**BACKGROUND**

- CRS with nasal polyps (CRSwNP) is a high-prevalence chronic inflammatory condition characterized by polyps in the nasal cavity and core symptoms of nasal congestion/obstruction, rhinorrhea, facial pain/pressure, and reduction/loss of smell.\(^1\)\(^2\) and a variety of other symptoms which collectively adversely affect quality of life (QoL) to a similar degree as other serious chronic diseases such as CHF, COPD, and Parkinson's disease.\(^3\)\(^4\)

- Intranasal corticosteroids (INCs) are recommended as a primary treatment but conventional INCs sprays deliver the majority of topically-acting drug to the anterior portion of the nasal cavity below the nasal valve, leaving much of the posterior and superior nasal regions, where polyps typically originate, undertreated.\(^4\)\(^5\)

- FLU-EDS (fluticasone propionate exhalation delivery system) is a novel intranasal drug delivery system capable of deeply and broadly distributing fluticasone in the nasal cavity, including much greater deposition of drug in the ostiomeatal complex (OMC) where sinus ostia drain/ventilate and polyps typically originate.\(^6\)\(^7\) (Figure 1)

- The primary objective of this study was to compare the efficacy of intranasal administration of 93 µg, 186 µg, and 372 µg of FLU-EDS twice daily (BID) with placebo EDS in nasal polyposis.

**METHODS**

- The study design is presented in Figure 2.

**RESULTS**

- Baseline demographics and characteristics (Table 1) are representative of the CRSwNP population and were similar among the 4 treatment groups.

- The placebo group had the highest drop-out rate (12.5%).

- Changes in both co-primary endpoints were significantly superior to placebo for each FLU-EDS dose versus placebo (p<0.001)

- AEs associated with FLU-EDS were local in nature and similar in frequency to that reported with conventional INCs when studied in similar populations for similar durations.\(^7\)

- The most frequent AEs in FLU-EDS recipients were identified on nasoendoscopy rather than by clinical report, and were mild epistaxis (defined as any visualized blood, including for example streaked mucous or old clots) and nasal septal ulceration. Both typically resolved with continued use of study meds. (Table 2)

**CONCLUSIONS**

- FLU-EDS, at doses of 93 µg, 186 µg, and 372 µg intranasally BID, significantly reduced both co-primary endpoints of nasal congestion/obstruction and total polyp grade.

- FLU-EDS resulted in clinically significant improvements in a broad range of objective and subjective outcome measures, including in all four core symptoms of CRS, QoL, and polyp elimination in some patients.

- Higher doses of FLU-EDS (186 µg and 372 µg) resulted in numerically greater responses for some endpoints and a more rapid onset of action.

- Subjective and objective measures of CRS continued to improve throughout the course of 24 weeks of follow-up.

- Treatment with FLU-EDS was well tolerated with an adverse event profile similar to that of other intranasal steroids studied in patients with CRSwNP.

**REFERENCES**


