Topline Results from ADDRESS-LC Trial

September 2026

FORWARD-LOOKING STATEMENTS

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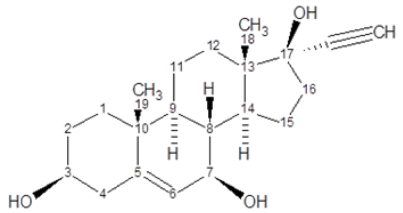
BEZISTERIM

Believed to block ERK/NFκB-mediated inflammatory signaling while preserving homeostatic function

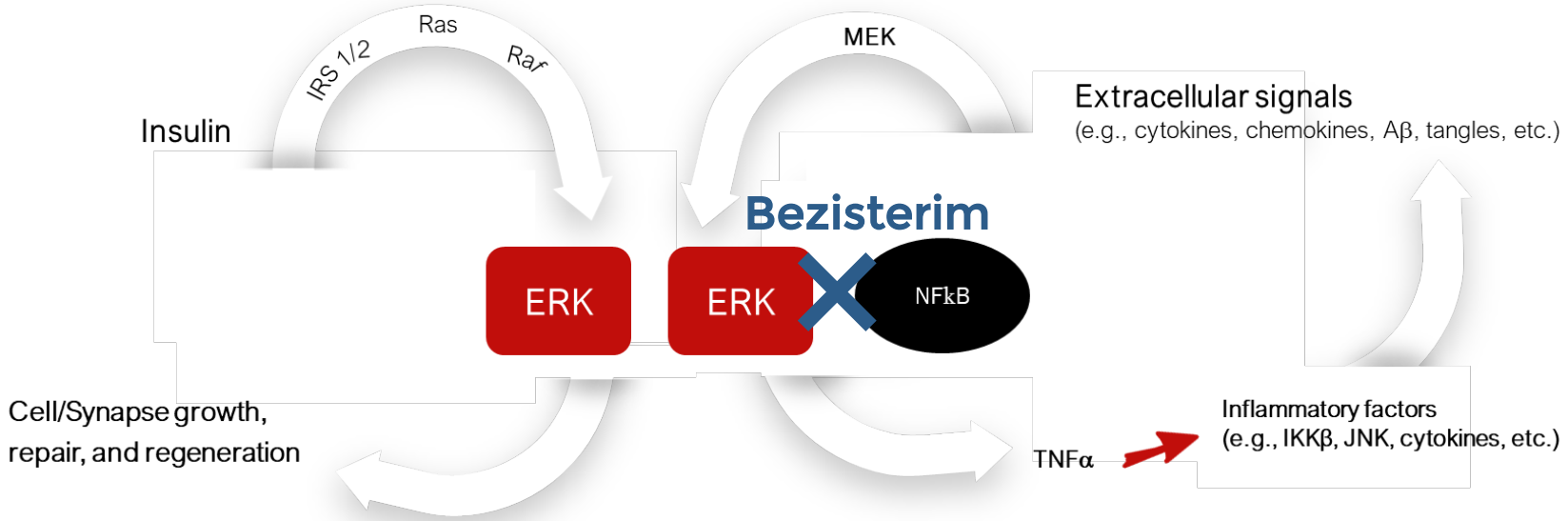


First-in-class molecule with desirable characteristics

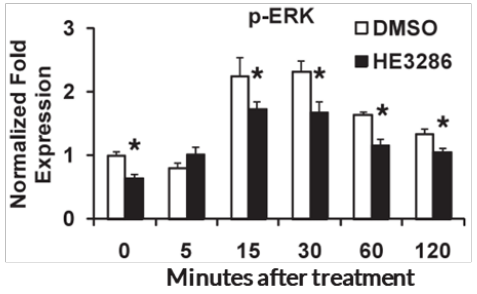
Small molecule; orally bioavailable

Crosses blood-brain barrier

No significant safety issues identified to date in pre-clinical and clinical trials (up to Phase 3)

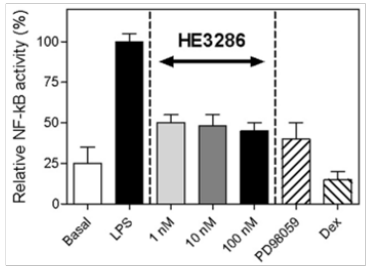


Bezisterim Reduces ERK Activation



Lu 2010 Am J Physiol Endocrinol Metab 298 E1036

Bezisterim Reduces NFkB Activation



Wang 2010 J Pharmacol Exp Ther 333 70

WHY STUDY BEZISTERIM IN LONG COVID?

ANTI-INFLAMMATORY MECHANISM

- Inhibits TLR-4 and TNF-stimulated NFκB activation
- Binds MAP kinases ERK1 and ERK2

ACTIVITY IN NEUROINFLAMMATION MODELS

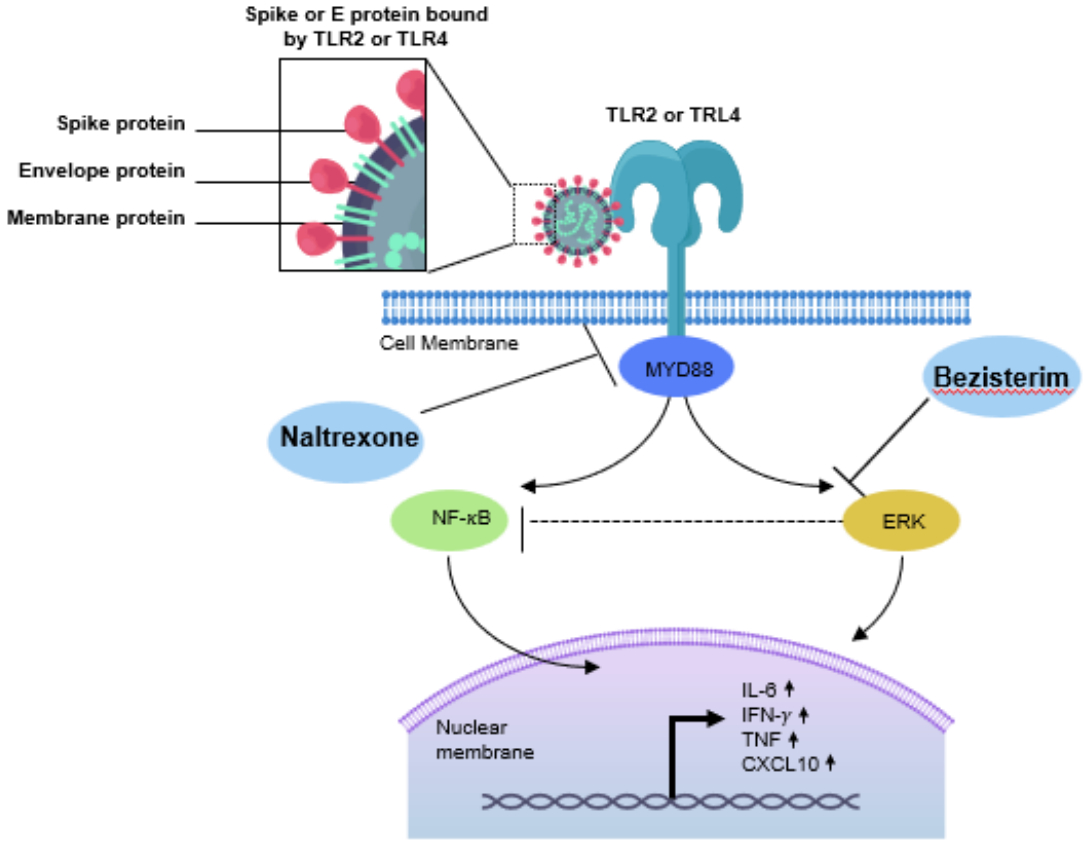
- MPTP-induced Parkinson's disease, glaucoma, optic neuritis, retinal uveitis, acute seizure

CLINICAL SIGNALS THAT MAY TRANSLATE

- Improved cognitive function in mild cognitive impairment and Alzheimer's disease
- Improved fatigue and energy in Parkinson's disease

TRANSLATIONAL LEARNING STUDY NEEDED

- Test bezisterim in Long COVID for the first time



ADDRESS-LC PHASE 2 TRIAL

- Designed as a signal-finding and proof-of-concept trial
  - Identify efficacy signals: endpoints with favorable treatment benefits
  - Measure the magnitude of treatment impact
  - Identify patient subgroups most likely to benefit
  - Enable design and sizing of Phase 3 trial
- Evaluated 22 clinical outcome measures
- Collected blood samples to assess a series of biomarkers, including a proteomics battery evaluating 380 different proteins
- The work is supported by the Assistant Secretary of War for Health Affairs and endorsed by the DoW by a fully funded award through the Peer-Reviewed Medical Research Program (PRMRP)*

* Opinions, interpretations, conclusions and recommendations are not necessarily endorsed by the Assistant Secretary of Defense for Health Affairs or the DoW

KEY FINDINGS

Long COVID patients fall into diverse, heterogeneous symptomatic subgroups

- Not all patients have all symptoms
- Patients can have combination of 1, 2 or 3 of fatigue, post-exertional malaise and/or cognitive impairment symptoms

Patients with severe baseline symptoms showed the strongest, statistically significant improvements; those without symptoms had little room to improve

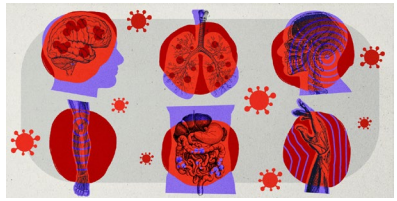
- Patients with high baseline fatigue showed statistically significant improvements vs. placebo on five different fatigue endpoints, along with positive trends in sleep and post-exertional malaise
- Patients with high baseline post-exertional malaise improved on malaise and cognition
- Patients with high baseline cognitive impairment improved on cognition

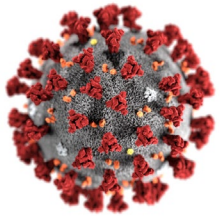
Safety/tolerability profile similar to placebo

- Minimizing side effect burden important given polypharmacy for Long COVID

LONG COVID IS A CHRONIC CONDITION

An infection-associated chronic condition present for at least 3 months affecting one or more organ systems.





Long COVID ≠ COVID

20%

RESPIRATORY

Dyspnea, cough, reduced exercise tolerance

20%

GENERAL / FATIGUE

Post-exertional malaise, unrefreshing sleep

18%

PSYCHOLOGICAL

Depression, anxiety, mood disturbance

16%

NEUROLOGICAL

Cognitive impairment, headache, dysautonomia

Diagnosis is clinical and by exclusion. There are no confirmatory diagnostic tests.

NASEM/HHS consensus definition (2024); Hou et al., Open Forum Infect Dis, 2025.

LARGE PATIENT POPULATION AND UNMET NEED

17-20 million US adults

are estimated to suffer from Long COVID, a persistent multi-system illness following SARS-CoV-2 infection.

No proven therapy

No non-pharmacological or pharmacological therapy has been demonstrated efficacious for the treatment of Long COVID.

A disabling symptom triad

Fatigue, cognitive impairment ("brain fog"), and post-exertional malaise often co-occur and are linked to a chronic inflammatory state.

17-20M

US adults estimated to be living with Long COVID[1]

3.8M

US adults whose Long COVID is disabling[2]

ME/CFS incidence is up 15× since the pandemic.

[1] U.S. Department of Health and Human Services (https://www.hhs.gov/longcovid/index.html)
[2] Bonuck et al. (2026). *Communications Medicine* (https://www.nature.com/articles/s43856-026-01516-7)

THE CHALLENGE IS NOT EFFICACY ALONE – IT IS KNOWING WHO BENEFITS

01

HETEROGENEOUS SYNDROME

Long COVID is not a single disease entity, but a heterogeneous syndrome with overlapping clinical phenotypes and biological endotypes.

02

NO VALIDATED BIOMARKERS

The absence of validated diagnostic and predictive biomarkers limits patient selection and prospective identification of treatment responders.

03

BACKGROUND VARIABILITY

Concomitant off-label medications and supplements introduce substantial background-treatment variability.

04

POLYPHARMACY SAFETY

Most patients prescribed multiple medications. Any new treatments should not add to side effect burden.

THE CENTRAL DEVELOPMENT CHALLENGE

Not only to demonstrate efficacy, but to determine which patients benefit – and why.

CLINICAL ENDPOINTS

Explored a series of cognitive and fatigue endpoints and biomarkers

CGIS	Clinician Global Impression Severity
CGIC	Clinician Global Impression of Change
PGIS	Patient Global Impression Severity
PGIC	Patient Global Impression of Change
PGIS-Fatigue	Patient Global Impression Severity Fatigue
PGIC-Fatigue	Patient Global Impression Change Fatigue
PGIS-Think	Patient Global Impression Severity Think Clearly
PGIC-Think	Patient Global Impression Change Think Clearly
PROMIS Fatigue	Patient Reported Fatigue Symptoms
PROMIS Cog	Patient Reported Perceived Cognition
PROMIS Sleep	Patient Reported Sleep Disturbance
SF12-PCS	Physical Component Score of SF12
SF12-MCS	Mental Component Score of SF12
DSQ Total	Patient Reported Total
DSQ-PEM	Patient Reported Post-exertional malaise
Cogstate Global	Global Cognition score
Cogstate Detection S.D	Cognitive Test for Detection & Psychomotor
Cogstate Ident-Attent.	Cognitive Test for Identification & Attention
Cogstate Proc Speed	Cognitive Test for Processing Speed
Cogstate Verbal Learn	Cognitive Test for Verbal Learning
Cogstate Verbal Mem	Cognitive Test for Verbal Memory
Cogstate Sust attention	Cognitive Test for Sustained Attention

HOW TO READ THE NUMBERS

Two yardsticks used throughout: effect size (how big) and the p-value (how sure)

Cohen's d – how big is the effect?

d ≈ 0.2	small
d ≈ 0.5	medium
d ≈ 0.8	large
Positive value	Treatment improvement

p-value – how sure are we?

Smaller p = less likely to be coincidental
$p < 0.05$ is the conventional bar for statistical significance

BASELINE CHARACTERISTICS

Treatment and placebo arms appear balanced at baseline

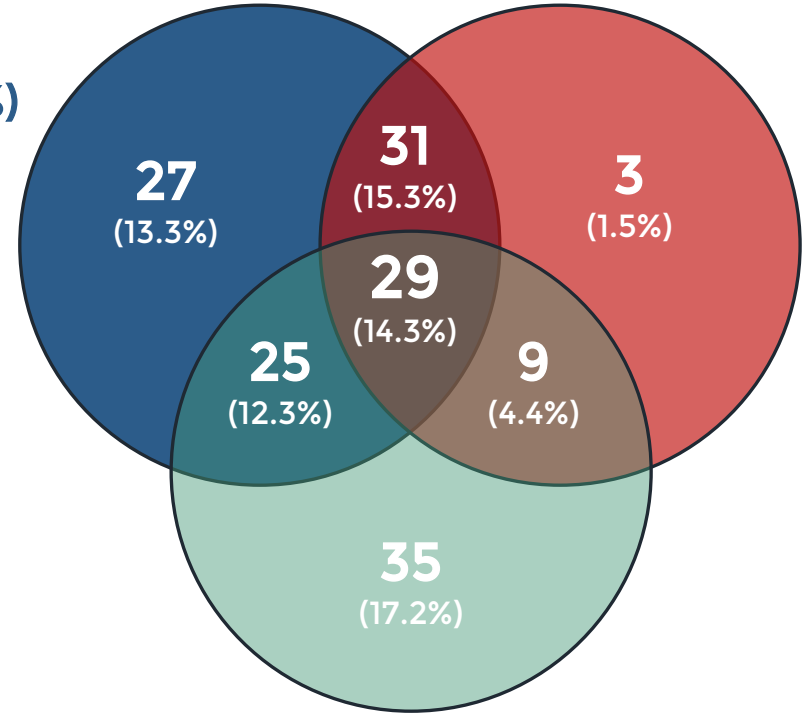
Characteristic	Bezisterim	Placebo
Age, years (mean ± SD)	47.6 ± 10.6	49.2 ± 12.9
Sex, Male / Female (n)	24 / 77	46 / 56
Clinician Global Impression – Severity	3.3 ± 0.7	3.3 ± 0.7
Cogstate detection / psychomotor	0.04 ± 0.92	-0.04 ± 1.07
Cogstate global cognition	0.06 ± 0.94	-0.05 ± 1.06
Cogstate identification / attention	0.01 ± 1.05	-0.01 ± 0.95
Cogstate verbal learning	0.09 ± 0.99	-0.09 ± 1.01
Cogstate verbal memory	0.03 ± 0.96	-0.03 ± 1.04
Cogstate processing speed	0.11 ± 1.00	-0.11 ± 1.00
Cogstate sustained attention	-0.02 ± 0.93	0.01 ± 1.07
DSQ-PEM case definition met	91/101 (90.1%)	94/102 (92.2%)
DSQ-PEM total (0–100)	57.4 ± 21.5	54.3 ± 22.1
Patient Global Impression – Severity: fatigue	3.7 ± 0.8	3.5 ± 0.8
Patient Global Impression – Severity: overall	3.6 ± 0.7	3.6 ± 0.8
Patient Global Impression – Severity: think clearly	3.8 ± 0.9	3.8 ± 0.9
PROMIS cognitive function	32.3 ± 6.3	33.4 ± 5.6
PROMIS fatigue	65.4 ± 6.0	64.0 ± 6.3
PROMIS sleep disturbance	57.0 ± 6.3	57.2 ± 7.6
SF-12 mental component	44.2 ± 9.4	43.1 ± 9.5
SF-12 physical component	33.0 ± 10.2	34.5 ± 10.4

BASELINE SYMPTOMATIC DIFFERENCES AMONG PATIENTS

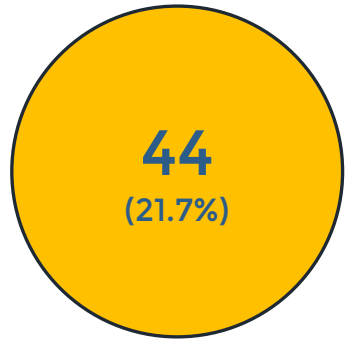
~78% of patients symptomatic with ≥ 1 severity criterion (N=159 / 203 total trial population)

Total N = 203

High Fatigue (N=112, 55.2%)
(PROMIS Fatigue
≥ median score of 65.0)



High Post-Exertional Malaise (N=72, 35.5%)
(DSQ-PEM ≥ top tertile score of 67.5)



Low on all 3 Symptoms

High Objective Cognitive Impairment* (N=98, 48.3%)
(Cogstate Global Baseline Z ≤ median score of -0.108)

* Objective cognition is conducted using an iPad that gives patients tasks to complete and measure the person's actual cognitive performance.

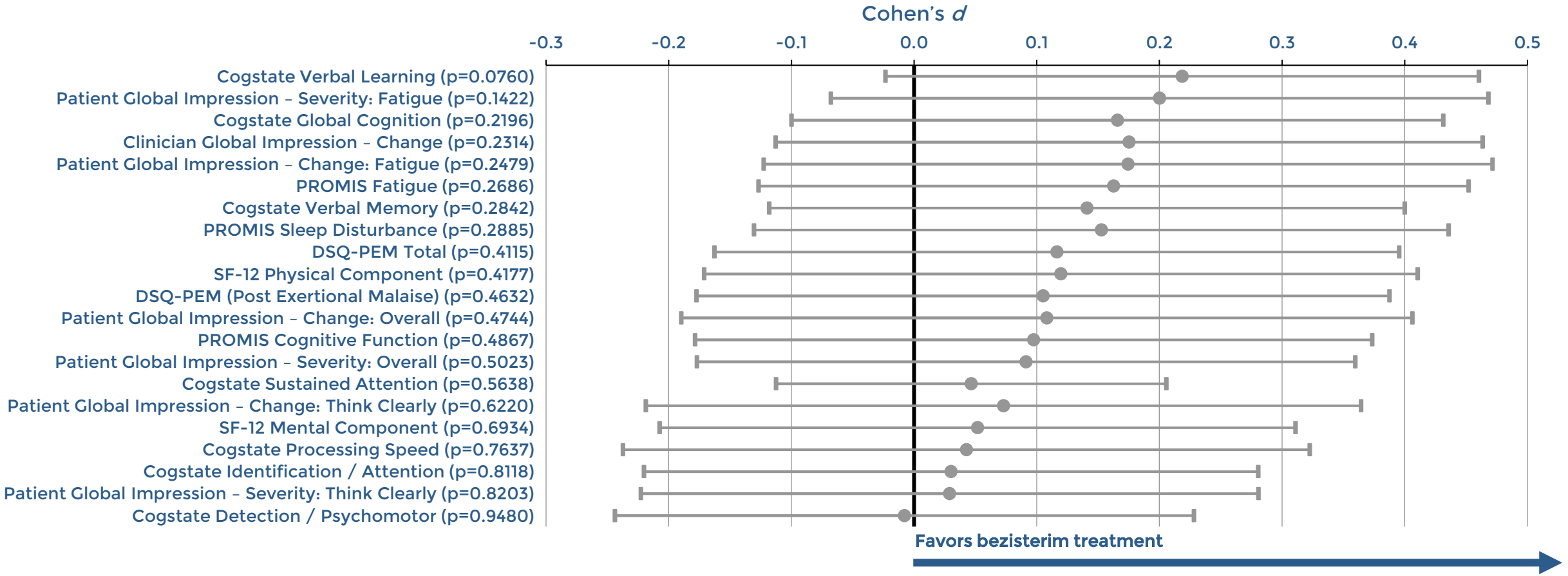
MULTIPLE LEVELS OF SYMPTOM SEVERITY REQUIRES A FOCUS ON THOSE WITH MOST SYMPTOMATIC NEED

Heterogeneity in the Long COVID population is driven by wide variation in symptoms and severity levels

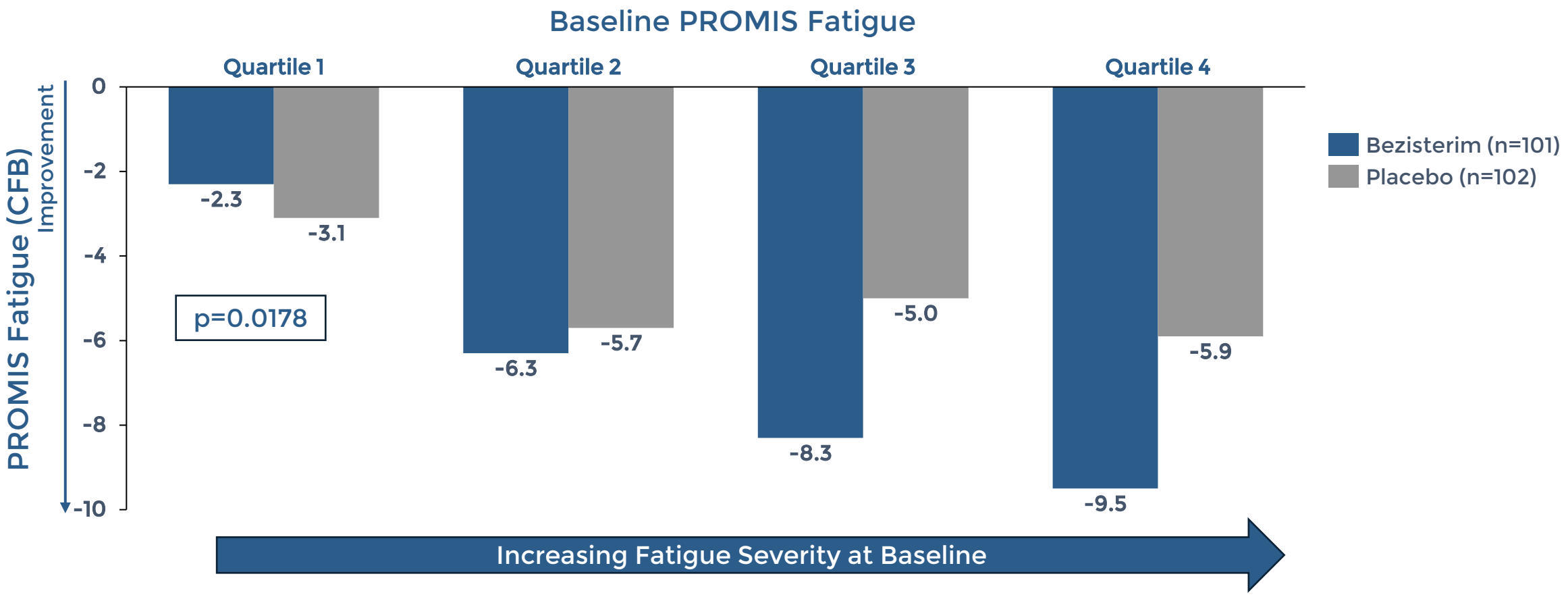
- Complicates overall signal detection and increases variance, making true treatment effects harder to discern.
- Necessitates focusing on patients with the most severe symptoms, where meaningful change can rise above background noise.
- Underscores the importance of identifying sub-groups most likely to benefit from treatment

PATIENTS TREATED WITH BEZISTERIM EXPERIENCED AN ADVANTAGE ON VIRTUALLY ALL ENDPOINTS

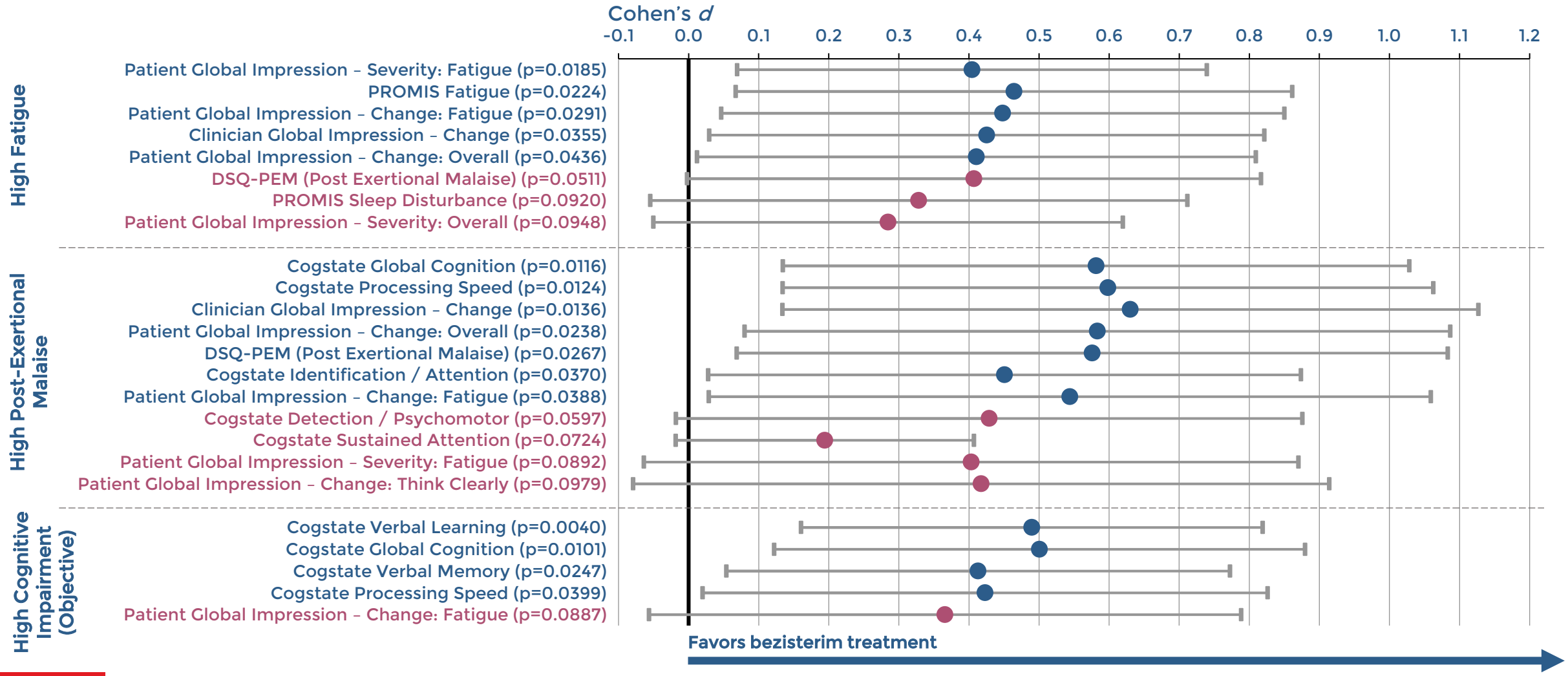
Bezisterim's impact on ITT population (n=203) – Highly unlikely to occur by chance



HIGHER BASELINE FATIGUE ASSOCIATED WITH GREATER IMPROVEMENTS WITH BEZISTERIM

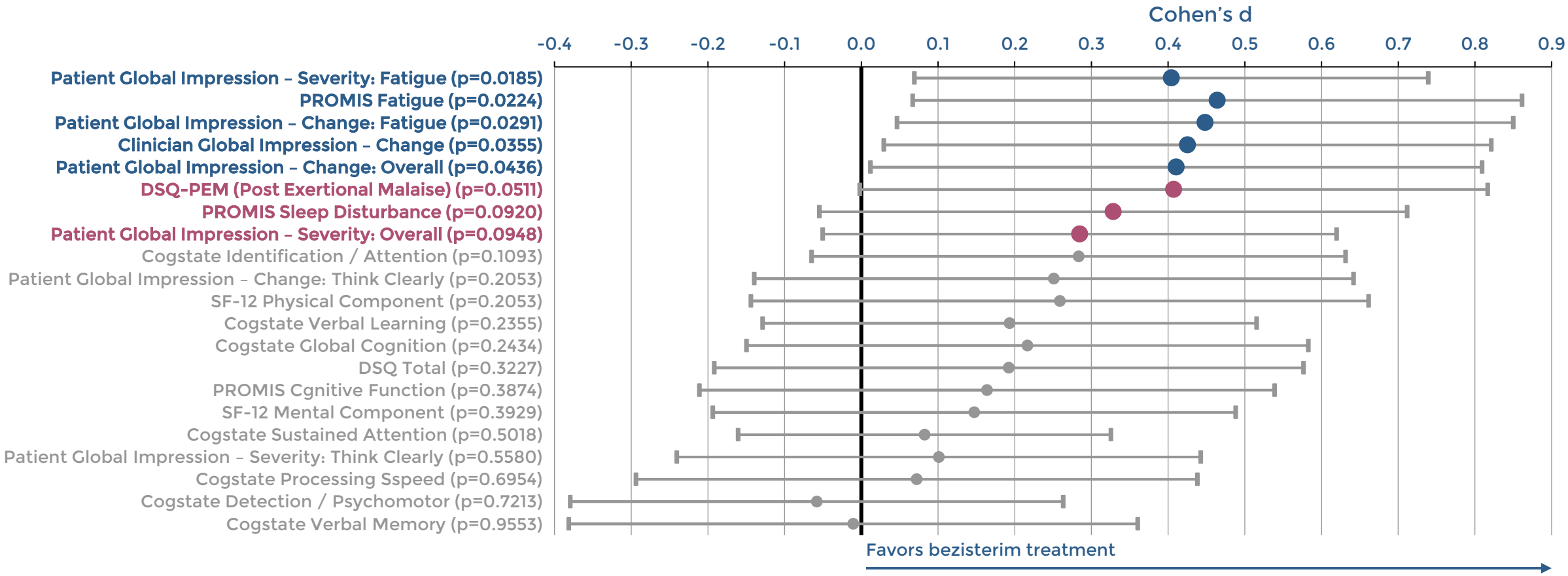


HIGH SYMPTOMATIC BURDEN AT BASELINE ASSOCIATED WITH STATISTICALLY SIGNIFICANT IMPROVEMENTS



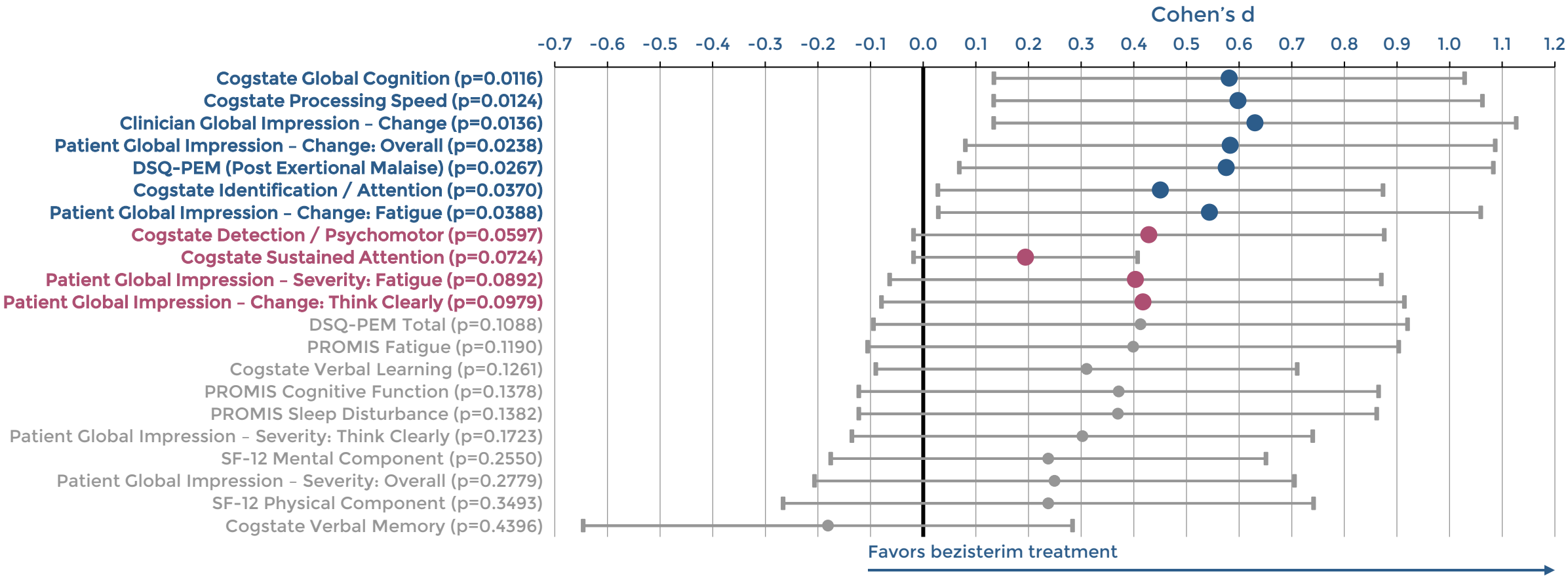
HIGH FATIGUE BEZISTERIM-TREATED PATIENTS EXPERIENCED STATISTICALLY SIGNIFICANT ADVANTAGE ON 5 ENDPOINTS; TRENDING ON 3 OTHERS

Bezisterim's impact on high fatigue subgroup (PROMIS Fatigue ≥ 65.0; n=112)



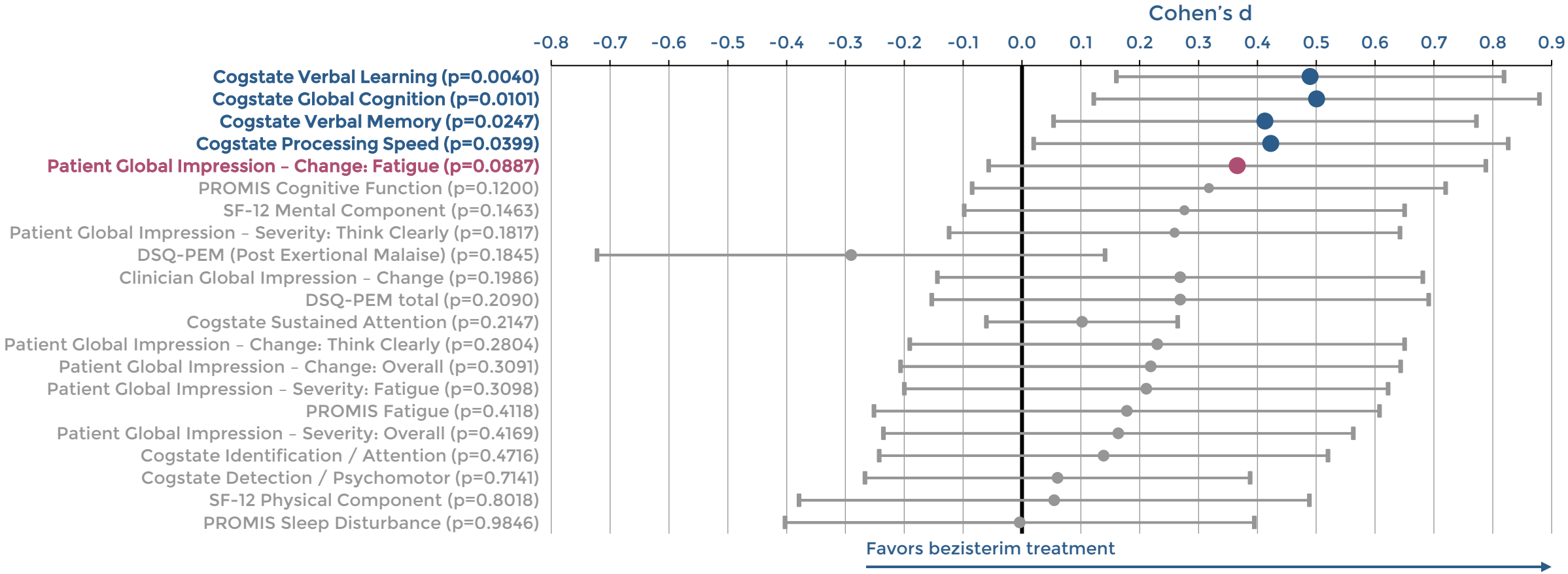
HIGH MALAISE BEZISTERIM-TREATED PATIENTS EXPERIENCED STATISTICALLY SIGNIFICANT ADVANTAGE ON 7 ENDPOINTS; TRENDING ON 4 OTHERS

Bezisterim's impact on high malaise subgroup (DSQ-PEM≥ 67.5; n=72)



HIGH COGNITIVE IMPAIRED BEZISTERIM-TREATED PATIENTS EXPERIENCED STATISTICALLY SIGNIFICANT ADVANTAGE ON 4 ENDPOINTS; TRENDING ON 1

Bezisterim's impact on high cognitive impairment subgroup (Cogstate Global≤0.130; n=98)



SAFETY & TOLERABILITY

Bezisterim safety and tolerability similar to placebo

	Bezisterim (N=101)	Placebo (N=102)
Subjects with at least one TEAE*	42 (41.6%)	57 (55.9%)
Subjects with at least one drug-related TEAE	19 (18.8%)	26 (25.5%)
Subjects with at least one serious TEAE	0	1 (1.0%)
Subjects with at least one severe TEAE	1 (1.0%)	1 (1.0%)
Subjects with at least one TEAE leading to discontinuation of study	5 (5.0%)	2 (2.0%)
Subjects with TEAE leading to death	0	0

- **Overall AEs:** Patients with any AEs: 41.6% bezisterim vs. 55.9% placebo
- **High-severity events:** Zero serious AEs for bezisterim vs. 1 for placebo, 1 severe unrelated AE for both, zero deaths.
- **Headache was the #1 reported drug-related AE**: 4% bezisterim vs. 4.9% placebo

* Treatment-Emergent Adverse Events

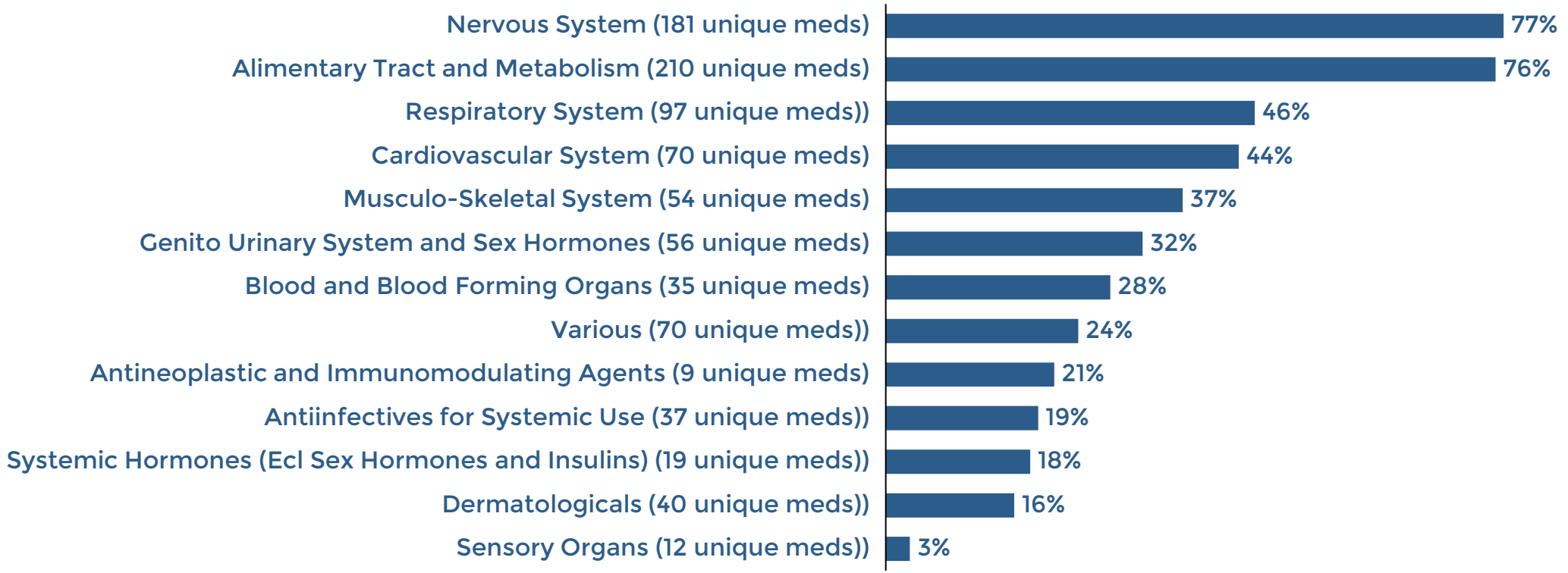
SAFETY/TOLERABILITY FINDINGS IMPORTANT GIVEN POLYPHARMACY

Percent of trial participants; N=203

96%
subjects on ≥1 concomitant medication

873
unique medications reported

13
distinct ATC Level 1 therapeutic categories



WHAT DOES IT ALL MEAN? OUR INTERPRETATION

Bezisterim has the potential to be the first treatment for Long COVID

- Bezisterim appears to help Long COVID patients with high baseline symptomatic burden
- Baseline severity on fatigue, post-exertional malaise and/or cognitive impairment associated with patient's ability to improve on that endpoint.
  - A patient not affected by a symptom has little room to improve
- Bezisterim's safety and tolerability allows for potential use with a patient population currently taking many medications
- Compelling signal identified for bezisterim warrants advancing to Phase 3 confirmatory trial

PERSPECTIVES FROM OUR INVESTIGATORS AND ADVISORS

12 / 12 Of our investigators and advisors recommend proceeding to Phase 3 confirmatory trials

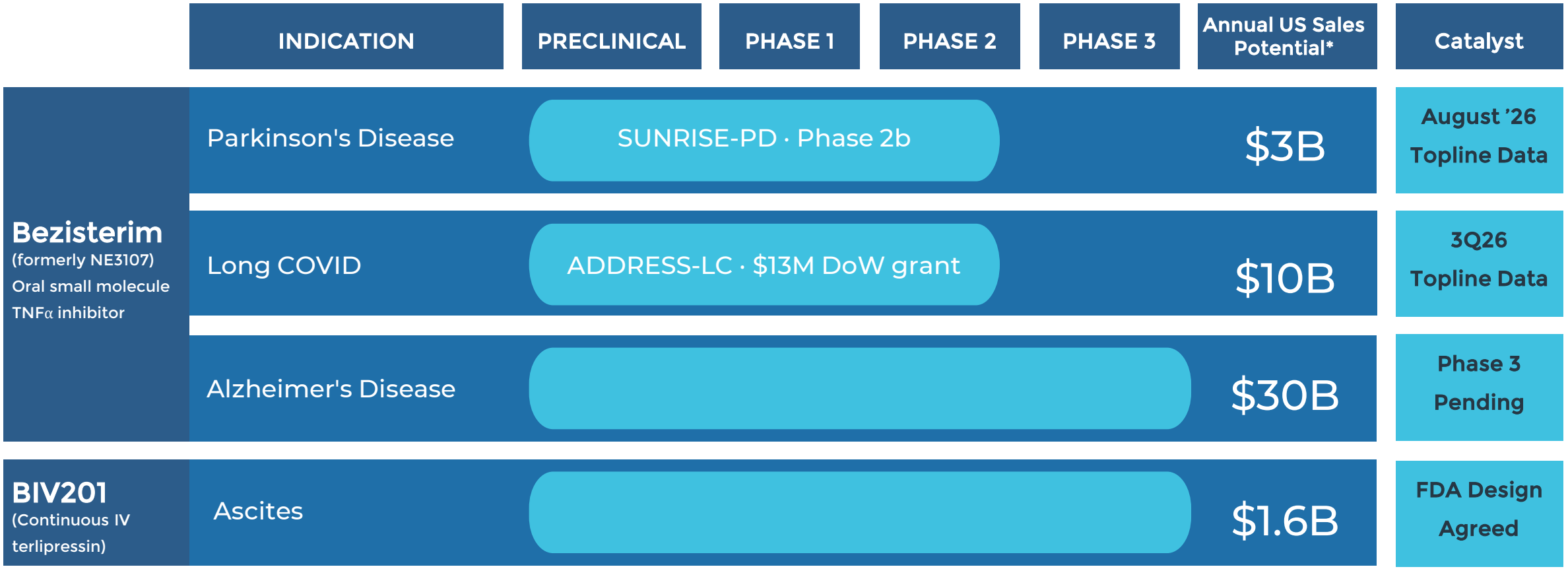
- **Hector Fabio Bonilla, M.D.**
  Clinical Professor of Medicine and Infectious Diseases
  Stanford University
- **Hannah Davis**
  Co-founder
  Patient-Led Research Collaborative (PLRC)
- **Jason D. Goldman, M.D., M.P.H.**
  Clinical Associate Professor
  University of Washington
  Providence Swedish Medical Center
- **Maureen Hanson, Ph.D.**
  Liberty Hyde Bailey Professor,
  Molecular Biology and Genetics
  Cornell University
- **Timothy Henrich, M.D.**
  Professor, Medicine, School of Medicine
  University of California, San Francisco (UCSF)
- **Jerry A. Krishnan, M.D., Ph.D.**
  Associate Vice Chancellor for Population Health Sciences & Professor of Medicine and Public Health
  University of Illinois Chicago (UIC)
- **Lyndsay McAlpine, M.D**
  Professor, Yale University School of Medicine.
  Founder, NeuroCOVID Clinic at Yale
- **Grace McComsey, M.D., FIDSA**
  Professor of Medicine; infectious diseases researcher
  Case Western Reserve University
- **Lisa McCorkell**
  Patient-Led Research Collaborative (PLRC)
- **Michael Peluso, M.D., M.H.S.**
  Associate Professor of Medicine
  University of California, San Francisco (UCSF)
- **David Putrino, Ph.D.**
  Professor, Department of Rehabilitation and Human Performance
  Icahn School of Medicine at Mount Sinai
- **Ezra Spier**
  Long COVID patient advocate

LOOKING AHEAD

- Incorporate biomarker data when they arrive
  - Biomarkers of inflammation, neuroinflammation, neurodegeneration and epigenetics
- Plan for End of Phase 2 meeting with the FDA
  - Parkinson's
  - Long COVID
- Plan Phase 3 potentially pivotal registrational trials
- Continue analyzing the data and preparing presentations for conferences and submitting publications to scientific journals
- Reactivate potential partnering conversations in due course

PIPELINE OVERVIEW

Multiple multi-billion-dollar US markets across the BioVie pipeline



* Company estimates


biovie
Thank You