Memorial Sloan Kettering Cancer Center

IP23-17: Rizedisben, a Novel Myelin-Binding Fluorophore for Intraoperative Fluorescent Imaging of Nerve Structures: Phase I Trial in Robotic Radical Prostatectomy

Samuel A. Gold, Maria M. Pere, Melissa Assel, Ouathek Ouerfelli, Andrew J. Vickers, Jonathan A. Coleman, Alvin C. Goh, Robert C. Smith, Behfar Ehdaie, Peter T. Scardino, James A. Eastham, Vincent P. Laudone, Timothy F. Donahue

Memorial Sloan Kettering Cancer Center, New York, NY

@goldurology @goldurology.bsky.social

AUA 2025 Las Vegas

Introduction & Objectives

- **Rizedisben** is a novel myelin-binding fluorophore that fluoresces in the blue light (370–425 nm) spectrum
- Iatrogenic nerve injury is a leading cause of morbidity associated with many common surgical procedures
- Fluorescence-guided surgery (FGS) utilizes enhanced visualization of critical structures to reduce iatrogenic injury or improve critical excisions

Objective: *To determine the safety and clinically effective dose of rizedisben for sustained (>90 minutes) fluorescence of nerve structures*

Methods

- Single-arm, open-label, phase I study (NCT04983862) of intravenous administration of **rizedisben** in patients undergoing robot-assisted radical prostatectomy (RALP)
- **Dose-escalation design**: increasing doses of rizedisben were administered after safety was documented at each level until a clinically effective dose was determined
- The **obturator nerve** served as the reference nerve for measuring fluorescence intensity
- Fluorescence of the **neurovascular bundles** was assessed at the clinically effective dose
- Intraoperative fluorescence was measured subjectively via Likert scale and objectively via post hoc software imaging analysis
- Neurologic assessments were performed as part of the safety assessments

Results

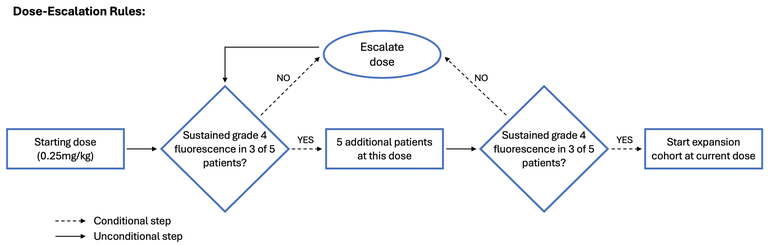

Figure 1: Dose-escalation protocol

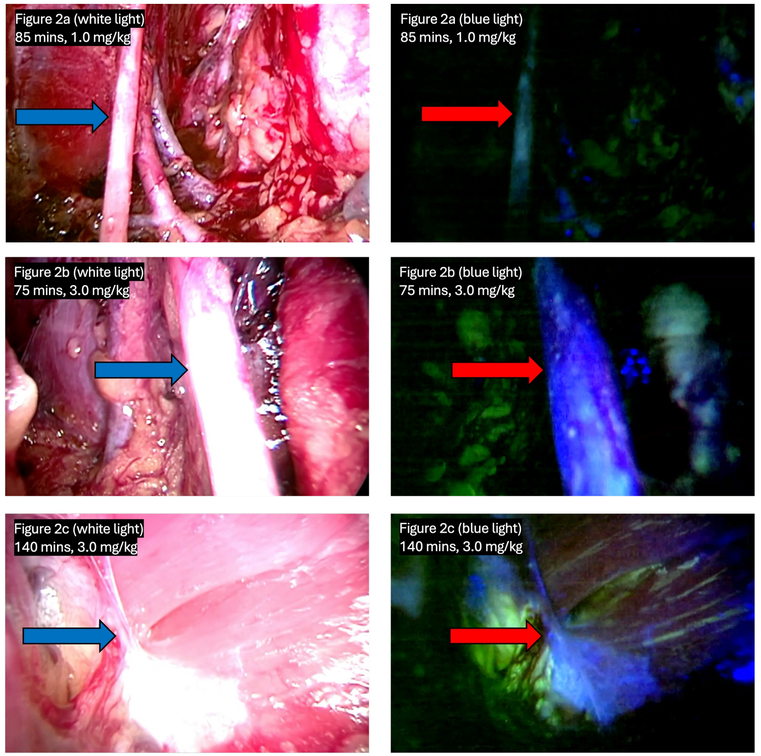

Figure 2: Obturator and neurovascular fluorescence at various timepoints under white and blue light conditions

Dose Level	0.25 mg/kg *N = 3*	0.50 mg/kg *N = 3*	1.0 mg/kg *N = 10*	1.5 mg/kg *N = 5*	2.0 mg/kg *N = 4*	2.25 mg/kg *N = 4*	3.0 mg/kg *N = 9*	Total *N = 38*
Age (years) (median)	61 (61, 77)	60 (59, 62)	62 (57, 66)	60 (50, 65)	61 (55, 66)	58 (53, 64)	66 (61, 68)	**62 (58, 66)**
BMI (kg/m^2) (median)	28 (25, 29)	32 (29, 40)	32 (27, 36)	30 (27, 35)	29 (27, 34)	27 (24, 27)	27 (26, 29)	**28 (26, 32)**
Dose (mg) (median)	21 (18, 24)	50 (47, 60)	102 (84, 124)	145 (128, 170)	188 (170, 220)	177 (154, 198)	252 (248, 278)	**142 (91, 213)**
Attributable AEs								
Grade 1	0	0	0	0	1	0	2	**3**
Grade 2	0	0	1	0	0	0	0	**1**
Any moderate (≥4 points) fluorescence	0 (0%)	0 (0%)	8 (80%)	5 (100%)	3 (75%)	4 (100%)	9 (100%)	**29 (76%)**
Sustained fluorescence (>90 minutes)	0 (0%)	0 (0%)	4 (40%)	2 (40%)	3 (75%)	3 (75%)	9 (100%)	**21 (55%)**

Table 1: Demographic and clinical data of trial participants by rizedisben dose level. BMI = body mass index, AE = adverse event.

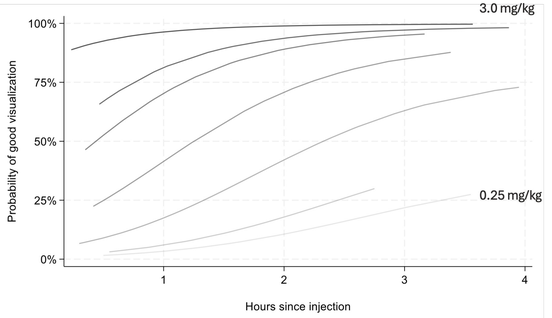

Figure 3a: Subjective scoring of obturator nerve fluorescence. Good visualization is defined as ≥4/5 by intraoperative surgeon assessment (odds ratio=11.1 per mg/kg, 95% CI 4.3–29; p<0.001)

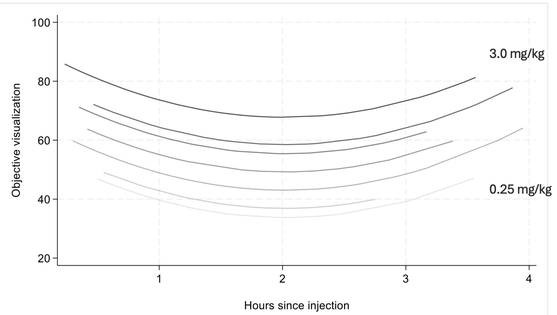

Figure 3b: Objective scoring of obturator nerve fluorescence. *Post hoc* objective image analysis (coefficient=12 per mg/kg, 95% CI 7.4–17; p<0.001)

Results & Conclusions

- 38 patients completed the protocol; **clinically effective dose was achieved at 3.0 mg/kg**
- **Strong fluorescence was seen in 41/42** observations at 3.0 mg/kg (at 14 to 210 mins post-injection)
- One adverse event (AE), grade 1 photophobia, was deemed “definitely” related to rizedisben
- One AE, grade 2 rash in a patient with significant dermatologic history, was deemed “possibly” related to rizedisben
- There were **no significant or durable neurologic changes** observed in any patients
- Phase II trials in open and laparoscopic surgeries are in progress

Research supported by the Ruth L. Kirschstein National Research Service Award T32CA082088