



SBI Holdings, Inc.

photonamic GmbH & Co. KG

SBI ALApharma Canada Inc.

## SBI ALApharma Canada Inc., a Subsidiary of photonamic GmbH & Co. KG (Germany), Enrolls First Patient in Pivotal Phase 3 Clinical Trial of PD G 506 A (5-ALA HCl) and Eagle Fluorescence Imaging System™ for Breast Conserving Surgery

May 7, 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) the leader in the pharmaceutical development, translation and global commercialization of 5-aminolevulinic acid (“5-ALA”) (\*) today announces that its Canadian subsidiary SBI ALApharma Canada Inc. (Head office: Toronto, Canada; CEO & CTO, Dr. Ralph DaCosta) (“SBI Canada”) has enrolled the first patient in its Pivotal Phase 3 randomized controlled trial (RCT) evaluating the safety and efficacy of PD G 506 A (5-ALA HCl) in margin assessment during breast conserving surgery (ClinicalTrials.gov Identifier: NCT04815083). This important milestone occurs on the heels of the company’s FDA IND clearance for the RCT on April 23, 2021. The multicenter trial involves 20 clinical centers in the United States and Canada and will use SBI Canada’s proprietary intraoperative handheld Eagle Fluorescence Imaging System™ to visualize PD G 506 A-induced protoporphyrin IX (PpIX) fluorescence.

SBI Canada was established in 2019 as part of photonamic’s strategic acquisition of the oncology business from MolecuLight Inc. (Toronto, Canada). Data from an earlier Phase 2 clinical study at Princess Margaret Cancer Center demonstrated that PD G 506 A-induced PpIX fluorescence (known to be selective for cancerous tissues) can be

visualized in surgical specimens and within the surgical cavity in real-time using the compact fully handheld camera of the Eagle Fluorescence Imaging System™.

“We are pleased having accomplished this milestone in our development for breast cancer surgery program” explains Ulrich Kosciessa, photonamic GmbH & Co. KG’s CEO. “It is an important step on our pathway to utilize the capabilities of 5-ALA as a precursor of PpIX and its tumor selectivity together with innovative technologies to help improve the lives of cancer patients around the world. With our proprietary handheld Eagle™ imaging device technology of our subsidiary SBI Canada, surgeons will now be able to investigate the surgical cavity following conventional lumpectomy allowing them to identifying residual disease as part of this Phase 3 trial in breast cancer surgery”. “This will allow us to further 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 product similarly helps neurosurgeons around the world to perform fluorescence-guided glioblastoma surgery.”

“We are delighted at achieving both FDA IND clearance and the first patient enrolled in our Pivotal Phase 3 trial within days of each other”, says Dr. Ralph DaCosta, SBI Canada’s CEO & CTO. “These achievements are important markers of progress in our on-going program to investigate 5-ALA and our novel Eagle™ imaging technology to improve intraoperative margin assessment and fluorescence-guided surgery. Our initial focus is on breast cancer surgery, but this work lays the foundation for other cancers where real-time visualization of carcinoma during surgery is a clinical priority”. “Despite the on-going COVID pandemic, our outstanding SBI Canada team, together with the support from the SBI group of companies have managed to bring us to this critical stage in clinical translation in breast cancer surgery”, says DaCosta.

**(\*) 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.

### **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 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.