SAFETY AND TOLERABILITY ASSOCIATED WITH CHRONIC INTERMITTENT USE OF DIAZEPAM BUCCAL FILM IN PEDIATRIC, ADOLESCENT, AND ADULT PATIENTS WITH EPILEPSY

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INTRODUCTION

Several studies on diazepam or diazepam-like medicines in many patient subsets with epilepsy have shown good tolerability and safety, with minimal or no loss of efficiency or response.

OBJECTIVES

The primary objective of this ongoing study (NCT03428360) is to assess the safety and tolerability of DBF in adult and pediatric patients with epilepsy when used as an adjunct to current anti-epileptic treatment.

STUDY DESIGN

• This is an open-label, phase 3, multicenter, open-label, long-term safety and tolerability study, where adult and pediatric patients received 1 dose of DBF up to 3x/day for up to 30 days.

PROCEDURES AND ASSESSMENTS

• Informed consent was documented for all adult participants. The consent procedures were not modified, and the informed consent form was not modified.

• Studies demonstrated that the investigational product, DBF, was administered by patients (oral route) without difficulty when administered by patients and caregivers.

RESULTS

STUDY PATIENTS

• A total of 64 patients from 12 centers for an eluted and used DBF at least once every 28 days (72.6% of patients; n=46) were included in the analysis. In 46 of 64 (71.9%) patients, DBF was successfully administered on at least one use occasion.

DBF SAFETY

• In contrast of Table 1, Table 2 lists the treatment-related adverse events (AEs) reported in ≥1 patient across any dose level.

DBF USEABILITY

• DBF was successfully administered in 443 of 471 (94.1%) use occasions (Table 4). All 64 patients had first-attempt success at DBF administration on at least one use occasion.

CONCLUSIONS

These results support further development and use of DBF as an easily administered alternative to diazepam rectal gel for patients with epilepsy who experience cluster seizures or other repeated episodes of more frequent or more severe seizures.

REFERENCES


ADDITIONAL TABLES:

Table 5 (available in electronic supplement) provides a description of adverse events not reported in ≥1% of patients.

Disclosures

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