5503 **Oral Abstract Session**

Phase 3, randomized, single-dose, open-label study to investigate the safety and efficacy of pafolacianine sodium injection (OTL38) for intraoperative imaging of folate receptor positive ovarian cancer.

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Background: Pafolacianine sodium is under investigation as an adjunct to visual inspection and palpation by providing intra-operative imaging of folate receptor positive (FR+) ovarian cancer. Since complete resection (R0) is the strongest predictor of overall survival, methods to enhance detection of lesions are expected to benefit patient outcomes. **Methods:** For this phase 3, randomized, multicenter, single dose, open-label pivotal trial (NCT03180307), patients with ovarian cancer who were scheduled to undergo cytoreductive surgery were recruited from 11 sites in the US and Netherlands from March 2018 through April 2020. The study objectives were to confirm efficacy and safety of pafolacianine sodium (0.025 mg/kg i.v., $\geq$1 h prior to imaging) in combination with intraoperative near-infrared fluorescence (NIRF) imaging to detect additional lesions not detected by palpation and normal white light alone. **Results:** Pafolacianine sodium was administered to 150 total patients (safety analysis set); 109 patients comprised the full analysis set for efficacy analyses. Patients had primarily serous adenocarcinoma (n = 72; 68.6%) and advanced stage disease (n = 83; 76.1%). In 33% of patients (36 of 109), NIRF imaging with pafolacianine sodium identified additional lesions that were not planned for resection and were not detected by normal white light and palpation ($P < 0.001$, 95% CI [0.243, 0.427]). Among patients who underwent interval debulking surgery, the rate was higher, at 39.7% of patients (23 of 58; 95% CI [0.270, 0.534]). At the individual lesion level, the accuracy of pafolacianine sodium with NIRF to detect ovarian cancer is reflected by sensitivity of 83% (95% CI [73.9, 89.4]) and a false positive rate of 32.7% (95% CI [25.6, 40.7]). Investigators reported achieving complete resection (R0) in 62.4% (68 of 109) of patients. Drug-related adverse events (AEs) were reported by 30% of patients (45 out of 150). The most frequently reported drug-related AEs were nausea (18.0%), vomiting (5.3%), and abdominal pain (4.7%). Infusion reactions at the time of the procedure were mostly (96%) mild or moderate in severity; 89% resolved within 24 hours of onset. No drug-related serious AEs or deaths were reported. **Conclusions:** This phase 3 trial of pafolacianine sodium with NIRF imaging met its primary endpoint, intraoperatively identifying additional cancer not planned for resection in a statistically significant number of patients. Therefore, pafolacianine sodium may offer a novel real-time adjunct to current surgical imaging practice in ovarian cancer surgery. Clinical trial information: NCT03180307. Research Sponsor: On Target Laboratory.