NX Development Corp (NXDC) Launches Gleolan™ Meningioma Orphan Designated Phase 3 Clinical Trial (NXDC-MEN-301)

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LEXINGTON, Ky., November 16, 2020/PRNewswire/ — NX Development Corp (NXDC), a privately-held life sciences company, today announced the enrollment of the first patient in the Phase 3 Multicenter Study of Gleolan (Aminolevulinic Acid Hydrochloride) to Enhance Visualization of Brain Tumor in Patients with Newly Diagnosed or Recurrent Meningiomas.

"We were pleased to initiate this landmark study evaluating the utility of fluorescence-guided surgery (FGS) in the meningioma patient population. We are excited about the execution of this important study as we continue to expand the use of Gleolan in cancer surgeries around the world," said Alan M. Ezrin, Ph.D., co-founder and CEO of NXDC. 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 by Prof Walter Stummer who is the co-Global Principal investigator in the MEN 301 study. (https://clinicaltrials.gov/ct2/show/NCT04305470)

The study is designed to possibly show the benefit of real time visualization of Gleolan-induced fluorescence helping surgeons to more accurately discriminate tumor from adjacent non-tumor tissues or scar tissues more reliably than conventional white light intraoperative assessment. The use of Gleolan-induced fluorescence in patients with meningioma may enable the surgeon to more clearly see mengioma tumor in real time and to determine if the tissue in question should be removed or not and to make more well-informed decisions.

Gleolan is an important visual aid not only for intraoperative real time visualization of the primary tumor but also of any remnants of tumor, of any satellite lesions, and of any infiltrating tissue in the meninges, bone flap, sinuses and brain parenchyma. The use of Gleolan may allow the surgeon to have greater confidence that the target tumor has been effectively removed.

NXDC obtained FDA and Orphan Drug approval in 2017 for the use of Gleolan as an intraoperative imaging agent. Gleolan is 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. In November 2020 the FDA awarded Orphan designation for the use of Gleolan in the visualization of meningioma.

About Gleolan™

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. To-date Gleolan has been used in more than 80,000 cases of high grade gliomas.

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)

About Photonamic GmbH & Co. KG

Photonamic PHN is a life science company engaged in research and development of drugs that use 5-ALA, primarily in Europe, as an intra-operative diagnostic drug, marketed under the name Gliolan. Gliolan was launched for the visualization of brain tumors and approved by the European Medicines Agency (EMA) in 2007. Today, Gliolan is sold in over 40 countries. PHN also distributes Gliolan through its business partners around the world. PHN is wholly owned by Strategic Business Innovations (Tokyo, Japan) who developed Gliolan in Japan.

SOURCE NX Development Corp