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Phase 3 Study of 5-ALA in Meningioma Surgery Meets Primary Endpoint

Pinneberg, Germany, April 23rd 2025.

photonamic GmbH & Co KG (Photonamic) are pleased to announce that our U.S. subsidiary, NX Development Corporation (NXDC), has successfully completed its phase 3 study (MEN-301) and comfortably met the primary endpoint, investigating 5-ALA as an adjunct in meningioma patients undergoing fluorescence-guided surgery.

Meningiomas are the most common type of primary brain tumor. Under the trade names Gleolan® in the United States and Gliolan® in Europe, 5-ALA has primarily been used in the approved indication of fluorescence-guided resections of malignant gliomas (WHO grade III and IV) in combination with a surgical microscope and blue light source. Meanwhile, experience has demonstrated that meningiomas may also show fluorescence. This was the motivation leading to the initiation of the MEN-301 study, conducted primarily at centers in the United States, as well as centers in Germany and Austria.

The main objective of the study was to determine the percentage of participants for which 5-ALA induced fluorescence status allows the surgeon to visually obtain correct information as to the presence or absence of tumor in tissue where there is uncertainty based on conventional white light visualization alone.

For this purpose, it was determined if any residual tumor which is no longer recognizable under conventional illumination at End of Surgery can be observed by fluorescence under blue light. In addition, when faced with uncertain tissue type (so-called “indeterminate” tissue), this study records how often surgeons make a correct decision based on fluorescence.
The pre-determined threshold for success for the primary endpoint was 30% of patients who have at least one tissue where identified Gleolan-induced PpIX fluorescence

status is consistent with histology. However, the actual study result was greater than 60%. This indicates that fluorescence status in the examined tissues was confirmed by histology in at least 60% of study participants.

Dr. Ulrich Kosciessa, Chairman of the Board of NXDC and CEO Photonamic, comments on the outcomes: “Meeting the primary endpoint is very encouraging for the potential of 5-ALA in this type of complicated surgery for meningioma patients. While further analysis for secondary endpoints is still ongoing, we hope to be able to bring this technology into clinical practice to the benefit of this patient group in a similar way as we have already done for glioblastoma patients”.

Further data analysis of secondary endpoints is still ongoing in close collaboration with the investigators, with the aim of publishing and presenting the full study results at conferences in the USA and Europe later this year.

About the MEN-301 Study
A phase 3 open-label, single-arm study designed to investigate the safety, diagnostic performance, and clinical usefulness of Gleolan®/Gliolan® (5-ALA) for the real time detection and visualization of meningiomas during tumor resection surgery.

About Gleolan®(USA) / Gliolan® (Europe)
Gleolan®/Gliolan® is indicated in adults for visualisation of malignant tissue during surgery for malignant glioma (WHO grade III and IV). It is taken orally by the patient prior to surgery. In combination with a specialist surgical microscope and blue light source, Gleolan®/Gliolan® fluoresces the malignant part of the tumour enabling the surgeon to make a distinction between malignant and normal tissue. For full prescribing information of Gleolan® in the USA, please see: www.gleolan.com. For the SPC of Gliolan® in Europe, please see https://www.gliolan.com/healthcare-professionals

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.