Press Release

Apogenix' Partner CANbridge Announces 67 % Five-Year Overall Survival Rate Compared to 8.2 % in Institutional Database With Asunercept Plus Standard of Care in Newly Diagnosed Glioblastoma Multiforme Patients

- **83 % overall survival at two years vs. 34.3 % OS from institutional database**
- **17.95 months median progression-free survival vs. 5.8 months PFS in historical group**
- **Data was presented at the ESMO Sarcoma and Rare Cancers Annual Congress**

Heidelberg, Germany, March 27, 2023 – Apogenix, a biopharmaceutical company developing next generation immunotherapeutics, announced today that its partner CANbridge presented compelling long-term follow-up data from its Phase I/II study (n = 10) with asunercept (CAN0008) plus temozolomide/radiotherapy in newly diagnosed glioblastoma multiforme (GBM) at the ESMO conference in Lugano, Switzerland. This long-term follow up showed an overall survival rate of 83 % at two years and 67 % at five years, three years after the trial ended. GBM, or grade IV astrocytoma, is a fast-growing and aggressive brain tumor with still very poor prospects: The American Association of Neurological Surgeons (AANS) indicates survival rates of approximately 40 % in the first year post diagnosis and 17 % in the second year.[1]

Thomas Hoeger, PhD, CEO of Apogenix, said*: "We would like to congratulate our partner CANbridge on this exceptional data. These data underline the clinical efficacy of the CD95 ligand inhibitor asunercept, which provides a dual benefit: not only inhibits asunercept the tumor's ability for immune escape, but it also limits its invasive growth, a characteristic for which glioblastoma is notorious. Since temozolomide's approval in 1999, no substance could demonstrate a positive effect on survival in this indication. A median of almost 18 months of progression-free survival could mean a major break-through for patients suffering from this devastating brain cancer. We strongly believe in asunercept's significant potential to address the enormous medical need for glioblastoma patients and we look forward to the Phase II data of our partner CANbridge."*

Apogenix would like to refer interested parties to the original announcement of CANbridge that can be accessed online:

- Begin of the original press release -

[1] https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Glioblastoma-Multiforme

Long-Term Data from CANbridge Pharmaceuticals CAN008 Phase 1/2 Trial in Glioblastoma Multiforme Shows 67% Five-Year Overall Survival Rate to 8.2% in Institutional Database

- **Data to be Presented at the ESMO Sarcoma and Rare Cancers Annual Congress**
- **83% overall survival at two years vs. 34.3% OS from institutional database**
- **17.95 months median progression-free survival vs. 5.8 months PFS in historical group**

Beijing, China; Burlington, Mass., March 16, 2023 — CANbridge Pharmaceuticals, Inc. (1228.HK), a global biopharmaceutical company, with a foundation in China, committed to the research, development and commercialization of transformative therapies to treat rare diseases and oncology, announced that long-term follow up data from the Phase 1/2 study of CAN008 (asunercept) plus temozolomide/radiotherapy (TMZ/RT) in newly diagnosed glioblastoma multiforme (GBM) showed a long-term survival rate of 67% at five years, three years after the trial ended. The data will be presented as a poster at the European Society of Medical Oncologists (ESMO) Sarcoma and Rare Cancers Annual Congress, March 20-22, in Lugano, Switzerland. The study was conducted at Chang Gung Memorial Hospital, Taoyuan, Taiwan, the site of the clinical study. The principal investigator is Wei Kuo-Chen MD, Professor, formerly at Chang Gung Memorial Hospital and now at New Taipei City Tucheng Hospital.

In the study, "Long term follow-up to the phase I/II study of CAN008 plus standard chemoradiotherapy treatment in patients with newly diagnosed glioblastoma multiforme," researchers reported that four out of the nine newly diagnosed glioblastoma multiforme patients treated in the CAN008 Phase 1/2 trial at this lead site were alive at the five-year follow up, three years after the completion of the trial. All four of the surviving patients were in the high-dose cohort of the trial, which received 400 mg of CAN008 in addition to standard temozolomide/radiotherapy (TMZ/RT). The overall survival rate of the high-dose CAN008 group was 83% at two years and 67% at three, four and five years. This compares to an overall survival rate in the institutional GBM database (n=218) (1) of 34.3% at two years, 19.5% at three years, 16.1% at four years and 8.2% at five years. In addition, the high-dose CAN008 cohort saw a median progression-free survival of 17.95 months. This compares to a historical median progression-free survival of 6.9 months for GBM patients on standard-of-care (TMZ/RT) (Stupp et al, 2009). The researchers also reported that a high tumor mutation burden and DNAH family gene mutation were associated with a favorable response to CAN008 treatment.

CAN008 is currently in an ongoing Phase 2 trial in glioblastoma multiforme (GBM) in China. An interim data analysis is expected in mid-2023.

"We are pleased to see a median progression-free-survival of 17.95 months in CAN008 glioblastoma multiforme patients, more than double the historical median PFS for standard-of-care GBM patients, and that 67% of the CAN008 high-dose patients were alive after five years, in a cancer where patients typically progress very rapidly and survival rates are dismal," said Gerry Cox, M.D., Ph.D., chief medical officer and chief development strategist at CANbridge and a study author. "Glioblastoma multiforme is one of the deadliest cancers, with survival rates of less than 15 months, few treatment advances and a high unmet medical need."

"While this is a small study, we are extremely encouraged by the high five-year survival rate of patients in our CAN008 Phase 1/2 trial, three years after its completion, in glioblastoma multiforme, a cancer with typically poor outcomes," said James Xue, Ph.D., CANbridge founder, chairman and CEO. "We look forward to the continued development of lead candidate, CAN008, currently in a Phase 2 GBM trial in China, and to bringing this potentially new and promising treatment to brain cancer patients."

POSTER INFORMATION

Title: “Long term follow-up to the phase I/II study of CAN008 plus standard chemoradiotherapy treatment in patients with newly diagnosed glioblastoma multiforme”
Authors: Ian Yi-Feng Chang, PhD, Hong-Chieh Tsai, MD, PhD, Chia-Hua Chen, PhD., Hsiu-Chi Chen, MSc, Chia-Wen Huang, MSc, Gerald. F. Cox, MD, PhD, Fang-Min Huang, MD, You-Yu Lin, PhD, Ko-Ting Chen, MD, PhD, Ya-Jui Lin, MD, PhD, Kuo-Chen Wei, MD
Poster : #2P
Poster Session: March 20-22
(1)Linkou Chang Gung Memorial Hospital, Taiwan, institutional database.

- End of the original press release -

About Apogenix
Apogenix is a private company developing innovative immunotherapeutics for the treatment of cancer and viral infections, such as COVID-19. The company’s pipeline of immunotherapy drug candidates targets different tumor necrosis factor (TNF) superfamily-dependent signaling pathways in order to restore the anti-tumor immune response in cancer patients and reduce lymphopenia and inflammatory cell death in patients with viral infections. Checkpoint inhibitor asunercept, the company’s lead immunotherapy candidate, is in late-stage clinical development for COVID-19 and glioblastoma with PRIME (PRIority MEdicines) designation by the European Medicines Agency for the treatment of glioblastoma. Based on its proprietary technology platform for the construction of novel TNF superfamily receptor agonists, Apogenix develops CD40 and GITR receptor agonists for cancer immunotherapy. The TRAIL receptor agonist program was out licensed to AbbVie and is currently in clinical phase I trials.

About Asunercept
Apogenix’ lead immunotherapy candidate asunercept is a fully human fusion protein that consists of the extracellular domain of the CD95 receptor and the Fc domain of an IgG1 antibody. The CD95 ligand inhibitor is being developed for the treatment of solid tumors, hematological malignancies, and viral infections, such as COVID-19. Asunercept was granted orphan drug designation for the treatment of glioblastoma and myelodysplastic syndromes (MDS) in both the EU and the US and PRIME (PRIority MEdicines) designation by the European Medicines Agency for the treatment of glioblastoma. Asunercept is exclusively licensed to CANbridge Life Sciences under a development and commercialization license covering China, Macao, Hong Kong, and Taiwan.

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