

Photonamic GmbH & Co. KG (Germany) Enrolls First Patient in Phase 2 Clinical Trial of PD L 506 (5-ALA HCl) for Interstitial Photodynamic Therapy (iPDT) of Glioblastoma

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photonamic GmbH & Co. KG (Head office: Pinneberg, Germany; CEO: Ulrich Kosciessa, Ph.D.) (“photonamic”), a subsidiary of SBI Holdings, Inc. (Head office: Minato-ku, Tokyo; Representative Director, President and CEO: Yoshitaka Kitao) the leader in the pharmaceutical development, translation and global commercialization of 5-aminolevulinic acid (“5-ALA”) (*) today announces that it has enrolled the first patient in its pilot Phase 2 clinical trial evaluating the feasibility of PD L 506 (5-ALA HCl) for stereotactic interstitial photodynamic therapy (iPDT) in adult patients with newly diagnosed supratentorial IDH wild-type glioblastoma (ClinicalTrials.gov Identifier: NCT03897491).

iPDT is a new, potentially promising treatment options for one of the most difficult to treat malignant tumor. In iPDT, thin optical fibers are placed in the tumor in a minimally invasive and millimeter-precise manner at predetermined target points in such a way that the tumor volume can be irradiated as completely as possible. In recently published case reports, it was surprisingly common to observe disease-free survival of more than 30 months in patients with a malignant brain tumor after using this new form of therapy.¹

PD L 506 has been approved under the brand name Gliolan® since 2007 for the visualization of tumor tissue in malignant gliomas (WHO grades III and IV) neurosurgery. It is available in more than 40 countries and more than 100.000 patients worldwide have undergone surgery using this technology. Although PD L 506 is used

¹ Schwartz et al. Neuro-Oncology 17:v214–v220, 2015.

for the first time in this controlled study for stereotactic interstitial photodynamic therapy in patients with a newly diagnosed malignant brain tumor, extensive knowledge of the safety and tolerability of PD L506 is available, which help to assess the tolerability profile of the study drug for iPDT.

“We are pleased to achieve this important milestone to our exploration to help patients diagnosed with glioblastoma” explains Ulrich Kosciessa, photonamic GmbH & Co. KG’s CEO. “The accumulation of the fluorescent photosensitizer protoporphyrin IX (PpIX) after systemic administration of 5-ALA proved high tumor selectivity. It is therefore very promising in this fascinating procedure of PDT of malignant glioma. The required light of the appropriate wavelength is administered through light fibers without the requirement of opening the scalp as being done for surgical intervention. Preclinical investigations resulted in the establishment of an appropriate treatment planning strategy and treatment parameters.”

(*) 5-aminolevulinic acid (“5-ALA”) is an endogenous amino acid derivative produced in mitochondria. Apart from its natural role as an important natural substance metabolized to heme and cytochromes serving the energy production in the mitochondrial membranes, 5-ALA is known to metabolize into the (pink/red) fluorescent compound protoporphyrin IX (PpIX) in cancer cells. This fluorescence can be detected with the appropriate instrumentation. In addition, PpIX, is a well known photosensitizer used in photodynamic therapy of cancers.

About photonamic GmbH & Co. KG

photonamic is a German based company involved in the development of 5-ALA in various applications as precursor for the photosensitizer PpIX. As a member of the SBI group with its parent company SBI ALApharma, photonamic has developed 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 aggressively extending the development activities with 5-ALA even outside the field of photodynamic application, e.g. immune modulation in infectious diseases, food supplement, cosmetics.

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