Videofluoroscopic Swallowing Study

This videofluoroscopic swallowing study was conducted with 9 patients with ALS before and after receiving a single dose of ROF. Nineteen events were characterized as oral or pharyngeal hypoesthesia.

Among 32 subjects who received at least 1 dose of the ROF in Study 162020, 17 events in 14 subjects were characterized as oral or pharyngeal hypoesthesia. A total of 44 treatment-emergent adverse events (TEAEs) were reported in the study; all were mild in severity. No serious AEs were observed, and no subject discontinued due to an AE. Among 32 subjects who received at least 1 dose of the ROF in Study 162020, 17 events in 14 subjects were considered treatment-related and 1 event was on pharyngeal hypoesthesia.

In the swallowing study, 66.6% of patients were able to swallow safely by PAS standards both pre- and post-dose. Very little numerical or categorical change was observed following the dose of ROF.

Similar findings were obtained for ALSFRS-R bulbar domain scores vs PAS scores and for EAT-10 scores vs PAS scores. In the swallowing study, 55.6% of patients were able to swallow safely by PAS standards both pre- and post-dose. In the swallowing study, 55.6% of patients were able to swallow safely by PAS standards both pre- and post-dose. Very little numerical or categorical change was observed following the dose of ROF. In the swallowing study, 55.6% of patients were able to swallow safely by PAS standards both pre- and post-dose. Very little numerical or categorical change was observed following the dose of ROF. In the swallowing study, 55.6% of patients were able to swallow safely by PAS standards both pre- and post-dose.