (*p<0.001)*

40.1% of patients on FT218 6 g compared to 6.1% of patients on placebo were rated as much or very much improved at Week 3; Odds Ratio 10.29 *(p<0.001)*

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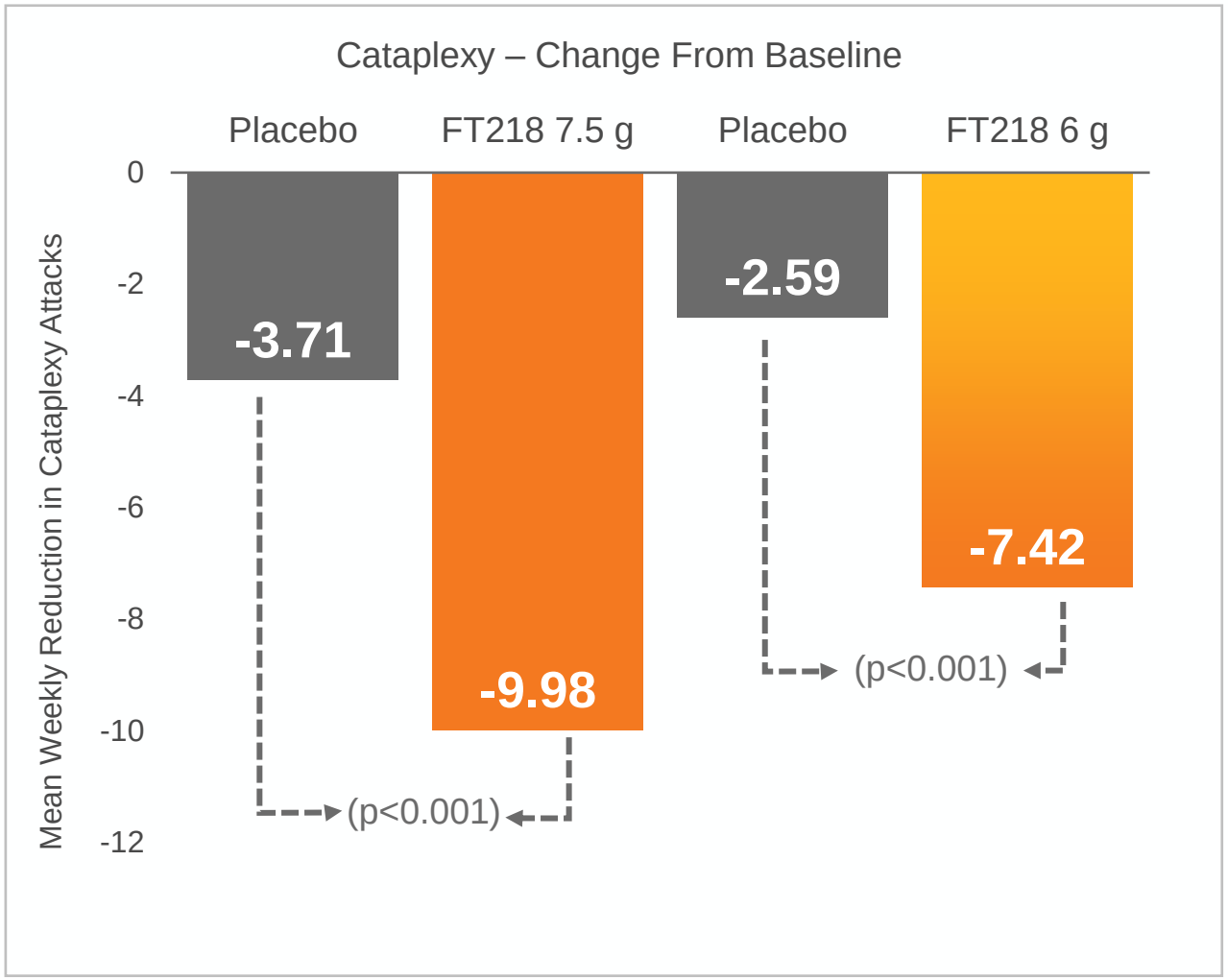
FT218 7.5 g and 6 g Had Significant Reductions in Mean Weekly Cataplexy Attacks Compared to Placebo



Change From Baseline in Weekly Cataplexy Attacks

Change from Baseline to Week 8 for FT218 7.5 g was -9.98, compared to -3.71

LS Mean difference between FT218 7.5 g and Placebo was -6.23 ($p<0.001$)

Change from Baseline to Week 3 for FT218 6 g was -7.42, compared to -2.59

LS Mean difference between FT218 6 g and Placebo was -4.63 ($p<0.001$)

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Q&A

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Closing Remarks

WHAT TO EXPECT:

Once-Nightly FT218 Next Steps

Event	Status
REST-ON completion and topline data	Complete
Switch and Open Label Extension study	In-progress
Full REST-ON analysis and complete study report	In-progress
Pre-NDA meeting	In-progress
NDA completion and submission	In-progress
Medical Communication Plan	In-progress
Market preparation and commercial planning	In-progress

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AT A GLANCE

Once Nightly FT218: All the Ingredients for Success

FT218

a differentiated product with high potential

Completed Pivotal Study

REST-ON Ph3 study, single study required for approval (SPA agreement)

DEMONSTRATED

highly significant results across all three co-primary endpoints at all doses studied

~$1.7B

Annualized and growing sodium oxybate market

ZERO

New Chemical Entity Risk

17 YEARS

intellectual property protection – until mid- 2037 with additional patents under development

THE RIGHT TEAM IN PLACE

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