



Avadel Pharmaceuticals plc

July 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 anticipated enrollment for the OLE/switch study for FT218 as well as the long-term safety and maintenance of efficacy data generated from that study may be delayed or include unanticipated results, (v) the FDA may determine there are deficiencies in the NDA for FT218 or may never approve the NDA for FT218, (vi) FT218 may not have the therapeutic benefits we anticipate, (vii) the commercial launch of FT218 could be delayed, (viii) FT218 may not achieve commercial acceptance, and (ix) other companies may develop competing products that may receive FDA approval before FT218; (d) 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.

Track Record of Achieving Strategic Milestones

Starting in Q1 2019

Consolidated operations in the U.S. to focus on development of FT218

1H 2020

Completed two financings for gross proceeds of \$190M

Starting in Q1 2019

Established a highly capable and committed executive team

Q2 2020

Divested legacy hospital products portfolio for \$42M

Q2 2020

Completed and announced positive top-line results for Phase 3 REST-ON Study

Q3 2020

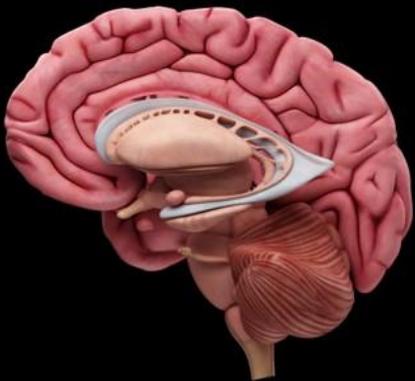
Commenced OLE/Switch Study and enrolled first patient

AT A GLANCE

The New Avadel: All the Ingredients for Success

FT218

a differentiated product with high potential and no new chemical entity risk



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



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Annualized and growing sodium oxybate market

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17 YEARS

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

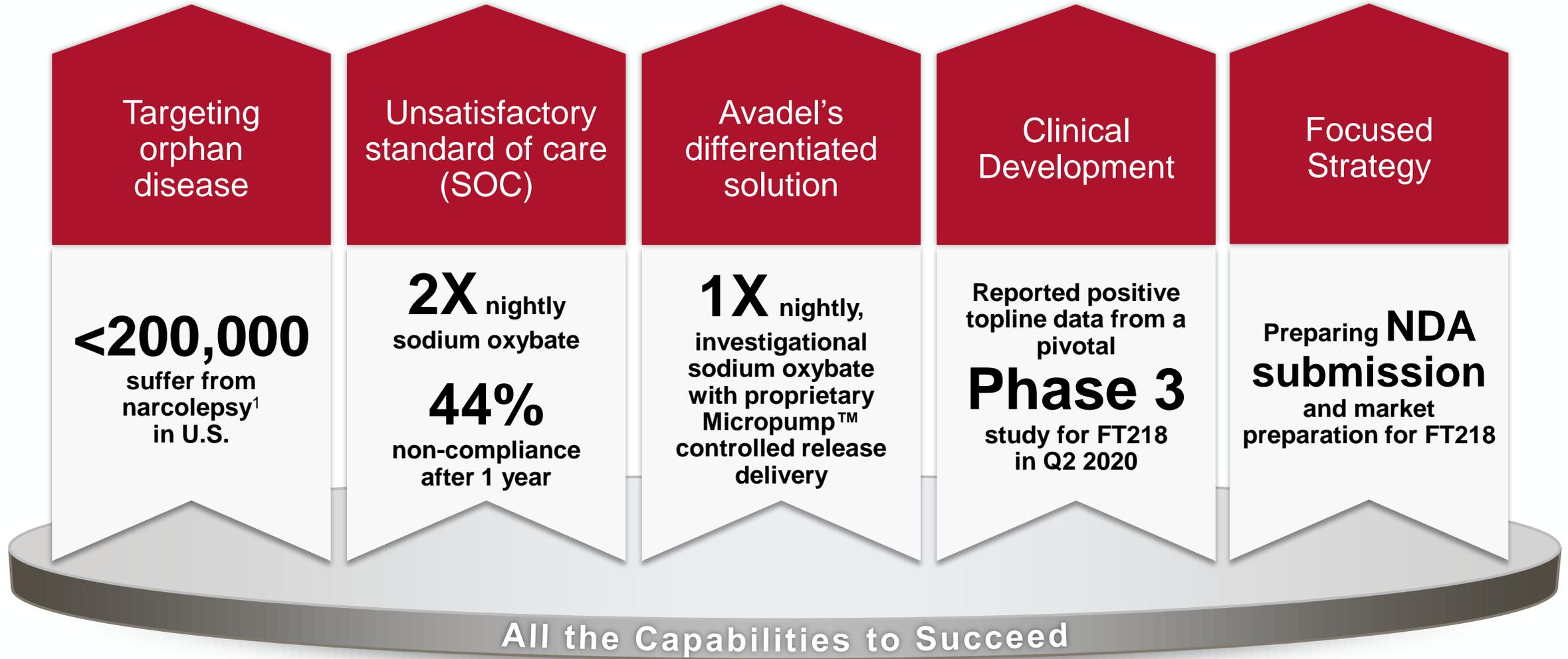


Strong Balance Sheet

to support the development and commercial preparation for FT218



Investigational FT218 is Positioned to Disrupt the Narcolepsy Market



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 2027¹



A New Paradigm of Treatment is Welcomed by Physicians

There is high unmet need in patients treated with the 2x-nightly product

"... I don't know of another medication where the patient has to wake up in the middle of the night to take it again, this is a serious problem for patients that already have a sleep disorder ..."

Sleep Specialist KOL, Major Academic Hospital Sleep Center in PA

"... The dosing schedule makes it complicated. It's hard for them to wake up, so they may miss their second dose or take it at the wrong time. It's also a burden on their spouse or parents or roommates ..."

Primary Care Physician, Private Clinic in NJ

FT218 target product profile strongly resonates with physicians

"... [FT218] is what we have been expecting, this is what we want. In my opinion, patients wouldn't be so confused about starting therapy... we would almost only use [FT218] over Xyrem ..."

Sleep Specialist, Academic Hospital Sleep Center in WV

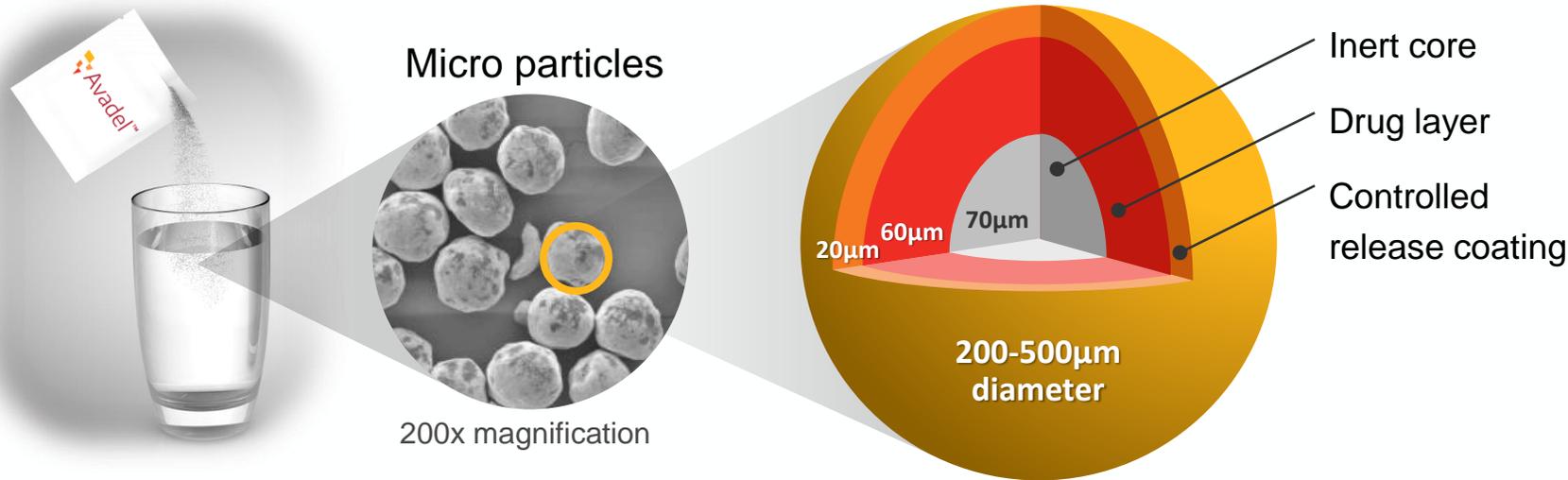
"... I would very much prefer [FT218], patients need quality sleep, and that's what I believe [FT218] could offer. I would welcome it ..."

Neurologist, Private Clinic in SC



Leveraging Our Proprietary Drug Delivery Technology – Delivering Investigational Once Nightly Sodium Oxybate

The Technology

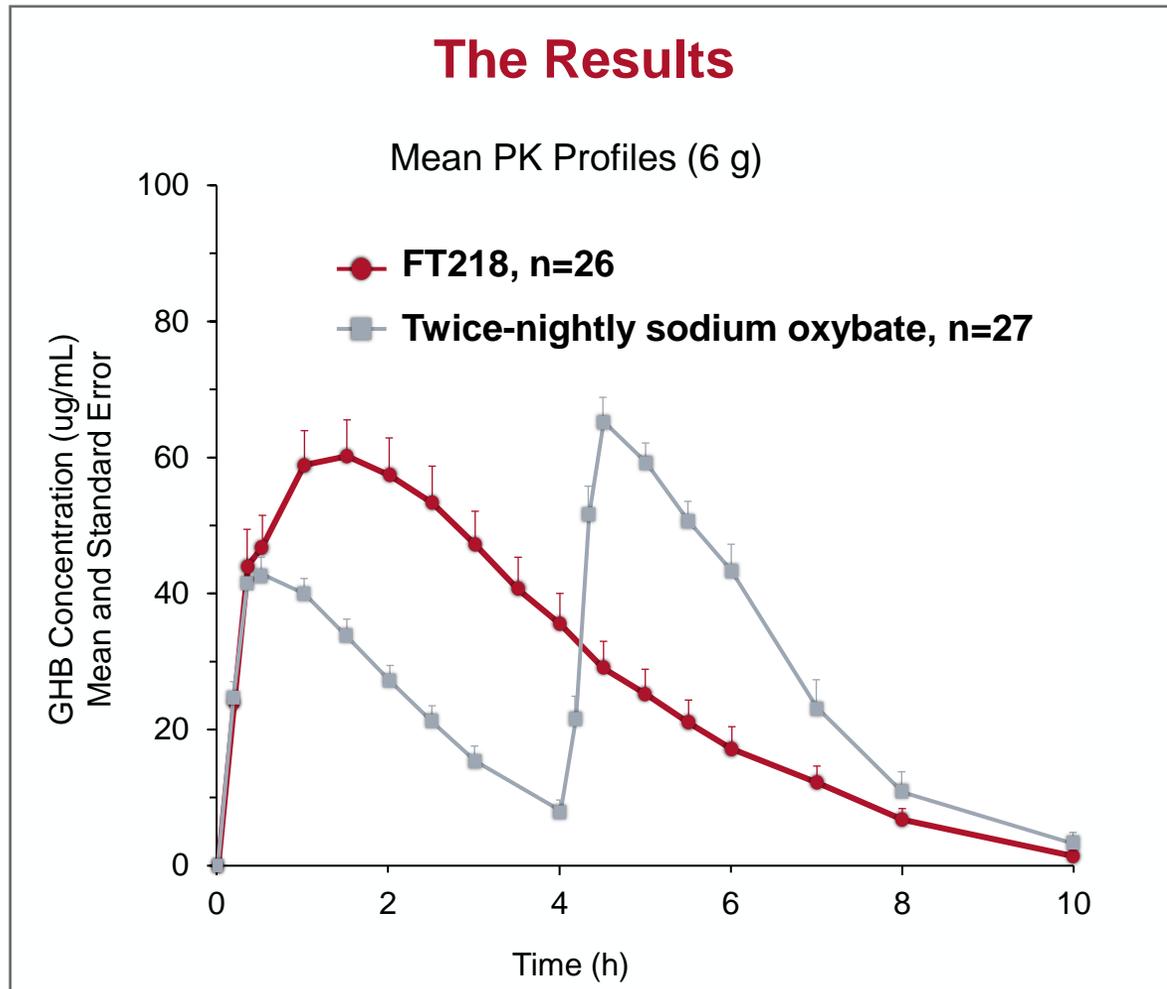


- **Technology contains thousands of micro particles**
 - Each is a miniature delivery system
- **Microparticulate design can be adapted to each drug's specific challenges**
 - Modify coatings / thickness

The Advantages

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

Initial Pharmacokinetic (PK) Studies Indicated Potential Advantages of Investigational, Once-Nightly FT218 at 6 g Dosing



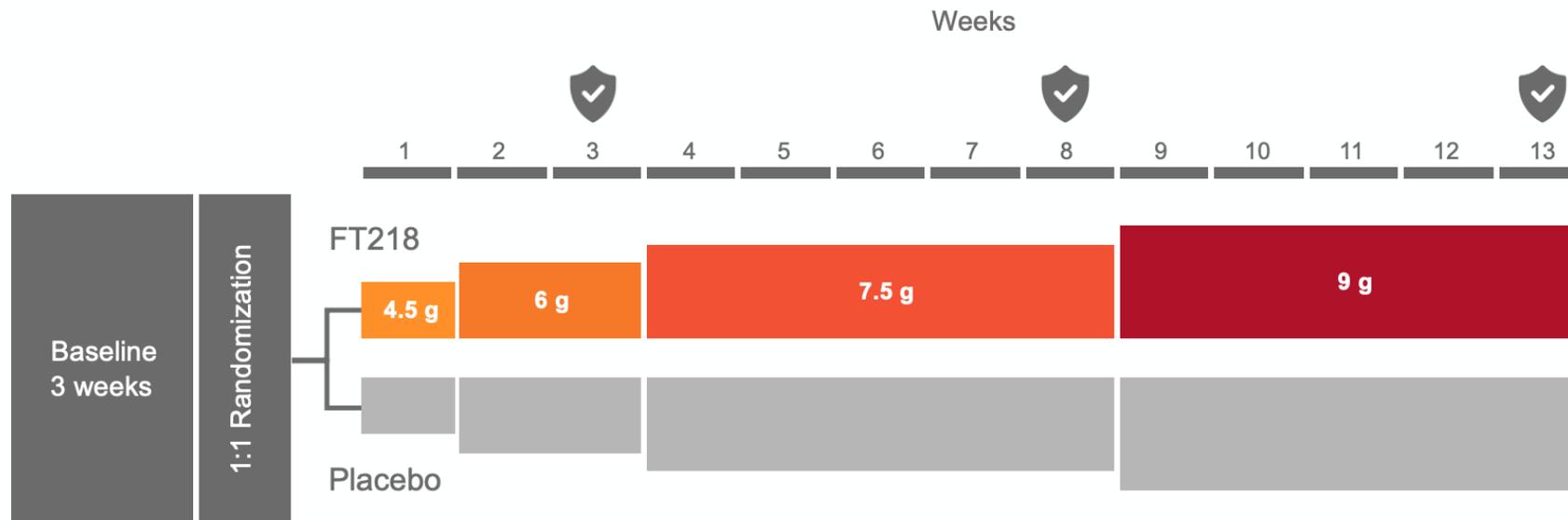
The Comparison to 2X Nightly

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

REST-ON Study

REST-ON was a pivotal Phase 3 double-blind, randomized, placebo-controlled study to assess the efficacy and safety of FT218, an investigational, once-nightly formulation of sodium oxybate, intended for the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy

- ✓ The study is under a Special Protocol Assessment agreement with FDA
- ✓ The study enrolled a total of 212 patients, was completed in March 2020 and announced topline data in April 2020



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



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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 ($p < 0.001$)

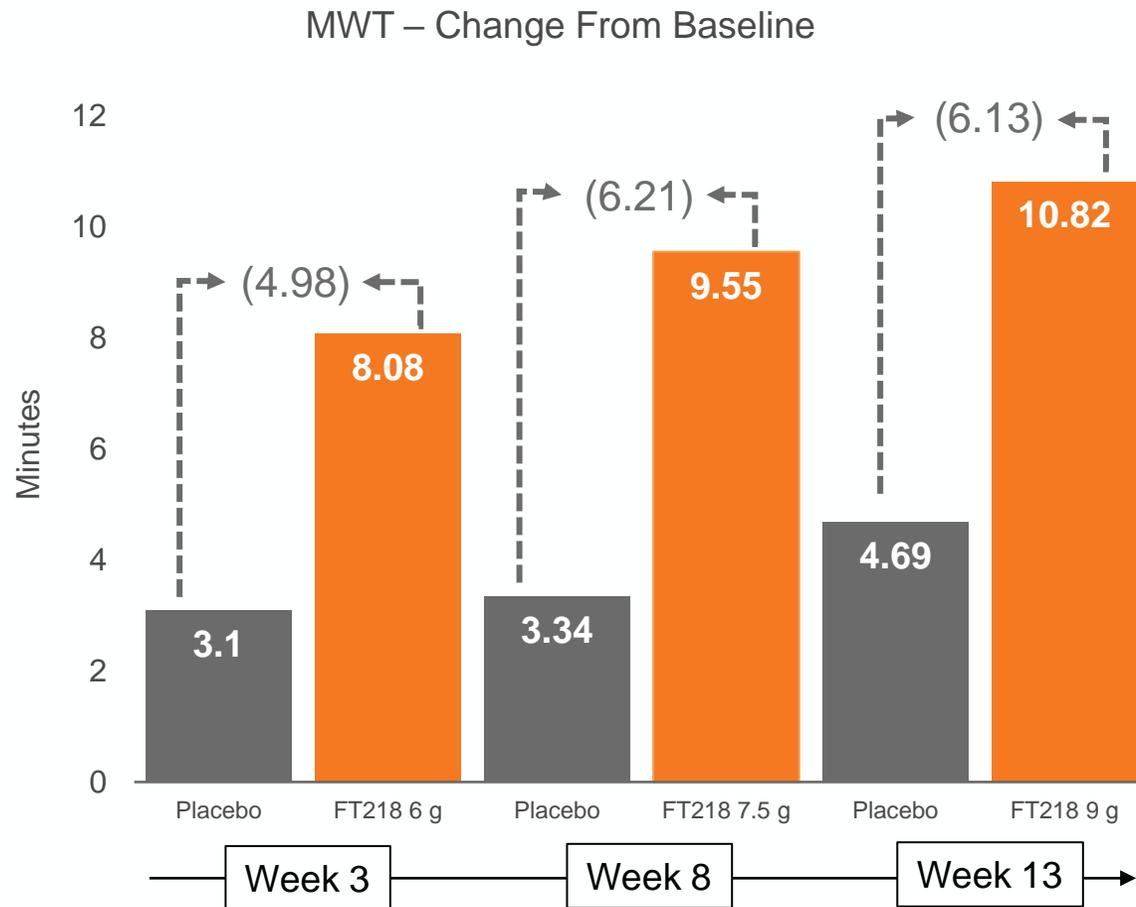


FT218 7.5 g and 6 g also demonstrated statistical significance for the three co-primary endpoints, compared to placebo



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

FT218 was Significant on the MWT Compared to Placebo



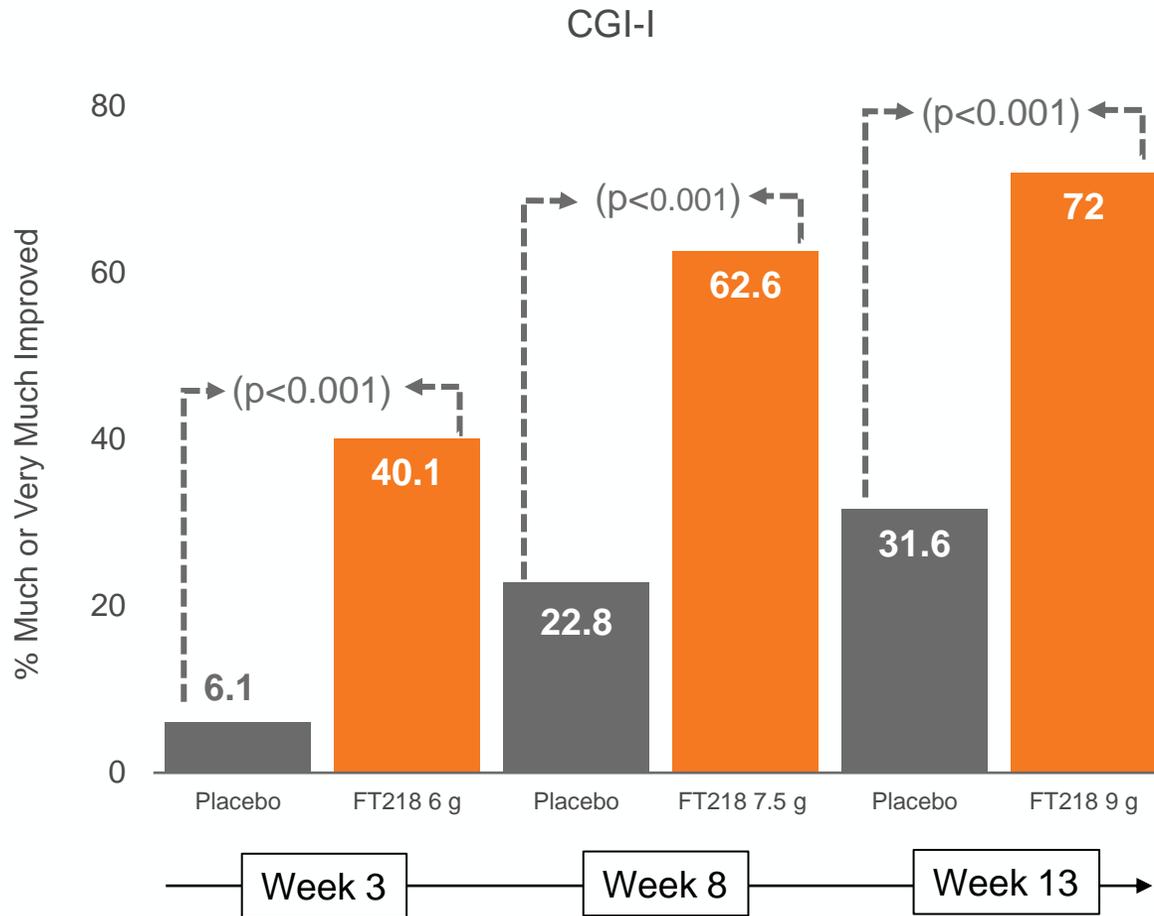
Change From Baseline in MWT

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

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

LS Mean difference between FT218 9 g and Placebo was 6.13 ($p < 0.001$)

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



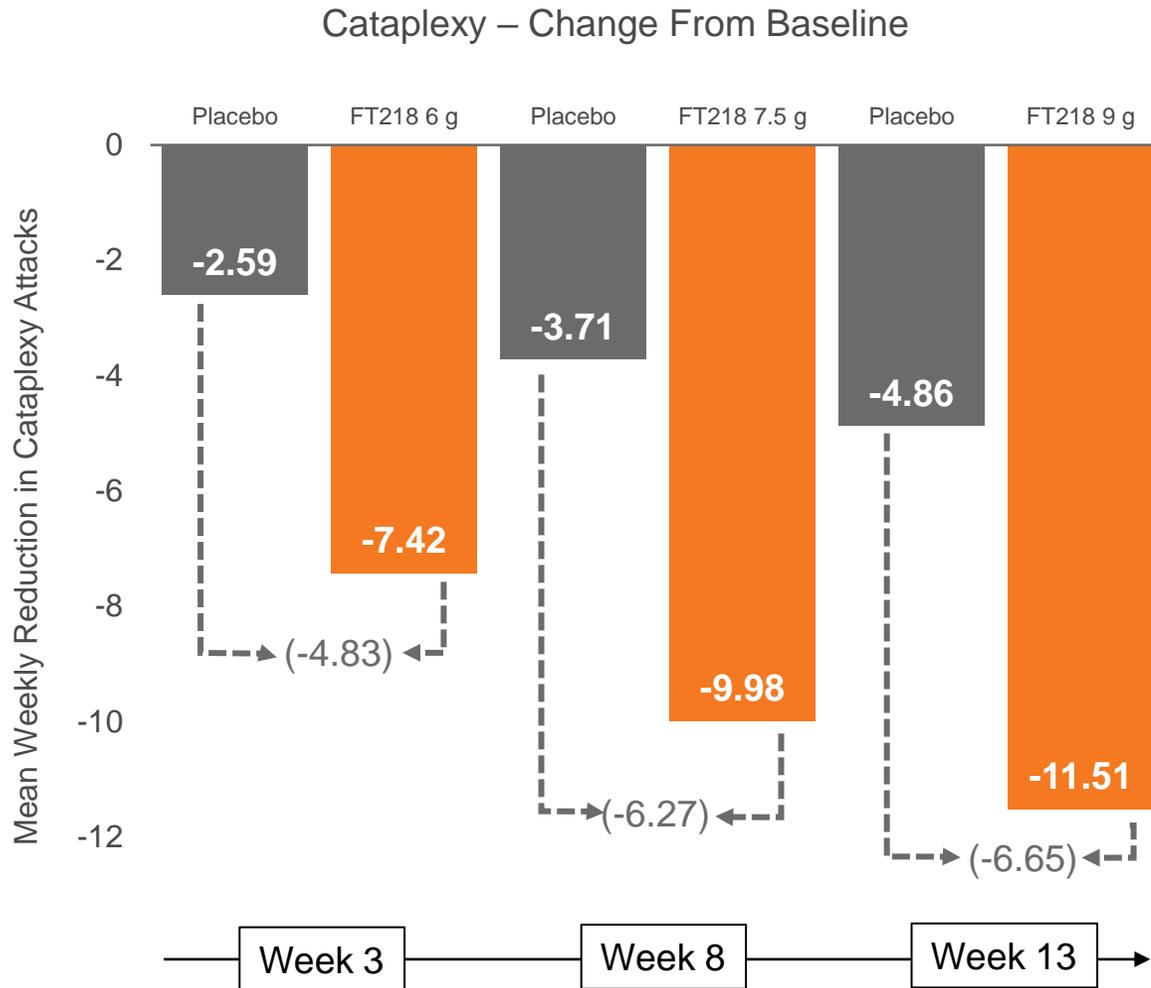
CGI-I - Percent Much or Very Much Improved

Odds ratio between FT218 6g and Placebo at week 3 was 10.29 ($p < 0.001$)

Odds ratio between FT218 9g and Placebo at week 8 was 5.67 ($p < 0.001$)

Odds ratio between FT218 9g and Placebo at week 13 was 5.56 ($p < 0.001$)

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



Change From Baseline in Weekly Cataplexy Attacks

LS Mean difference between FT218 6 g and Placebo was -4.83 ($p < 0.001$)

LS Mean difference between FT218 7.5 g and Placebo was -6.27 ($p < 0.001$)

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

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

FT218 - Priorities Going Forward

- 1.** Laser focus on successful completion of FT218 and NDA submission
- 2.** Execute additional clinical programs including OLE/Switch study
- 3.** Advance FT218 “go to market” planning



Near-Term Key Milestones

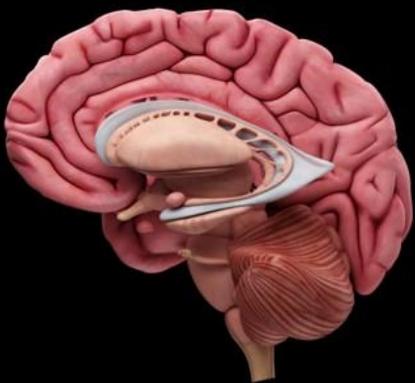
Event		Status
• Completion of patient enrollment (205)	▶	Completed ✓
• Announce topline data REST-ON study	▶	Completed ✓
• Sale of hospital sterile injectable drug portfolio – focus resources on FT218	▶	Completed ✓
• File NDA submission	▶	In process
• Establish commercial capabilities	▶	In process
• Complete OLE/Switch study	▶	In process

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