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FOR RELEASE ON OCTOBER XX, 2018

NX Development Corp. (NXDC) Launches FDA-Approved Gleolan™ (aminolevulinic acid HCl) for Enhanced Visualization of High-Grade Gliomas (including Glioblastomas)

Lexington, Kentucky | October XX, 2018 — NX Development Corp. (NXDC), a life sciences company, today announced the U.S. commercial launch of its flagship product Gleolan™ (aminolevulinic acid HCl), the first and only FDA-approved optical imaging agent indicated in patients with high-grade gliomas (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery.

Gliomas refer to tumors occurring in the glial cells of the brain. There are 4 grades of glioma, with Grades III and IV being the most aggressive. Glioblastoma, a type of Grade IV glioma, has the highest incidence of mortality with the potential to spread rapidly. Glioblastomas represent nearly 15% of all primary brain tumors and more than 56% of all gliomas with an estimated 12,760 new cases predicted for 2018.[1]

Gleolan is a lyophilized powder which is reconstituted with drinking water and administered orally to patients 3 hours (range 2-4 hours) before the induction of anesthesia.

The active substance in Gleolan is aminolevulinic acid (ALA) and, when orally administered, leads to the accumulation of the active metabolite protoporphyrin IX (PpIX) within high-grade tumor cells. During surgery, the neurosurgeon uses a standard operating microscope adapted with a blue emitting light source. Because tumor cells accumulate higher levels of PpIX, the result is that malignancy appears as a unique red-violet fluorescence under blue light. Tissues lacking sufficient PpIX concentrations appear blue. False negatives and false positives may occur. Non-fluorescing tissue in the surgical field does not rule out the presence of tumor in patents with glioma. Fluorescence may be seen in areas of inflammation or metastases from other tumor types.

Gleolan under blue light may allow the neurosurgeon to see malignancy they may not have been able to see under standard white light. In pivotal trials, Gleolan demonstrated a 95% positive predictive value in identifying malignant tissue, which directly correlated with a high degree of precision to what the

[1] Brain Tumor Statistics. (2018, Septemeber). Retrieved from https://www.abta.org/tumor_types/glioblastoma-gbm/

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pathologist observes. Gleolan's safety is supported by data from five open label clinical studies, which included 527 patients with glioma who received the product. Adverse reactions occurring in >1% of patients in the week following surgery were pyrexia, hypotension, nausea, and vomiting. (Please see additional safety information related to Gleolan below).

"We are very pleased to make Gleolan available to neurosurgeons and their patients in the U.S.," said Alan Ezrin, Ph.D., co-founder and CEO of NXDC. "ALA HCl is already in use for high grade glioma surgery in more than 40 countries. With the U.S. launch of Gleolan, we are proud to offer neurosurgeons an already proven adjunctive method for improving Grades III and IV glioma visualization during surgical procedures."

As noted in the Full Prescribing Information, neurosurgeons will need to complete an online neurosurgeon training program, provided by NX Development Corp, on the use of fluorescence in surgery before utilizing Gleolan.

For more information on Gleolan, please visit www.gleolan.com or email customersupport@nxdevcorp.com.

Please refer to Full Prescribing Information here.

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About NX Development Corp. (NXDC)

NX Development Corp. (NXDC), a life sciences company based in Lexington, KY, dedicated to the development of ALA HCl for tumor visualization. NXDC is wholly-owned subsidiary of photonamic GmbH & Co. KG (Head office: Pinneberg, Germany; "PHN"). PHN is the licensor of Gleolan™ (aminolevulinic acid HCl (ALA HCl)) to NXDC. The companies share an eight-year working relationship and are wholly-owned by SBI Holdings Inc. (Tokyo, Japan)

About Gleolan

Gleolan is an FDA-approved optical imaging agent indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery. Because of its unique mechanism-of-action, Gleolan may allow neurosurgeons to see malignant tissue during surgery under blue light that they may not see under standard white light.

Important Safety Information

Contraindications

Do not use Gleolan in patients with:

- Hypersensitivity to the active substance
- Acute or chronic types of porphyria

Warnings and Precautions

Due to the risk of phototoxic reactions, do not administer phototoxic drugs for 24 hours during the perioperative period. Reduce exposure to sunlight or room lights for 48 hours after administration of Gleolan.

Errors may occur with the use of Gleolan for intraoperative visualization of malignant glioma, including false negatives and false positives. Non-fluorescing tissue in the surgical field does not rule out the presence of tumor in patients with

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glioma. Fluorescence may be seen in areas of inflammation or metastases from other tumor types.

Hypersensitivity reactions, including serious hypersensitivity reactions have occurred; these
reactions include anaphylactic shock, swelling, and urticaria. Always have cardiopulmonary resuscitation personnel and equipment readily available and monitor all patients for hypersensitivity reactions.

Adverse Reactions
Adverse reactions occurring in >1% of patients in the week following surgery were pyrexia, hypotension, nausea, and vomiting.

Nervous system disorders occurred in 29% of patients within the first week after surgery and events occurring in >1% of patients included: aphasia (8%), hemiparesis (7.8%), hemianopsia (3.2%), headache (2.7%), seizure (1.9%), hemiplegia (1.9%), monoparesis (1.3%) and hypoesthesia (1.1%). Brain edema occurred in <1% of patients in the first 6 weeks after surgery. In a randomized clinical trial, the numbers of serious neurologic adverse events in the post operative period were higher in patients randomized to ALA fluorescence arm compared to the control arm. An imbalance was notable for the adverse events aphasia, ataxia, convulsion and hemianopsia and is likely related to the higher amount of brain resection performed in the ALA arm. At longer follow up periods, the numbers between the two arms appeared similar.

Worsening of >= 2 Common Toxicity Criteria grades in alanine aminotransferase and gamma-glutamyl transferase occurred in 15.8% and 11.6% of patients, respectively, within the first week after surgery. Absolute levels ranged from 2 times to greater than 10 times the upper limit of normal for each parameter. At 6 weeks, these measurements remained elevated in 2.9% and 7.5% of patients, respectively. There were no cases of liver failure.

Drug-Drug Interactions
See information under Warning and Precautions regarding phototoxic reactions.

Please see **Full Prescribing Information**

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