**INVENTION DESCRIPTION**

Lung cancer is the leading cause of cancer death in the world and non-small cell lung cancer (NSCLC) accounts for 85% of the lung cancer deaths. In recent years, epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKIs) have shown remarkable effects in patients with certain genetic alternations in EGFR. However, all the FDA-approved TKIs are not effective in patients bearing the EGFR- (~4% of EGFR mutated NSCLCs) or HER2-exon20 (2-4% in NSCLCs) insertion mutations.

DBPR112 is a new generation EGFR-TKI, which displays potent \textit{in vitro} activities on various forms (EGFR\textsubscript{WT}, EGFR\textsuperscript{L858R/T790M}, EGFR\textsuperscript{L858R} and different types of exon20 insertions in EGFR or HER2 such as EGFR\textsuperscript{R770N,T771insNP} or HER2\textsuperscript{A775,G776YVMA}). DBPR112 also demonstrates potent anti-proliferation effect against several human lung cancer cells (HCC827, H3255 and HER2-exon20 insertions such as H1781 cells). DBPR112 also showed good inhibition in cancer cells with HER2 wild-type and specific mutants. Head-to-head comparison with lapatinib showed that DBPR112 has superior anti-cancer efficacy than lapatinib in a xenograft model harboring human BT474 breast cancer cells.

**COMPETITIVE ADVANTAGES OF DBPR112**

- The pharmacokinetics properties of DBPR112 are superior to those of afatinib; demonstrating the potential of DBPR112 as a therapeutic agent for various solid tumors.
- Genotoxicity tests and safety pharmacology tests (cardiovascular, respiratory and nervous system) indicated the high safety of DBPR112.
- DBPR112 is potentially better than afatinib and may be superior to osimertinib in the treatment of specific lung cancers harboring exon20 insertions in EGFR or HER2.

**MARKET POSITIONING/OPPORTUNITY**

Because of unmet medical needs in cancers harboring exon20 insertions, DBPR112 has the potential to be designated as breakthrough drug candidate. After fast track approval, the indications of DBPR112 can be expanded in the future. DBPR112 was shown to have anti-tumor activity in animal models for lung cancer, head and neck cancer, breast cancer and esophageal cancer.