ProLynx announces initiation of Phase II clinical trial of its DNA-damaging agent PLX038 in patients with platinum-resistant Ovarian Cancer at the Mayo Clinic

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SAN FRANCISCO, Oct. 07, 2022 (GLOBE NEWSWIRE) -- ProLynx Inc. today announced that the first patient was treated with PLX038 (PEG~SN-38) in a Phase II clinical trial for platinum-resistant ovarian cancer at the Mayo Clinic. Mayo Clinic investigators Drs. Andrea E. Wahner Hendrickson and Scott H. Kaufmann are conducting the trial.

There are about 20,000 new cases of and 14,000 deaths from ovarian cancer yearly in the US, making it the 5th leading cause of cancer death in U.S. women. The current standard-of-care is surgery and carboplatin-based chemotherapy followed by maintenance therapy with a PARP inhibitor. Carboplatin responses become shorter with each recurrence, and in platinum-resistant ovarian cancer the response rate to subsequent agents is only 15- to 20%. Previous studies have shown that conventional inhibitors of the enzyme topoisomerase 1 have clinical activity in platinum-resistant ovarian cancer, and the Mayo trial seeks to improve this activity with the new PLX038.

PLX038 is a long-acting prodrug of the potent topoisomerase 1 inhibitor, SN-38, which is also the active component of the anti-cancer agents Irinotecan and TRODELVY® (sacituzumab govitecan-hziy). In PLX038, SN-38 is covalently bound to a circulating nanoparticle and slowly released to provide a long half-life, a low concentration in the bloodstream, and very high exposure – important facets for optimal safety and efficacy. Further, in preclinical studies PLX038 accumulates in tumors, where it slowly releases the SN-38. These properties are expected to increase efficacy and diminish side effects seen with earlier topoisomerase 1 inhibitors.

The Mayo trial will assess whether PLX038 induces remissions in platinum-resistant ovarian cancer. The study will also measure target engagement in biopsies or circulating tumor cells of patients to ensure SN-38 is getting to the tumor and having its anticipated effects. In addition, certain tumor biomarkers – such as BRCAness, SLFN11, ATM and RAD51 – will be monitored and correlated with response. Such correlations would identify biomarkers of response that can be prospectively used to identify future patients who would be most responsive to the drug.

Drs. Hendrickson and Kaufmann stated “We are excited to be able to bring this novel treatment to patients with relapsed, platinum-resistant ovarian cancer, in hopes of improving the outcome of this disease.” Added ProLynx co-founder and President Daniel V. Santi “Conventional short-acting topoisomerase 1 inhibitors have clinical activity in platinum-resistant ovarian cancer. Accordingly, we are optimistic that the additional benefits of a long-acting SN-38 will result in increased efficacy and safety in patients treated with PLX038”.

Additional information on this clinical trial is available at clinicaltrials.gov, through identifier number NCT05465941. Patients interested in enrolling in this trial can call the Mayo Clinic at (855) 776-0015 or contact mayocliniccancerstudies@mayo.edu.

About ProLynx. ProLynx is a biotechnology company developing proprietary systems to improve pharmacokinetics, efficacy and safety of proteins, peptides and small molecules. The company is located in San Francisco, CA. For further information visit www.ProLynxinc.com.

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Tags

SN-38 | ATM | DDR | DNA damage response