Early clinical development program, including results of a first-in-human trial of LIB-01, a novel, first in class potential oral erectile dysfunction drug with unique pharmacodynamic properties

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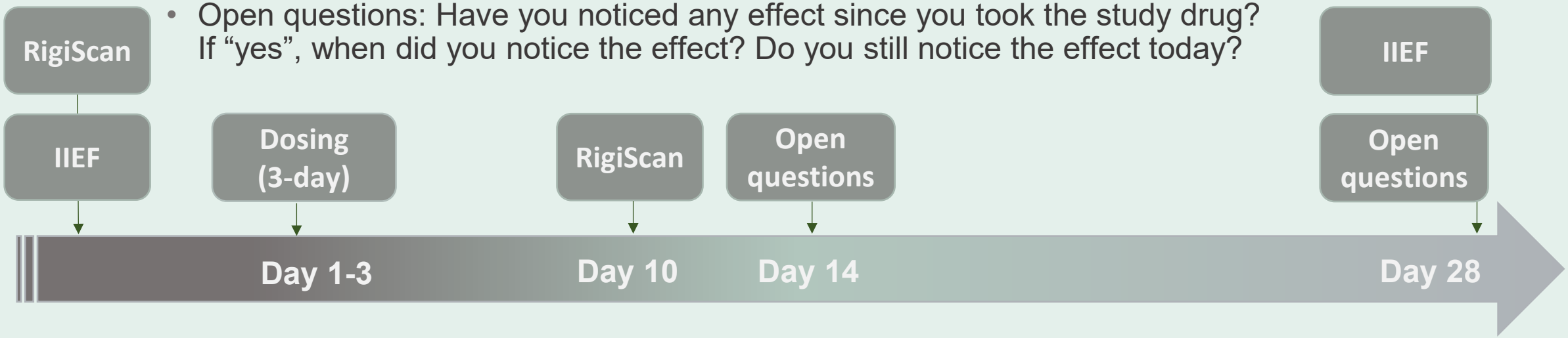
LIB-01: A novel and first-in-class small molecule (*phragmalin-type limonoid*) for ED

Phase 1 Design

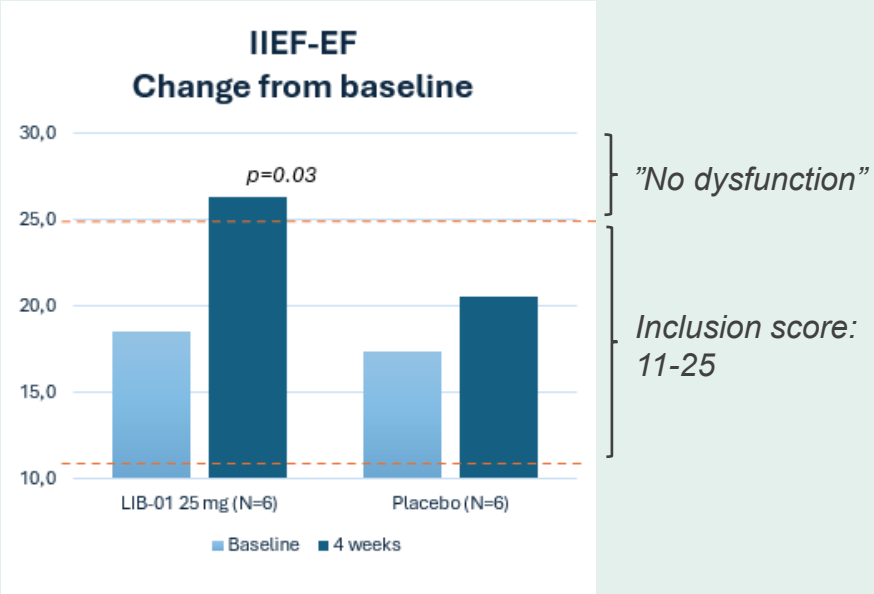
- Safety following single (SAD, N=40) and multiple ascending dosing (MAD, N=24)
- ED participants in MAD part of trial (age18-65 and IIEF-EF score 11-25 for inclusion)
- 3-day dosing; 25mg QD, 25mg BID, 50mg QD or Placebo
- 28 days follow up
- Exploratory efficacy:
  - IIEF-EF and Real-time RigiScan®
  - Open questions: Have you noticed any effect since you took the study drug? If “yes”, when did you notice the effect? Do you still notice the effect today?



Results

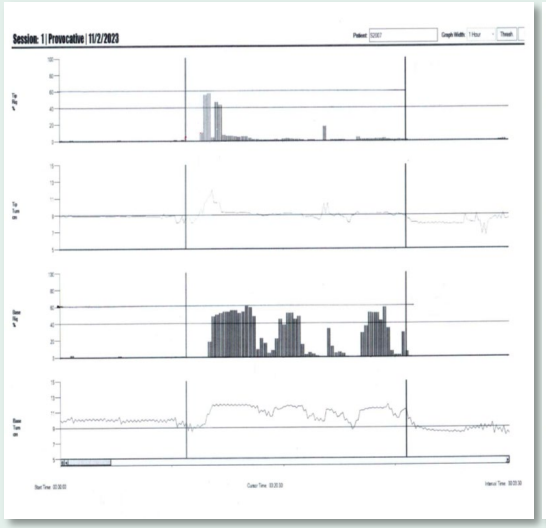
- Improved erectile function by IIEF-EF domain score – mean change 7.8
- Increased erectile rigidity by RigiScan®
- At least 28 days duration of pro erectile effect
- Safety – few, mild, and self-limited GI symptoms on day one

IIEF-EF mean score

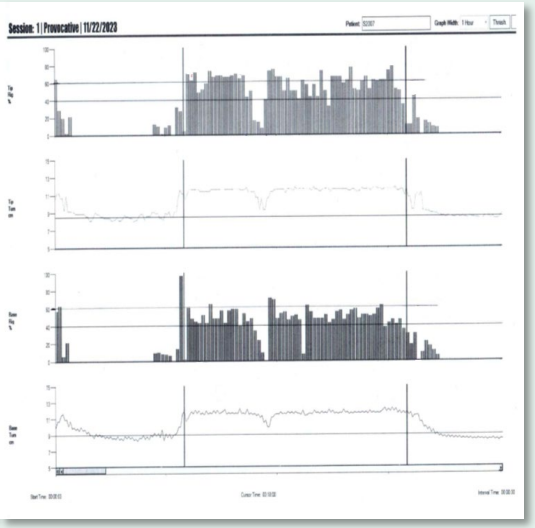


Rigiscan

Baseline



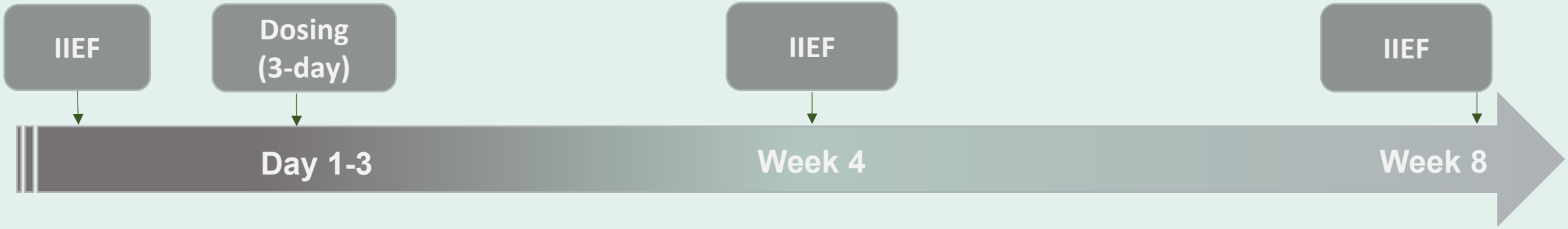
Day 10



Phase 2a Ongoing

Phase 2a Design

- Safety and Efficacy of LIB-01 in treatment of ED “Proof of Concept”
- 140 male ED participants in (age 25-65 and IIEF-EF score 11-25 for inclusion)
- Six sites in EU (Sweden, Denmark, Netherlands)
- 3-day dosing; LIB-01 (three dose levels) or Placebo
- 8 weeks follow up
- Efficacy:
  - Primary: IIEF-EF on Week 4
  - SEP questions 2 (*Were you able to insert your penis into your partner's vagina?)* and 3 (*Did your erection last long enough for you to have successful intercourse?)* throughout the trial period



Conclusions LIB 01

- Phase 1
  - Safe and well tolerated
  - Improved erectile function demonstrated by IIEF-EF and RigiScan®
  - Duration of pro erectile effect of at least 28 days following a 3-day dosing
- This new molecule has the potential to dramatically change the paradigm of ED management
- Phase 2a results expected in mid-2025