Reduced gastric injury with a novel, liquid lipid-aspirin formulation: results from a pooled, patient level analysis of two randomized endoscopy studies In healthy volunteers

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Background: Gastrointestinal (GI) toxicity from aspirin is high at the time of initiation of therapy.

Objective: The current analysis aimed to determine rates of endoscopically detected gastroduodenal erosions and ulcers after 7 days of either immediate release aspirin (IR-ASA) or a novel, pharmaceutical lipid-aspirin complex (PL-ASA) liquid formulation that has an antiplatelet effect similar to IR-ASA.

Methods: Two randomized, single blind, multicenter active control studies comparing upper GI damage after 7 days of 325 mg PL-ASA or IR-ASA in healthy volunteers not taking a gastroprotectant and who had a negative baseline endoscopy were pooled at the patient level. The primary outcome was the composite of >5 erosions and/or ≥ 1 ulcer (≥ 3 mm deep) assessed by a treatment-blinded reviewer at repeat endoscopy on day 7.

Results: Out of 451 randomized subjects (mean age 57 years, 47% males), 441 completed the 7-day endoscopy and represent the full analysis set. PL-ASA significantly reduced the primary outcome by 34% compared with IR-ASA (25.7% vs. 39%, p=0.0032) (figure). Notably, for ulcers there was a 61% reduction with PL-ASA (6.0% vs. 14.8%, p=0.0018) (Figure 1). The mean number of gastric erosions per patient was also reduced with PL-ASA (2.8±7.3 vs. 4.2±7.5, $p<0.0001$), while erosions in the duodenum were not different (1.4±7.1 vs. 0.9±2.3, p=0.45).

Conclusion: The novel PL-ASA liquid capsules reduced rates of GI injury compared with IR-ASA tablets. The combination of reliable platelet inhibition with less GI injury makes PL-ASA an attractive new aspirin therapy option.

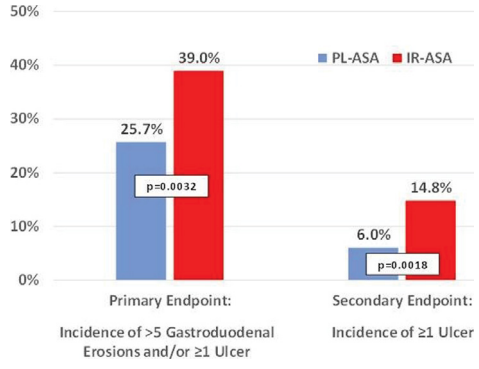

Figure 1