Cullgen Announces First-In-Human Dose in Phase I/II Trial of CG001419, a First-in-Class TRK Protein Degrader for Treatment of Cancer Patients

CG001419 is Cullgen's first protein degrader to enter clinical development

SAN DIEGO and SHANGHAI, July 27, 2023 -- Cullgen Inc., a leading biotechnology company developing small molecule therapeutics based on its proprietary uSMITE™ platform of targeted protein degradation technology, today announced that it has initiated dosing with its orally bioavailable pan-TRK degrader, CG001419, in a Phase I/II clinical trial for patients with solid tumors. CG001419 is a potential first-in-class, highly active small molecule developed to selectively degrade both mutant and wild-type TRK proteins. In preclinical research, CG001419 demonstrated strong potency against solid tumors harboring various oncogenic TRK abnormalities, such as *NTRK* gene fusions and wild-type TRK protein over-expression.

"We are excited to initiate human dosing for CG001419," said Dr. Ying Luo, Chairman and CEO of Cullgen, "This is a significant milestone for Cullgen as it marks our first entry into the clinic for one of our targeted protein degraders. I am very proud of the progress that our entire company has made to advance our first program into the clinic in only a few years since inception of the program."

The first-in-human trial of CG001419 is a Phase I/II trial with adaptive design. The Phase Ia portion of the trial is an open label, non-randomized, dose escalation study to evaluate the safety, tolerability, PK profile, and preliminary efficacy of CG001419 in patients with advanced or metastatic solid tumors, particularly those harboring *NTRK* gene fusions, point mutations, amplifications or over-expression. Patients that complete the Phase Ia trial may transition into the Phase Ib or Phase II portions of the trial depending on safety and tolerability results, the patient's *NTRK* aberration type, and the judgment of physicians. Compared with traditional kinase inhibitor drugs approved in treating cancer with *NTRK* gene fusions, CG001419 may offer potential advantages in overcoming secondary drug-resistant mutations in *NTRK* fusions, as well as an expanded clinical profile to include cancers with other *NTRK* gene/TRK protein abnormalities.

About Cullgen Inc.:

Cullgen is a privately held clinical-stage biopharmaceutical company dedicated to the development of first-in-class new chemical entities (NCEs) for the treatment of diseases lacking effective therapeutic approaches. The company applies its proprietary uSMITE™ (ubiquitin-mediated, small molecule - induced target elimination) platform to expand the drug design paradigm beyond functional site

inhibition, enabling the targeting of historically “undruggable” proteins for selective destruction. Leveraging years of work by its founders on the proteasome system and key discoveries regarding its functionality, Cullgen has successfully generated multiple highly potent, selective, and bioavailable targeted protein degrader compounds that utilize proprietary novel E3 ligands. For more information, visit www.cullgen.com.

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