Title: Oral Anaphylm Symptom Intervention Study (OASIS)

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Rationale: Oral physiological changes in anaphylaxis are common. Characterizing the impact of such changes on the absorption, pharmacokinetics (PK), pharmacodynamics (PD) and time course of symptom resolution after Anaphylm administration is essential to inform potential conditions of use.

Methods: This was a Phase 2, open-label, 2-part, 3 treatment randomized study comparing the pharmacokinetics of Anaphylm to intramuscular (IM) epinephrine injection in adult Oral Allergy Syndrome (OAS) patients. The study evaluated single and repeat doses of Anaphylm, both with and without oral allergen challenge (OAC), and IM epinephrine. Symptoms were assessed using a Verbal Rating Scale (VRS).

Results: Following allergen exposure, 94% (34/36) of subjects exhibited moderate or severe symptoms at screening. Single doses of Anaphylm with OAC matched or exceeded manual IM across all primary and secondary PK parameters. There was no statistically significant difference noted in PK parameters between OAC and no OAC groups. Importantly, symptom resolution was rapid with median time to symptom resolution occurring by 12 minutes compared to 74 minutes without intervention. The mean time to resolution of angioedema symptoms was 5 minutes.

Conclusions: This study demonstrates that oral physiological changes induced by allergen exposure in subjects with OAS do not alter the pharmacokinetic or pharmacodynamic profiles of Anaphylm. A challenge model of OAS may serve as a potential tool to better understand the value of new epinephrine technologies that cannot be ethically or feasibly studied in anaphylaxis.