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### **NMPA has approved GNI Group's Subsidiary Cullgen's IND for TRK Degradar Clinical Trial**

Cullgen Inc. (hereinafter referred to as Cullgen), one of the consolidated subsidiaries of GNI Group Ltd. (hereinafter referred to as the Group), has received an approval from China's National Medical Products Administration (hereinafter referred to as NMPA) for its Investigational New Drug (hereinafter referred to as IND) application of its TRK degrader's clinical trial.

Cullgen Inc., a leading biotechnology company developing targeted protein degraders based on its proprietary uSMITE™ platform technology, has received an approval from the Chinese NMPA on the IND application for CG001419, a TRK degrader for the treatment of solid tumors. CG001419 is a first-in-class, selective, potent oral targeted protein degrader for the treatment of neurotrophic tyrosine receptor kinase (NTRK) fusion-positive cancers, which have been identified in numerous solid tumors including non-small cell lung, breast, and pancreatic cancers.

Cullgen will commence a Phase I clinical trial program in humans for CG001419 in China promptly.

“NMPA’s approval of this IND application for CG001419 represents an important milestone for Cullgen”, said Dr. Yue Xiong, Cullgen’s co-founder and Chief Scientific Officer. “Our TRK degrader program was one of the first programs pursued by Cullgen, and this IND approval by NMPA demonstrates that we are able to successfully advance a program from discovery phase into clinical development. In addition to cancer, we are also exploring other potential clinical indications of our TRK degraders.”

The impact of this matter on the Group's financial figures will not be material at this point.

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#### **About GNI Group, Inc.:**

GNI Group is a global healthcare company listed on the Growth Board of the Tokyo Stock Exchange and engaged in drug discovery, pharmaceutical development, biomaterial development, clinical studies, manufacturing, and sales in both the United States and China. For more information, please visit our website below

<https://www.gnipharma.com/>



**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. For more information, visit [www.cullgen.com](http://www.cullgen.com).

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