Alume Delivers Positive Topline Results for Bevonescein, a Potential First-in-Class Surgical Nerve Visualization Drug

Alume Biosciences delivers positive topline results for three pivotal trials of Bevonescein, advancing toward NDA submission with US FDA in 2H 2026

SAN DIEGO, CA, UNITED STATES, February 27, 2026 /EINPresswire.com/ -- Alume Biosciences, a clinical-stage biotechnology company advancing precision drugs for surgery, today announced topline pivotal results from three concurrent Phase 3 registrational clinical trials evaluating bevonescein (ALM-488), a potential first-in-class, targeted fluorescent nerve-visualization drug candidate engineered to illuminate vulnerable nerves in real time. The company completed three pivotal studies in patients undergoing head and neck surgery with a favorable safety profile. Two of the studies achieved both co-primary endpoints and the third study achieved one of the co-primary endpoints. A key secondary endpoint, nerve branching delineation, also showed a statistically significant positive difference across the three trials. Additionally, Alume has completed a thorough QT study to further expand on the safety profile of bevonescein. No safety and no cardiac concerns were identified in patients receiving up to 1000mg of bevonescein, representing twice the amount of intended dose. Alume is preparing to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in 2H 2026.

> “Even with meticulous technique, surgeons are limited by what they see under white light. Real-time nerve identification using fluorescence could meaningfully advance surgical precision.”
>
> *Eben L. Rosenthal, MD*

By improving intraoperative real-time nerve visualization, such drug candidates may have the potential to decrease surgical time, shorten recovery, decrease need for follow-up procedures, and lower long-term burden on healthcare resources.

KEY HIGHLIGHTS:

- Bevonescein is a drug candidate designed to support improved surgical nerve visualization in real time.
- Two concurrent pivotal trials met co-primary endpoints of nerve conspicuity and length measurements and key secondary endpoint of nerve branching delineation in patients undergoing head-and-neck surgery.

- NDA submission of bevonescein is on track for 2H 2026.

“Completing our pivotal clinical program and reporting positive topline results marks an important milestone for Alume,” said Quyen T. Nguyen, MD, PhD, Founder and CEO of Alume Biosciences. “This achievement reflects sustained disciplined execution with six clinical trials over five years, starting first-in-human trials during the COVID-19 pandemic; strong partnerships with our surgical colleagues; and our commitment to advancing a potential first-in-class solution for improved intraoperative nerve visualization toward regulatory submission.”

The clinical need for improved nerve visualization remains a persistent challenge across multiple surgical specialties, where unintended nerve injury can lead to chronic pain, loss of function, or diminished quality of life. Even in the hands of highly experienced surgeons, anatomy can be difficult to distinguish under conventional white light. Nerve illuminating technologies that enhance visualization may help standardize precision across operating rooms and reduce variability in patient outcomes.

“Surgeons have long relied on experience and meticulous technique to avoid nerve injury, yet visualization under conventional white light remains inherently limited,” said Eben L. Rosenthal, MD, Chair of Otolaryngology–Head and Neck Surgery at Vanderbilt University Medical Center. “A drug candidate that enables real-time identification of critical anatomy has the potential to meaningfully elevate surgical precision.”

Geoffrey Ling, MD, PhD, Alume Biosciences Strategic Advisory Board Member and former founding director of the Defense Advanced Research Projects Agency (DARPA) Biological Technologies Office, added, “Translating breakthrough science into scalable clinical technology requires both scientific rigor and operational discipline. At scale, molecularly targeted visualization drug candidates have the potential to impact surgical safety in various settings including major surgical centers, out-patient care and military settings. As bevonescein is optimized for use with only fluorescent lights and filter-modified surgical loupes and does not need advanced imaging equipment, it has the potential to be adopted across various resource-constrained settings.”

Bevonescein reflects broader progress in molecular targeting and translational medicine. By applying biological specificity to surgical visualization, the drug candidate illustrates how advances in genomics and molecular science can be translated into practical clinical tools that directly benefit patients in the operating room.

“Transformative advances in medicine occur when foundational biological insight becomes clinically actionable,” said Craig Venter, PhD, Alume Biosciences Strategic Advisory Board Member. “Bevonescein represents that evolution: by applying molecular targeting to illuminate anatomy in ways previously not possible and signaling a broader future in which biology directly enhances procedural care.” Alume Biosciences remains focused on advancing the program toward submission to the US FDA in 2H and, ultimately, bringing this innovation to the market.

ABOUT BEVONESCEIN
Bevonescein is a potential first-in-class, targeted fluorescent peptide-dye conjugate drug candidate designed for intraoperative use. When visualized with compatible systems, including ZEISS Yellow 560 and Designs for Vision platforms, bevonescein enables real-time visualization of critical nerves and may improve surgical precision. Bevonescein is investigational and is on track for U.S. Food and Drug Administration (FDA) New Drug Application (NDA) submission in 2H 2026.

ABOUT ALUME BIOSCIENCES
Alume Biosciences is a late clinical-stage biotechnology company pioneering targeted drugs to enhance surgical precision and preserve function. The company's lead technology was co-invented by Nobel Laureate Roger Y. Tsien, PhD, and surgeon-scientist Quyen T. Nguyen, MD, PhD, translating foundational fluorescence science into practical tools for the operating room.

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