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3210 Merryfield Row, San Diego, CA 92121

PHASE 1/2 TRIAL OF ALM-488 IN PATIENTS UNDERGOING HEAD & NECK SURGERY

PROTOCOL NUMBER: ALM-488-001

Product: ALM-488 Sterile Solution

Sponsor: Alume Biosciences, Inc.
3210 Merryfield Row
San Diego, CA 92121

Date of Protocol: 24 August 2020

Protocol Version	Issue Date
Original Protocol	26 April 2020
Amendment 1	24 August 2020

STUDY SUMMARY

Name of Sponsor	Alume Biosciences, Inc.
Name of Investigational Product	ALM-488 Sterile Solution
Name of Active Ingredient	ALM-488
Protocol Title	Phase 1/2 Trial Of ALM-488 In Patients Undergoing Head & Neck Surgery
Protocol Number	ALM-488-001
Phase of Development	Phase 1/2
Study Duration	18 months
Study Center(s)	Multi-center study (United States)
Objectives	Primary Objective: • To evaluate the safety of ALM-488 administered by intravenous (IV) infusion to patients undergoing head and neck surgery. Secondary Objectives: • To characterize the pharmacokinetics (PK) of ALM-488 in patients undergoing head and neck surgery. • To determine the recommended dose of ALM-488 needed to generate an adequate fluorescence signal in nerves. • To evaluate the effect of timing of administration of ALM-488 relative to surgery (e.g., up to 5 hours before surgery) on adequacy of fluorescence nerve labeling.
Diagnosis and Main Inclusion/Exclusion Criteria	This study will be conducted in patients who are undergoing head and neck surgery. Each subject must meet the following criteria to be enrolled in this study: Inclusion: 1. The subject has a neoplasm located in the head and neck including parotid neoplasm, thyroid neoplasm, squamous cell carcinoma or an unknown primary with metastases to the cervical lymph node(s) or is undergoing a neck dissection for head and neck neoplasm in an unknown location. 2. The subject's primary surgical treatment is by parotidectomy (superficial or total) or thyroidectomy (unilateral or bilateral) or cervical neck dissection, respectively. 3. The subject can understand and is willing to sign a written informed consent document. 4. The subject is a ≥18 years of age. 5. The subject has a life expectancy of at least 6 months. 6. The subject has a total bilirubin within institution's normal laboratory limits. 7. The subject has an aspartate aminotransferase (AST)/serum glutamic-oxaloacetic transaminase (SGOT) and alanine aminotransferase (ALT)/serum glutamic-pyruvic transaminase (SGPT) within institution's normal laboratory limits. 8. The subject has adequate renal function, defined as glomerular

	filtration rate (GFR) $\geq$ 60 mL/min/1.73 m^2. 9. The subject, if of childbearing potential, must have a negative urine or serum pregnancy test and be using a medically acceptable form of contraception (e.g., hormonal birth control, intrauterine devices, double-barrier method) or abstinence. The subject, if male, must use a medically acceptable form of contraception (e.g. condom) or abstinence. 10. The subject is willing to remain on-site for approximately 23 hours after administration of ALM-488 or, if required, stay overnight after the surgical procedure. 11. The subject plans to undergo head and neck surgery. Exclusion: 1. The subject has had prior radiation or chemotherapy for any prior head and neck neoplasm. 2. The subject has had open surgery in the ipsilateral head and neck within 1 year before administration of the investigational product (IP). 3. The subject has abnormal cardiac rhythm not controlled with medication, history of stroke within 1 year, history of coronary events within 1 year, and/or heart failure within 1 year before administration of the IP. 4. The subject has a history of drug-induced acute tubular necrosis. 5. The subject has current evidence of renal disease defined as glomerular filtration rate (GFR) < 60 mL/min/1.73 m^2. 6. The subject has received a systemic investigational drug of any kind for any indication within 6 weeks before administration of the IP. 7. The subject is pregnant or breastfeeding. 8. The subject has unresolved acute toxicity from prior anti-cancer therapy, as graded by the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v5.0. Alopecia, neuropathy $\leq$ Grade 2, and other non-acute toxicities are acceptable. 9. The subject has a history of fluorescein allergy. 10. The subject has a history of severe or steroid dependent asthma. 11. Any other criteria deemed by the PI that may prevent the patient from successfully completing the trial.