

Results of a first-in-human trial of LIB-01. A novel, first in class potential oral ED drug with unique pharmacodynamic properties

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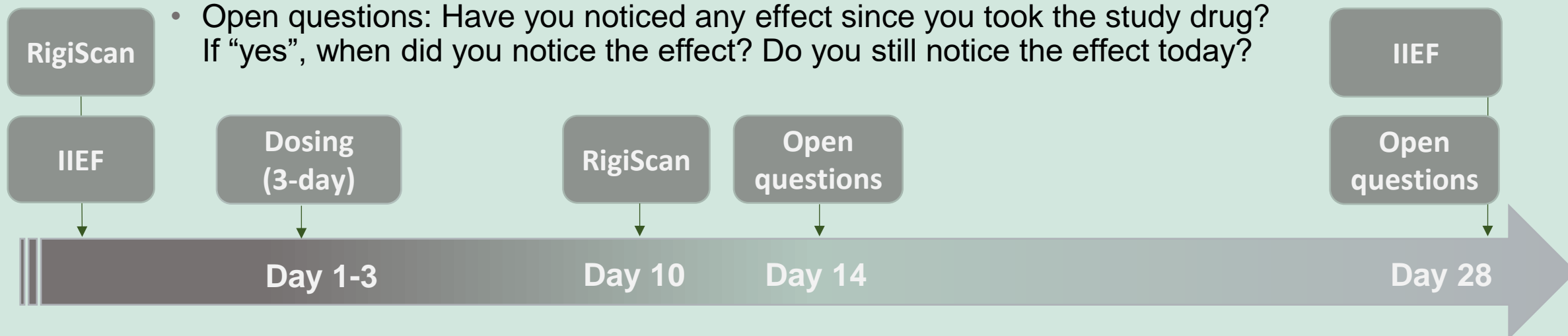
Disclosures

- Harin Padma-Nathan, MD, FRCS
 - Consultant, Dicot Pharma
 - Founder, Vella Bioscience Inc. & Otrera Medical Inc.

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

Phase 1 Design

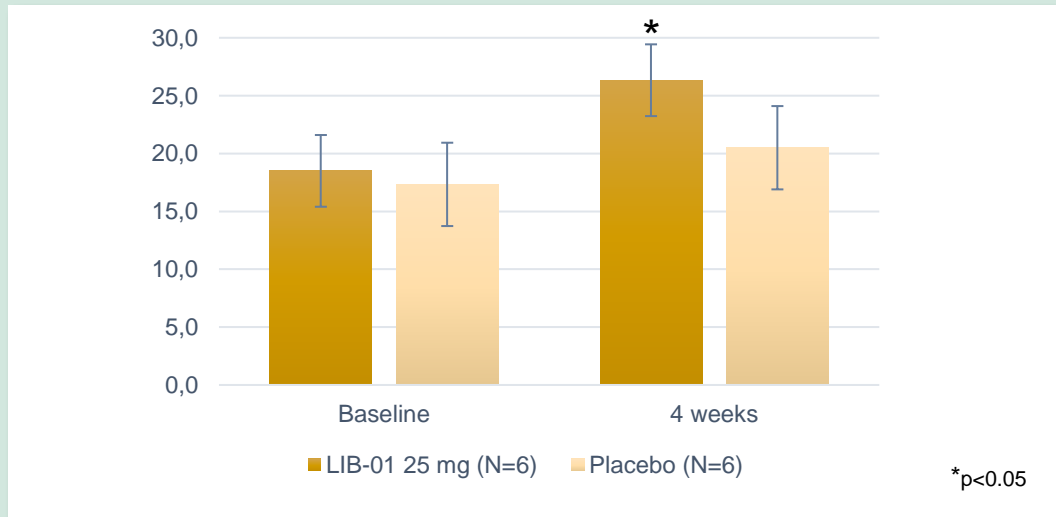
- Safety following single (SAD, N=40) and multiple ascending dosing (MAD, N=24)
- ED participants in MAD part of trial (age 18-65 and IIEF-EF score 11-25 for inclusion)
- 3-day dosing; 25mg QD, 25mg BID, 50mg QD or Placebo
- 28 days follow up
- Exploratory efficacy:
 - IIEF-EF and Real-time RigiScan[®]
 - 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 (83% normalized)
- Increased erectile rigidity by RigiScan®
- At least 28 days duration of pro erectile effect
- Safety – mild, self-limited GI symptoms on day one

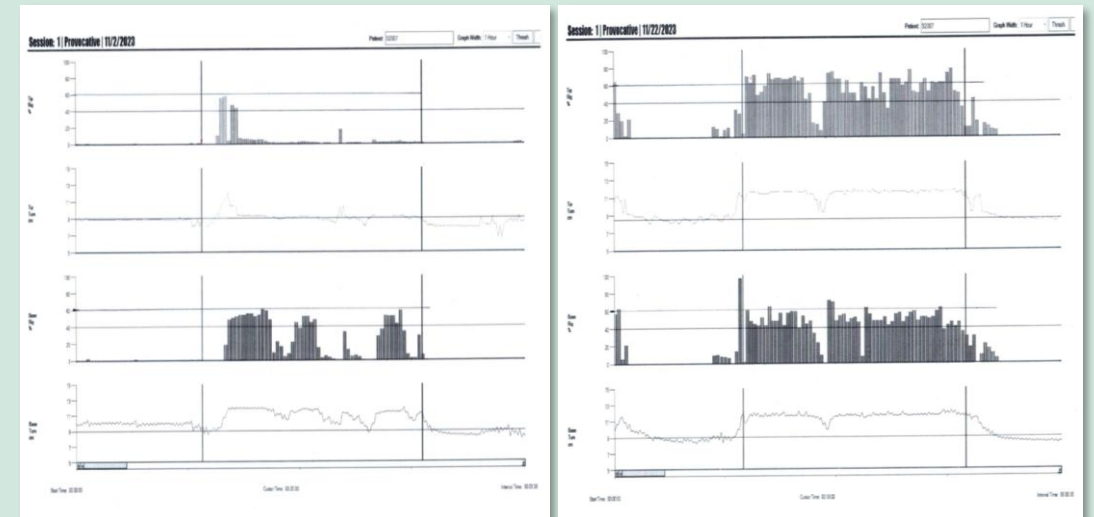
IIEF-EF mean score



Rigiscan

Baseline

Day 10



Conclusions LIB 01, phase 1 trial

- 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

*A Phase 2a trial initiated in Europe with
Prof. MD François Giuliano as medical expert*