Safety, Tolerance, and Preliminary Efficacy of LiRIS® 400 mg in Women With Ulcerative Interstitial Cystitis

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INTRODUCTION
- Interstitial cystitis (IC) is an inflammatory bladder condition with characteristic lesions (Hunner’s lesions) noted on cystoscopy that are associated with bladder pain and voiding frequency.
- LiRIS®, a lidocaine-releasing intravesical system, is a passive, nonresorbable, intravesical system designed to provide continuous, controlled release of lidocaine into the bladder over a 2-week period.
- A previous study in IC patients demonstrated beneficial changes in lesion reduction with LiRIS®. This study attempted to replicate those findings in a pure Hunner’s lesion population.

OBJECTIVES
- To assess the safety and tolerability of LiRIS 400 mg over up to 2 consecutive 14-day treatment periods and 4 weeks post-treatment.
- To assess the preliminary efficacy of LiRIS 400 mg in:
  - Reduction or resolution of Hunner’s lesions
  - Improvement in pain, voiding frequency, and O’Leary-Sant Interstitial Cystitis Symptom Index (ICSI)/Interstitial Cystitis Problem Index (ICPI) scores

METHODS
- This 2-center, open-label, Phase Ib study in women aged ≥18 years evaluated the safety, tolerability, and preliminary efficacy of LiRIS 400 mg over 2 14-day treatment periods and up to 12 weeks of follow-up (Day 12).
- Inclusion criteria included a pain Numeric Rating Scale (NRS) score of 3 to 9.5, ≥1 Hunner’s lesion at screening cystoscopy, and ≥1 daily voids.
- A second LiRIS 400 mg system was inserted at Day 14 of Hunner’s lesions appeared unimproved or unchanged on Day 14. It was removed on Day 28.
- Treatment-emergent adverse events (TEAEs) occurred in 6/10 patients, with 3 patients being excluded.
- Ten patients were enrolled per-protocol population thus not completing follow-up. The nonresponders were 6/7 patients.

RESULTS

Patients
- Ten patients were enrolled (Table 1).
- Three patients were excluded from the analysis: 1 had only one LiRIS treatment, 1 expelled LiRIS prior to Day 28, and 1 did not complete follow-up. The per-protocol population thus comprised 7 patients.

Safety
- TEAEs occurred in 6/10 patients (2 procedure-related, 2 disease–related).
- 1 patient discontinued due to TEAEs.

RESULTS

Treatment
- A previous study in IC patients demonstrated beneficial changes in lesion reduction with LiRIS®, a lidocaine-releasing intravesical system, is a passive, nonresorbable, intravesical system designed to provide continuous, controlled release of lidocaine into the bladder over a 2-week period.
- A second LiRIS 400 mg system was inserted at Day 14 if Hunner’s lesions appeared

RESULTS

Efficacy
- By Days 14 and 28, 6/7 patients (86%) and 7/7 patients (100%), respectively, responded to treatment with decreased Hunner’s lesion affected area, lesion number, and/or lesion severity.

CONCLUSIONS
- LiRIS® demonstrated a favorable safety profile for LiRIS 400 mg in patients with IC and Hunner’s lesions. Double-blind, placebo-controlled studies will be required for further evaluation of this potential new therapy.

DISCLOSURES
- Results from this small proof-of-concept study demonstrate a favorable safety profile for LiRIS 400 mg in patients with IC and Hunner’s lesions. A clinical effect and response in a group of patients in Hunner’s lesions (number, severity, and size) was seen in 86% of patients on Day 14 and 100% of patients on Day 28. No patients had a complete response during the study.
- Double-blind, placebo-controlled studies will be required for further evaluation of this potential new therapy.

REFERENCES