ABSTRACT
Objective: To evaluate the efficacy and tolerability of an oral mucoadhesive buccal tablet containing acyclovir 50 mg (ABT 50 mg) in immunocompetent patients with at least 4 recurrent labial herpes per year.

Methods: A randomized, double-blind, placebo-controlled clinical study was conducted in 537 patients with at least 4 recurrent labial herpes episodes per year. Patients were randomized to receive ABT 50 mg (n=267) or placebo (n=270) tablets during the prodromal symptoms of an upcoming labial herpes episode until healing of the initial vesicular lesion. The primary endpoint was the time to healing (TTH) of the initial vesicular lesion. Good safety and tolerability were found in both ABT 50 mg and placebo groups.

RESULTS
- The median TTH for ABT 50 mg and placebo was 224 (95% CI: 180-585) and 170 (95% CI: 142-212) days, respectively (p=0.049).

CONCLUSIONS
- ABT 50 mg significantly reduced the TTH of labial herpes episodes compared to placebo.

INTRODUCTION
Labial herpes is caused by herpes simplex virus type 1 (HSV-1), a double-stranded DNA virus that causes recurrent infections of the lips, mouth, and skin. The disease is characterized by the development of vesicular lesions, followed by the formation of crusts and ulcers. HSV-1 can remain latent in the trigeminal ganglion and in the oral mucosa (basal layers) and is activated by various factors, including stress, sun exposure, and menstruation. The natural history of labial herpes and its oral mucosa is characterized by episodic outbreaks, with periods of latency in between.

OBJECTIVE
Given the lack of an effective treatment for labial herpes, the study aimed to evaluate the efficacy and tolerability of an oral mucoadhesive buccal tablet containing acyclovir 50 mg (ABT 50 mg) in immunocompetent patients with at least 4 recurrent labial herpes episodes per year.

PATIENTS and METHODS
Inclusion/Exclusion Criteria: Patients were enrolled if they had at least 4 recurrent labial herpes episodes per year and were willing to use a daily oral mucoadhesive buccal tablet containing acyclovir 50 mg until healing of the initial vesicular lesion. The primary endpoint was the time to healing (TTH) of the initial vesicular lesion.

RESULTS
- The median TTH for ABT 50 mg was 224 days (95% CI: 180-585), while for placebo it was 170 days (95% CI: 142-212) (p=0.049).

CONCLUSIONS
- ABT 50 mg significantly reduced the TTH of labial herpes episodes compared to placebo, indicating its potential as a valuable treatment option for patients with frequent labial herpes episodes.

REFERENCES

DISCUSSION
A single application of acyclovir (200 mg) on the base of the affected area has been shown to be effective in reducing the duration of labial herpes episodes. However, the efficacy of this treatment strategy has been limited due to the high rate of recurrence. The use of mucoadhesive buccal tablets offers a promising approach for the treatment of labial herpes, as it allows for sustained-release local exposure to acyclovir, reducing the time to healing and increasing the incidence of healing.

CONCLUSION
ABT 50 mg represents a novel treatment option for patients with frequent labial herpes episodes, offering a significant reduction in the time to healing compared to placebo, without compromising safety and tolerability.