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ProLynx announces Phase 1B clinical trial of its DNA-damaging agent PLX038 (PEG~SN-38) with the PARP inhibitor Rubraca® (rucaparib) at the National Cancer Institute

SAN FRANCISCO, April 13, 2020 (GLOBE NEWSWIRE) -- ProLynx LLC today announced that the first patient was treated with its PLX038 in a Phase 1B clinical trial for small-cell lung cancer at the National Cancer Institute (NCI). The trial combines its long-acting PEGylated SN-38, PLX038, with the Clovis Oncology PARP inhibitor, rucaparib. In preclinical studies, the PEG~SN-38 nanomolecule accumulates and is retained for long periods in tumors where it slowly releases the DNA-damaging agent SN-38. The DNA repair enzymes PARP-1, -2 and -3 are inhibited by rucaparib and prevent the repair of damaged tumor DNA. This mechanism is synergistic with DNA-damaging agents like SN-38 in shrinking tumors. To date, synergistic antitumor combinations of DNA-damaging agents and PARP inhibitors have been accompanied by synergistic toxicities to normal tissues, particularly bone marrow.

The NCI trial will attempt to retain the synergistic antitumor activity of SN-38 and PARP inhibition while avoiding the potential accompanying toxicities of the combination by using a "gapped-schedule" approach – a novel tactic described by NCI investigators Yves Pommier, M.D., Ph.D. and Anish Thomas, MBBS, M.D., who are conducting the trial. Here, patients will first be treated with PLX038, which will be allowed to accumulate in the tumor; then, after a period of time to allow PLX038 to leave normal tissue – including bone marrow – but not the tumor, patients will be treated with rucaparib.

ProLynx founder and President Daniel V. Santi, M.D., Ph.D, stated, “The beauty of the gapped-schedule approach is that upon treatment with rucaparib, both SN-38 and rucaparib should be present in the tumor at the same time, so they should act together to exert synergistic anti-cancer effects and enhance synthetic lethality. However, they should not be present at the same time in normal tissues including bone marrow, so the combination should not show synergistic toxicities.”

Drs. Thomas and Pommier, part of the Developmental Therapeutics Branch in the NCI’s Center for Cancer Research, are collaborating with ProLynx through a Cooperative Research and Development Agreement (CRADA).

Additional information on this clinical trial is available at clinicaltrials.gov, through identifier number NCT04209595. Patients interested in enrolling in this PLX038 clinical trial can call the National Cancer Institute’s toll-free number 1-800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615).

About ProLynx. ProLynx is a biotechnology company developing proprietary drug delivery systems for half-life extension of proteins, peptides and small molecules. The company improves properties of off-patent therapeutics for its own portfolio, and applies its technology to extend half-lives of drug candidates of pharmaceutical companies. The company is located in San Francisco, CA. For further information visit www.ProLynxllc.com.

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