Ivy Brain Tumor Center and SonALAsense to Test Novel Drug-Device Combination for Glioblastoma

First-in-human clinical trial will determine effectiveness of promising, non-invasive therapy for brain cancer

(Phoenix, Ariz. – Nov. 21, 2019) – The Ivy Brain Tumor Center at the Barrow Neurological Institute, today announced a strategic collaboration with SonALAsense to develop and test a new, non-invasive drug-device combination, sonodynamic therapy (SDT), for recurrent glioblastoma through a Phase 0/2 clinical trial. Details of the study, as well as the results of two other clinical trials will be announced by Dr. Nader Sanai, director of the Ivy Brain Tumor Center, at the 2019 Society of Neuro-Oncology Annual Meeting (SNO) in Phoenix, Ariz. on Nov. 22.

SonALAsense Phase 0/2 Clinical Trial
SonALAsense, in conjunction with the Ivy Brain Tumor Center, is collaborating with Insightec®, the innovator of Magnetic Resonance-Guided focused ultrasound (MRFUS) to adapt its technology for use at non-thermal energy levels in combination with SonALAsense’s proprietary formulation of 5-aminolevulinic acid (ALA) for glioblastoma.

By adapting the Ivy Center’s Phase 0/2 clinical trial model, SonALAsense’s ALA drug will be administered intravenously, metabolized exclusively by glioblastoma cells, and accumulated as a fluorescent metabolite protoporphyrin IX. This tumor metabolite is then stereotactically activated using Insightec’s MR-guided focused ultrasound which results in reactive oxygen species that are lethal to every tumor cell. This combination of metabolic targeting by ALA and activation by non-invasive focused ultrasound represents an innovative potential new therapeutic modality for glioblastoma patients. This novel technology is called ALA sonodynamic therapy.

Preclinical studies of ALA sonodynamic therapy have shown promise and, by evaluating this therapy through the Ivy Center’s Phase 0/2 clinical trial design, investigators will rapidly assess safety and biological and clinical efficacy in a first-in-human clinical trial. The clinical trial is scheduled to open for enrollment in 2020.

“Our goal at the Ivy Brain Tumor Center is to live at the forefront of first-in-human and first-in-class therapies for glioblastoma, which is why this collaboration with SonALAsense makes so much sense,” said Dr. Nader Sanai. “New modalities are desperately needed in brain tumor therapy. As we evolve our approaches through Phase 0/2 clinical trials, we are committed to developing non-invasive interventions that deliver results to patients as quickly as possible.’

“SonALAsense’s vision is for sonodynamic therapy to change glioblastoma from a deadly cancer into a chronic disease, and glioblastoma patients into long-term cancer survivors. I look forward to working with Dr. Sanai and his experienced team at the Ivy Brain Tumor Center to determine if our vision can become a reality through our planned Phase 0/2 clinical study,” said Dr. Stuart Marcus, MD, PhD, founder, chief executive officer and chief medical officer of SonALAsense. He added, “We are very grateful for the financial support of the Ivy Foundation to conduct the clinical study.”

Ribociclib in Meningioma
At SNO, Dr. Sanai will also share the results of a new Ivy Center Phase 0/2 clinical trial of a CDK4/6 inhibitor in recurrent aggressive meningioma patients. The study demonstrates that the drug ribociclib (Kisqali®), recently-developed to treat aggressive breast cancer, has the ability to penetrate the blood-brain barrier and target the brain tumor cell mechanisms – providing the first evidence of biological activity in meningioma patients. Based on the results of this study, investigators at the Ivy Center are now working to test new drug cocktails deploying ribociclib for multiple brain tumor types.
Ceritinib in Brain Metastases and Glioblastoma
In addition, the Ivy Brain Tumor Center will be underscoring the importance of the Phase 0/2 clinical trial approach at SNO with a poster presentation of its clinical study of ceritinib in brain metastases and recurrent glioblastoma. Ceritinib is an orally bioavailable, small molecule inhibitor of several cancer cell signaling pathways highly expressed in glioblastoma and brain metastases. The trial assessed the pharmacokinetics and pharmacodynamics of ceritinib in recurrent glioblastoma and brain metastasis patients. This study found that ceritinib is highly bound to plasma proteins and was ineffective in penetrating the human CNS in patients with glioblastoma. The trial’s negative results exemplify how the Ivy Center’s Phase 0/2 clinical trial design can rapidly identify drug development strategies to accelerate as well as flag new drugs that should be de-emphasized for specific brain tumor indications.

For more information about the Ivy Brain Tumor Center and its latest developments, please visit www.ivybraintumorcenter.org.

Ivy Brain Tumor Center at the Barrow Neurological Institute in Phoenix, AZ is a non-profit translational research program that employs a bold, early-phase clinical trials strategy to identify new treatments for aggressive brain tumors, including glioblastoma. The Ivy Center’s Phase 0 clinical trials program is the largest of its kind in the world and enables personalized care in a fraction of the time and cost associated with traditional drug development. Unlike conventional clinical trials focusing on single drugs, its accelerated trials program tests therapeutic combinations matched to individual patients. Learn more at IvyBrainTumorCenter.org. Follow the Ivy Brain Tumor Center on Facebook, Instagram, Twitter and LinkedIn.

SonALAsense is a clinical-stage company developing ALA sonodynamic therapy (SDT) as a first-in-class, non-invasive drug-device combination for the treatment of recurrent glioblastoma multiforme and other deadly cancers. SDT utilizes MRI-guided focused ultrasound (the device) in combination with aminolevulinic acid (a drug) to selectively target and kill tumor cells. SonALAsense is working closely with the Ivy Brain Tumor Center to advance ALA SDT into a Phase 0/2 clinical trial in recurrent GBM in 2020. For more information about SonALAsense, visit www.sonalasense.com.

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