

PhoenixMD and WuXi STA to Support Phase I/Ib Study of PMD-026 for TNBC

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Drug supply milestone reached desired clinical trial supply manufacture for PMD-026, accelerating PhoenixMD's Phase I readiness



Phoenix Molecular Designs (PhoenixMD), a privately-held biotechnology company designing precise cancer therapeutics targeting essential kinases, announces the completion of clinical trial supply manufacture for PMD-026 on 4 June 2019, in Vancouver, British Columbia and San Diego.

PhoenixMD's lead program, PMD-026, is the first RSK inhibitor built for the treatment of triple-negative breast cancer (TNBC). The clinical trial supply was undertaken by STA Pharmaceutical (WuXi STA), a subsidiary of WuXi AppTec, and is being used to support IND-enabling toxicology studies and an upcoming Phase I/Ib study in women with breast cancer.

In March 2018, the companies entered into a major manufacturing agreement, and have since produced a multi-kilogram drug supply for PMD-026 under GMP manufacturing practices. This represents a significant milestone, accelerating PhoenixMD's Phase I readiness.

In order to further the collaboration, WuXi STA expanded its USA operations to include capsule production under GMP regulatory compliance. Dr Minzhang Chen, CEO of WuXi STA, commented "The opportunity to enable PhoenixMD's first-in-man studies came at an opportune moment for STA's San Diego facility."

Sandra E. Dunn, CEO of PhoenixMD, said: "Our partnership with WuXi STA has been critical for PhoenixMD to advance this stage of our development. Working with such a high quality, globally recognized manufacturing partner has allowed us to rapidly advance PMD-026 through IND-enabling GLP toxicology studies and has enabled us to be ready to initiate our Phase I/Ib study with high-quality API in capsules. The rapid achievement of this milestone brings us one step closer to initiating our study for women suffering from breast cancer. More specifically, metastatic triple-negative breast cancer, which is the most deadly type of breast cancer. RSK2 is a promising new drug target for the treatment of TNBC, and PMD-026 is the first drug to ever reach clinical use against this novel target."

The drug supply is sufficient to treat all of the patients in the Phase 1 study. This is coupled with the completion of PhoenixMD's CDx for measuring activated RSK2 in tumours signals, enabling the two key elements needed for this precisely designed clinical trial to advance.