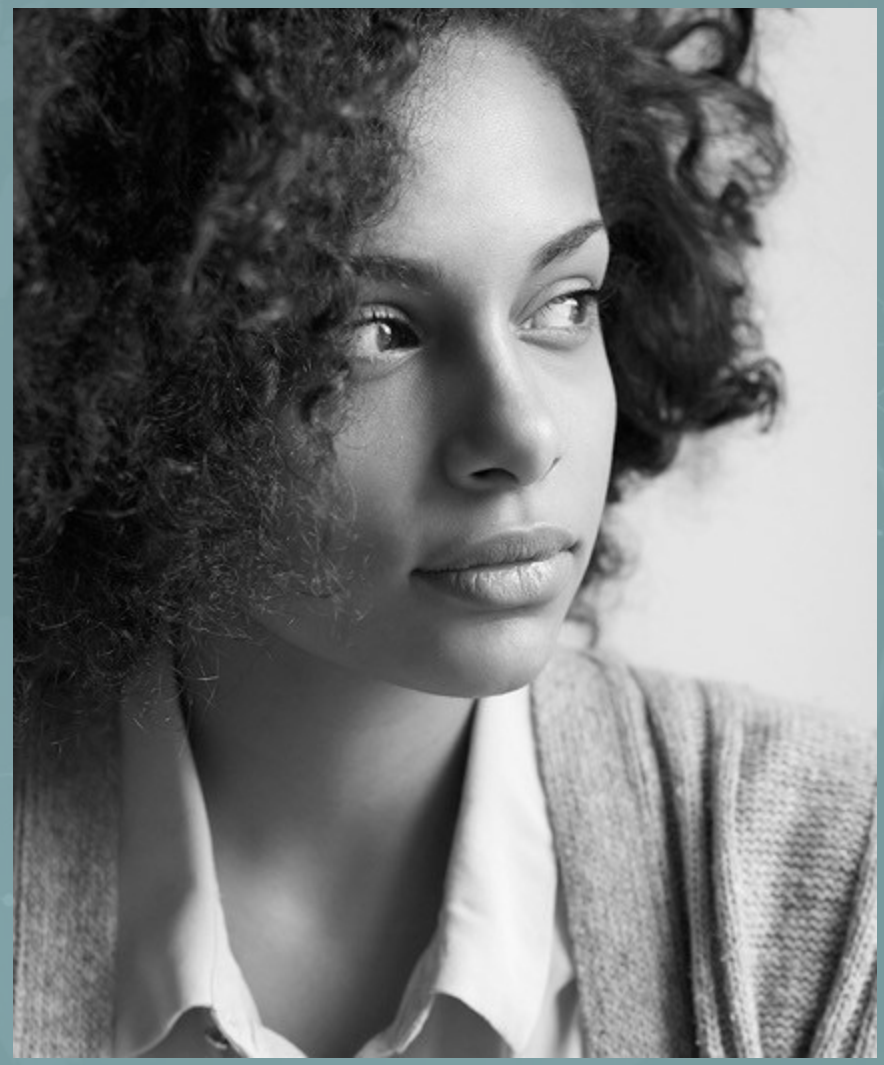
NLS Pharmaceutics
Connecting Brains

Quilience (Mazindol ER) a New Approach to treat Type I & Type II Narcolepsy

POLARIS Clinical Development Program

Why study mazindol ER in narcolepsy – Key Highlights

- Unmet medical need in narcolepsy
- **Novel mechanism of action** targeting both Orexin (OX2R) and monoaminergic systems: norepinephrine, dopamine, serotonin
- **Once daily dose**
- **Long history of positive safety** data and well tolerated
- **Clinical evidence** that the drug addresses **both sleepiness and cataplexy (NT1 and NT2)**
- **Proven low potential for abuse**, misuse, or diversion
- **Possibility to be use as monotherapy** for narcoleptic patients (with and without cataplexy)



Polaris: Mazindol ER development program in Narcolepsy

Connecting Brains

Polaris program currently represents
two U.S. clinical trials both approved by FDA/ WIRB

- **NLS-1021 Phase IIa** A four-week double-blind, placebo controlled, randomized, US multi-center study of Mazindol ER 3 mg once daily vs. placebo (1:1)

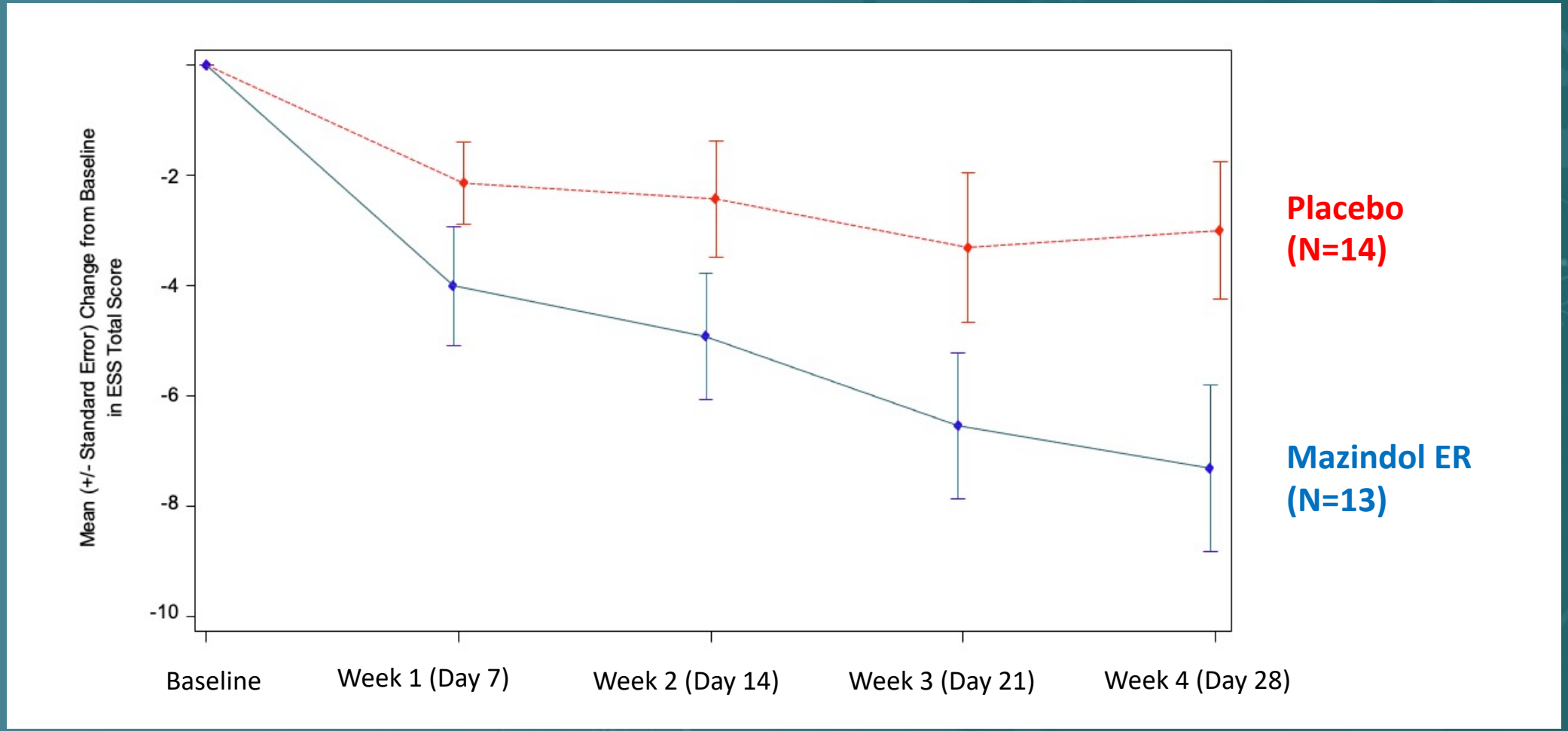
- **NLS-1022 Open Label Extension,** An Open Label Extension Study available for individuals following completion of the four-week NLS 1021 study.
  This OLE study offers participants the opportunity to take oral Mazindol ER once daily in the morning for up to six months.

Summary of Interim Top-Line Efficacy Results

- Clinically meaningful improvement in ESS score at 4 weeks:
  - -7.3 ESS score reduction vs. baseline in the active group
  - -4.3 ESS score difference vs placebo.
- Rapid onset of action and clinical effect (within 1 week)
- Sustained EDS improvement all along the treatment period
- Placebo effect seen up to 2nd week, stabilized from week 3
- Statistical power affirmed; Phase 2a trial to continue as initially designed

Primary Endpoint: Change from Baseline to Last Visit on Epworth Sleepiness Scale (ESS)
(ITT Population)

Mean (+/- Standard Error) Change from Baseline in Epworth Sleepiness Scale (ESS) Total Score by Visit



Summary of Interim Top-Line Safety Results

- **No** patient discontinued treatment to due to adverse reactions
- **All AEs resolved spontaneously**, no intervention was required
- **No** serious adverse events or unexpected AEs
- **Well-tolerated** with the most commonly known adverse reactions occurring at low frequencies
- **Possible dose increases** given solid safety profile