The ability of local anesthetics to provide effective analgesia after shoulder arthroscopy was the focus of a study involving 107 randomized patients. All patients received treatment and completed both the initial component of the trial and the 18-month long-term follow-up. This was a long-term extension of a randomized, double-blind, placebo-controlled study. 46.9% (27–68) of patients preferred the SABER-Bupivacaine 13.2% 5 mL over the placebo. MRI studies showed no new degenerative changes to the glenohumeral joint or cartilage in any group. Surgical-site healing and local tissue evaluation were assessed, and no safety concerns were identified based on 18-month MRI results. Overall, no safety concerns were identified based on 18-month MRI results from 60 patients who received treatment in the primary study. The long-term safety of SABER-Bupivacaine in ASD was examined in 2 separate studies, and the objective of this analysis is to examine its long-term safety when instilled into the subacromial space following arthroscopic subacromial decompression (ASD). 

RESULTS

EUROPEAN STUDY

- All 107 randomized patients received treatment and completed both the initial component of the trial and the 6-month safety evaluation.
- At 6 months, 101 patients had evaluable MRI scans and 103 were assessed for surgical wound healing.
- The number, type, relationship, and severity of treatment-emergent AEs (TEAEs) reported were determined.
- Overall, no safety concerns were identified based on 18-month MRI results from 60 patients who received treatment in the primary study.
- The long-term safety of SABER-Bupivacaine in ASD was examined in 2 separate studies, and the objective of this analysis is to examine its long-term safety when instilled into the subacromial space following arthroscopic subacromial decompression (ASD).

AUSTRIAN STUDY

- Of the 60 patients who received treatment in the primary study, 47 were evaluated in the 18-month long-term extension study (Table 3).
- MRI studies showed no new degenerative changes to the glenohumeral joint or cartilage compared with pretreatment baseline and no new radiographic changes.
- No safety concerns were identified based on 18-month MRI results from 60 patients who received treatment in the primary study.
- Overall, no safety concerns were identified based on 18-month MRI results from 60 patients who received treatment in the primary study.
- The number, type, relationship, and severity of treatment-emergent AEs (TEAEs) reported were determined.
- Overall, no safety concerns were identified based on 18-month MRI results from 60 patients who received treatment in the primary study.
- The long-term safety of SABER-Bupivacaine in ASD was examined in 2 separate studies, and the objective of this analysis is to examine its long-term safety when instilled into the subacromial space following arthroscopic subacromial decompression (ASD).

CONCLUSIONS

- There were no trends of SABER-Bupivacaine with long-term follow-up, no safety concerns were identified in the 6-month or 18-month postoperative assessments compared with placebo or bupivacaine HCl.
- There was no evidence of bupivacaine-related chondrolysis or rotator cuff injury based on patient-reported clinical outcomes, MRI, and AEs.
-Taken together with the short-term safety and efficacy findings from the primary studies, these long-term safety results support the potential role of SABER-Bupivacaine as a primary component of multidimensional postoperative analgesia in arthroscopic subacromial decompression.