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Photonamic GmbH & Co. KG Receives Orphan Drug Designation in Europe for 5-ALA as an Intraoperative Imaging Agent in Ovarian Cancer Surgeries

Pinneberg, Germany, Jan 14th, 2026.

Photonamic GmbH & Co. KG (Photonamic) today announced that the European Commission has granted Orphan Drug Designation for the company's 5-aminolevulinic acid (5-ALA) for the diagnosis of ovarian cancer. 5-ALA is meant as an intraoperative imaging agent to assist surgeons during ovarian cancer surgeries. Ovarian cancer remains one of the most severe gynecological malignancies with a high mortality rate due to late diagnosis and complex surgical requirements. Improved intraoperative visualization can play a critical role in achieving more optimal tumor resection for these patients, which may correlate to better patient outcomes. This orphan designation underscores the potential of 5-ALA to address a critical unmet need for patients undergoing surgery for ovarian cancer.

Building on Proven Expertise

The technology behind this orphan designation is based on photonamic's long-standing experience in fluorescence-guided surgery. Photonamic's 5-ALA technology is already approved and widely used in certain types of malignant brain tumor surgeries (e.g. as Gliolan® in Europe, Gleolan® in the US, and Alabel® in Japan). Neurosurgeons utilize 5-ALA to enable real-time visualization during surgery, helping them better distinguish tumor tissue from healthy tissue. Leveraging this proven platform, we are expanding its application to ovarian cancer to hopefully bring similar benefits in surgical precision and patient outcomes.

Ulrich, Kosciessa, CEO of photonamic comments on the decision of the European Commission: "*Through continuous collaboration with leading experts in the field and experience from several trials underway, we have confirmed the strong interest and urgent need for improved surgical guidance in ovarian cancer. The orphan designation in Europe reinforces our commitment to delivering an innovative and proven technology, which can make a real difference for patients undergoing ovarian cancer surgery*"

The US FDA granted Orphan-Drug Designation Status for Gleolan® (5-ALA) in Ovarian and Related Cancers in 2024. Currently, within the SBI group two Phase III clinical trials are conducted - one in the United States and one in Japan - with the ultimate goal of achieving regulatory approval in these and other markets worldwide.

More information about the trials can be found here:

Link to clinical trial in the USA: https://clinicaltrials.gov/study/NCT05804370

Link to clinical trial in Japan:
https://rctportal.mhlw.go.jp/en/detail?trial_id=jRCT2021250012

About photonamic GmbH & Co KG

photonamic is a German based company focused on the development and manufacturing of 5-ALA in various applications in the healthcare field. As a member of the SBI group with its parent company SBI ALApharma, the main achievement of photonamic to date is the development and registration of 5-ALA for the fluorescence-guided resection of glioblastoma which is marketed as Gliolan®, Gleolan® or Alabel™ in Europe, United States, Canada, Japan, Australia and Korea. Within the group, photonamic and its affiliated companies in the US, Canada and Japan are diligently extending the development activities with 5-ALA even outside the field of photodynamic application, e.g. immune modulation in infectious diseases, food supplement and cosmetics.