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FOR RELEASE ON JANUARY 12, 2021

**NX Development Corp. (NXDC) Receives FDA Orphan-Drug Designation for Gleolan® (aminolevulinic acid HCl) in Meningioma**

**LEXINGTON, KY |GlobeNewswire| January 12, 2021** — NX Development Corp. (NXDC), a life sciences company wholly owned by photonamic GmbH & Co. KG., today announced FDA orphan-drug designation for Gleolan, an optical imaging agent for the visualization of tumor tissue in patients undergoing surgical resection for meningioma. Gleolan is currently indicated in the United States for patients with glioma [suspected World Health Organization (WHO) Grades III or IV on preoperative imaging] as an adjunct for the visualization of malignant tissue during surgery. Orphan-drug designation is provided to drugs intended for the treatment, prevention or diagnosis of a rare disease or condition.

Meningiomas are tumors that affect the membranes that surround the brain and spinal cord and account for about 36% of all primary brain tumors.[1] The surgical debulking of the tumor mass is an important tool in the management of this rare disease.

"We were thrilled to receive orphan-drug designation to support our efforts in evaluating the potential utility of fluorescence-guided surgery (FGS) in the meningioma patient population." said Alan M. Ezrin, Ph.D., co-founder and CEO of NXDC. "To date, the use of Gleolan in patients with suspected high grade gliomas has been performed in excess of 80,000 patients worldwide and the expansion into meningioma is a key initiative of our company's worldwide strategy as we strive to develop surgical application in a variety of tumor types."

Last month, NXDC announced enrollment of the first patient in the Phase III multicenter study of Gleolan to enhance visualization of brain tumor in patients with newly diagnosed or recurrent meningiomas (NXDC-MEN-301). This international study will enroll 100 patients and is expected to be completed in approximately 15 months. The first patient was enrolled at the University Hospital Münster in Germany by Prof. Dr. Walter Stummer, who is joined by surgeons at 9 other key brain tumor centers in the US, Germany and Austria (https://clinicaltrials.gov/ct2/show/NCT04305470).

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

Please refer to Full Prescribing Information here.

[1] CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2007–2011

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**About NX Development Corp. (NXDC)**

NXDC is a privately held life science company dedicated to the commercialization of Gleolan in the U.S. The company was acquired in 2018 by photonamic (PHN) GmbH & Co. KG. (Pinneberg, Germany). PHN is wholly owned by SBI ALApharma (Hong Kong) a subsidiary of SBI Holdings, Inc. (Tokyo , Japan)

**About Gleolan**

**US INDICATION AND IMPORTANT SAFETY INFORMATION**
Gleolan is an FDA-approved optical imaging agent indicated in patients with glioma [suspected World Health Organization (WHO) Grades III or IV on preoperative imaging] as an adjunct for the visualization of malignant tissue during surgery. Gleolan helps neurosurgeons see malignant tissue in real time during surgery and is provided orally 20mg/kg, 2-4 hours prior to glioma surgery. During operation, the surgeon utilizes a modified surgical microscope with a specific blue light filter for the visualization of red-violet fluorescence.

**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,

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including false negatives and false positives. Non-fluorescing tissue in the surgical field does not rule out the presence of tumor in patients with 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 the 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 Warnings and Precautions regarding phototoxic reactions.

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Please see **Full Prescribing Information**

**NX Development Corp. Forward-Looking Statement**

*This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of pharmaceutical products. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on historical performance and current expectations and projections about our future goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, that future study results will be consistent with the results to date, that Gleolan may not receive regulatory approval for the additional indication described in this release.*