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Results of A First-in-Human Study for New Application of Photodynamic Therapy with 5-Aminolevulinic Acid for Extracorporeal Photopheresis Published in “Pharmaceutics”

October 12th, 2021

photonamic GmbH & Co. KG (Head office: Pinneberg, Germany; CEO: Ulrich Kosciessa, Ph.D.) (“photonamic”), a subsidiary of SBI Holdings, Inc. (Head office: Tokyo, Japan; Representative Director, President and CEO: Yoshitaka Kitao) and a leader in the pharmaceutical development, translation and global commercialization of 5-aminolevulinic acid (“5-ALA”) (*1) today announces that results of an investigator-initiated proof-of-concept study conducted by St. Olavs Hospital, Trondheim University Hospital (Trondheim, Norway) with a drug support from photonamic to evaluate treatment safety and tolerability of Extracorporeal Photopheresis (ECP) (*2) with 5-ALA in patients with chronic graft-versus-host disease (cGvHD) were published in “Pharmaceutics” on September 26th 2021.

Article

Christensen, E. *et al.* Application of Photodynamic Therapy with 5-Aminolevulinic Acid to Extracorporeal Photopheresis in the Treatment of Patients with Chronic Graft-versus-Host Disease: A First-in-Human Study. Pharmaceutics 2021, 13(10), 1558.

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ECP is an immunomodulatory therapy for the treatment of T-cell-mediated diseases like cGvHD, which exposes isolated white blood cells to a photosensitizer and ultraviolet (UVA) light. The purpose of the study was to improve the current ECP technology by replacing a conventional photosensitizer by 5-ALA, together with UVA light. This phase I-(II) study included 82 treatments in five patients, and the results indicate that ALA-ECP is safe and is mainly tolerated well by cGvHD patients.

“We are pleased by the achievement of this remarkable milestone in Norway to show another potent application of 5-ALA PDT.” explained by Dr. Ulrich Kosciessa, photonamic GmbH & Co. KG’s CEO. “With the well-known characteristics of 5-ALA as a precursor of photosensitizer protoporphyrin IX which selectively accumulates in proliferative or activated cells, including tumour cells, the modification of today’s standard ECP with the introduction of 5-ALA based PDT may improve treatment efficacy. We will further continue to explore this treatment modality as a potential benefit for patients suffering from GvHD and autoimmune disease.”

(*1) 5-aminolevulinic acid (“5-ALA”) is an endogenous amino acid 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.

(*2) Extracorporeal photopheresis (ECP) is an immune modulating treatment commonly used for the treatment of cutaneous T-cell lymphoma (CTCL) and chronic graft-versus-host disease (cGVHD). ECP exposes isolated white blood cells to a photosensitizer and UV-A to induce the apoptosis of T-cells and, hence, to modulate immune responses.

About photonamic GmbH & Co. KG

photonamic is a German based company involved in the development of 5-ALA in various applications as a 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™, Gliolan™ 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 expanding the development activities with 5-ALA even outside the

field of photodynamic application, e.g. immune modulation in infectious diseases, food supplements, cosmetics.

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