

**Samson SL et al. Maintenance of Acromegaly Control in Patients Switching From Injectable Somatostatin Receptor Ligands to Oral Octreotide. J Clin Endocrinol Metab. 2020;105(10):e3785-97. doi: 10.1210/clinem/dgaa526.**

**PURPOSE:** The phase 3 CHIASMA OPTIMAL trial (NCT03252353) evaluated efficacy and safety of oral octreotide capsules (OOCs) in patients with acromegaly who previously demonstrated biochemical control while receiving injectable somatostatin receptor ligands (SRLs).

**METHODS:** In this double-blind study, patients (N = 56) stratified by prior SRL dose were randomly assigned 1:1 to OOC or placebo for 36 weeks. The primary end point was maintenance of biochemical control at the end of treatment (mean insulin-like growth factor 1 [IGF-1]  $\leq 1.0 \times$  upper limit of normal [ULN]; weeks 34 and 36). Time to loss of IGF-1 response and proportion requiring reversion to injectable SRLs were assessed as broader control measures.

**RESULTS:** Mean IGF-1 measurements were 0.80 and 0.97  $\times$  ULN for OOC and 0.84 and 1.69  $\times$  ULN for placebo, at baseline and end of treatment, respectively. Mean growth hormone (GH) changed from 0.66 to 0.60 ng/mL for OOCs and 0.90 to 2.57 ng/mL for placebo. Normalization of IGF-1 levels ( $\leq 1.0 \times$  ULN) was maintained in 58.2% for OOCs vs 19.4% for placebo (P = .008); GH levels were maintained ( $< 2.5$  ng/mL) in 77.7% for OOC vs 30.4% for placebo (P = .0007). Median time to loss of response (IGF-1  $> 1.0$  or  $\geq 1.3 \times$  ULN definitions) for patients receiving placebo was 16 weeks; for patients receiving OOCs, it was not reached for both definitions during the 36-week trial (P  $< .0001$ ). Of the patients in the OOC group, 75% completed the trial on oral therapy. The OOC safety profile was consistent with previous SRL experience.

**CONCLUSIONS:** OOCs may be an effective therapy for patients with acromegaly who previously were treated with injectable SRLs.