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photonamic GmbH & Co. KG

SBI ALApharma Canada Inc.

## Results of Phase II Trial for Breast Cancer Surgery Published in Breast Cancer Research

July 19th, 2021

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) and the leader in the pharmaceutical development, translation and global commercialization of 5-aminolevulinic acid (“5-ALA”) (\*), and its Canadian subsidiary SBI ALApharma Canada Inc. (Head office: Toronto, Canada; CEO & CTO, Dr. Ralph DaCosta) (“SBI Canada”) today announces that results of an investigator-sponsored Phase II randomized controlled trial (RCT) conducted at the world-renowned Princess Margaret Cancer Center, University Health Network (Toronto, Canada) evaluating the safety, feasibility, and diagnostic accuracy of a patented handheld intraoperative fluorescence imaging device *plus* 5-ALA for intraoperative visualization of invasive breast carcinomas during breast cancer surgery (ClinicalTrials.gov Identifier: NCT01837225) were published in the peer-reviewed and open access journal Breast Cancer Research on July 12<sup>th</sup> 2021.

### Article

Ottolino-Perry, K., Shahid, A., DeLuca, S. *et al.* Intraoperative fluorescence imaging with aminolevulinic acid detects grossly occult breast cancer: a phase II randomized controlled trial. Breast Cancer Res 23, 72 (2021).

<https://doi.org/10.1186/s13058-021-01442-7>

This important milestone is followed by an ongoing FDA IND approved Pivotal Phase III RCT involving 20 clinical centers in the United States and Canada (ClinicalTrials.gov Identifier: NCT04815083) that is currently recruiting eligible patients.

“We are pleased having accomplished another milestone in our development for breast cancer program” explains Ulrich Kosciessa, photonamic GmbH & Co. KG’s CEO. “This

study played a role in our strategic acquisition of the imaging technology in 2019 and potentiated our current development in breast cancer. We will further continue to develop our technology to one day benefit breast cancer patients in a manner similar to our current 5-ALA-based product currently FDA approved for neurosurgery.”

“This publication will have broad clinical exposure and impact specifically in breast surgical oncology as the journal is widely read globally by general surgeons and breast cancer clinicians”, says Dr. Ralph DaCosta, senior author of the paper and SBI Canada’s CEO & CTO. “We strive in our on-going image-guided surgical oncology program to investigate 5-ALA and our novel handheld Eagle™ fluorescence imaging technology to improve intraoperative margin assessment and fluorescence-guided surgery for breast cancer, as well as other cancers where real-time visualization of carcinoma during surgery is a clinical priority”.

**(\*) 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 supplements, cosmetics.

#### **About SBI ALApharma Canada Inc.**

SBI ALApharma Canada Inc. is a Toronto-based medical imaging company that is expanding the clinical translation and applications of its proprietary handheld intraoperative Eagle™ imaging technology in conjunction with 5-ALA to improve the

outcomes and lives of cancer patients with surgical needs. Established in August 2019, SBI Canada is a 100% subsidiary of photonamic as part of the acquisition of Toronto-based MolecuLight Inc.'s oncology imaging platform technology and business.

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Source: photonamic GmbH & Co. KG; SBI ALApharma Canada Inc.