Principia Presents Phase 1 Data of PRN1371 in Patients with Metastatic Bladder Cancer

May 20, 2019

-- FGFR inhibitor PRN1371 well tolerated in 36 patients in dose-escalation phase; dose expansion in metastatic urothelial carcinoma patients ongoing --

SOUTH SAN FRANCISCO, Calif., May 20, 2019 (GLOBE NEWSWIRE) -- Principia Biopharma Inc. (Nasdaq: PRNB), a late-stage biopharmaceutical company dedicated to bringing transformative oral therapies to patients with significant unmet medical needs in immunology and oncology, today announced data from its Phase 1, multicenter, dose-escalation clinical trial of PRN1371, an irreversible covalent FGFR1-4 kinase inhibitor, in patients with advanced solid tumors. The poster was presented at the AACR Bladder Cancer: Transforming the Field meeting in Denver, Colorado.

PRN1371 is a potent, covalent, highly selective FGFR1-4 inhibitor, which targets a cysteine residue within the kinase domain. This approach has the potential to enable selective and sustained inhibition of FGFR without the need to maintain high systemic exposure of the drug.

The Phase 1, open-label dose escalation portion of the PRN1371 trial in adult patients with advanced solid tumors has been completed in 36 patients. PRN1371 was well tolerated and two patients continued on study. While the trial was not designed to assess efficacy, stable disease after two 28-day treatment cycles was observed in 11 out of 36 patients. The most common treatment related adverse event was hyperphosphatemia, a known side effect of FGFR inhibitors.

A cohort expansion portion of the study has been initiated in metastatic urothelial carcinoma patients with identified FGFR genetic alterations at a dose of 35 mg once daily and is currently ongoing.

“As with other FGFR inhibitors, in a non-selected patient population, we did not see partial or complete responses (PRs/CRs). However, we are encouraged by the observed duration of stable disease, by the remaining two patients on study, and by the established tolerability profile of our molecule,” said Martin Babler, president and CEO of Principia Biopharma.

Multiple human cancers harbor alterations in FGFRs that drive tumor growth, including mutations, fusions and amplifications. There is mounting data from many Phase 1 and Phase 2 clinical trials demonstrating encouraging utility of FGFR inhibitors for the treatment of cancers that harbor various FGFR alterations across a broad range of tumor types. The incidence of FGFR activating mutations, translocations, or fusions in urothelial cancer is reported to be approximately 20 percent.

The poster may be found on www.principiabio.com.

About Principia Biopharma
Principia is a late-stage biopharmaceutical company dedicated to bringing transformative oral therapies to patients with significant unmet medical needs in immunology and oncology. Principia’s proprietary Tailored Covalency ® platform enables the company to design and develop reversible and irreversible covalent, small molecule inhibitors with potencies and selectivities that have the potential to rival those of injectable biologics yet maintain the convenience of a pill. PRN1008, a reversible covalent BTK inhibitor, is being evaluated in a Phase 3 clinical trial in patients with pemphigus, an orphan autoimmune disease, and in a Phase 2 clinical trial in patients with immune thrombocytopenia, a rare hematological disease. PRN2246/SAR442168, a covalent BTK inhibitor which crosses the blood-brain barrier, has commenced a Phase 2 clinical trial in patients with multiple sclerosis, and has been partnered with Sanofi for development in that disease and, potentially, for other diseases of the central nervous system. PRN1371, a covalent inhibitor of Fibroblast Growth Factor Receptor (FGFR) is being evaluated in a Phase 1 trial in patients with bladder cancer. For more information, please visit www.principiabio.com.

Forward-Looking Statements
This press release contains forward-looking statements. These forward-looking statements reflect the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, Principia’s expectations regarding the Principia pipeline of product candidates, the ability of PRN1371 to inhibit FGFR without the necessity to maintain systemic exposure of the drug, the PRN1371 Phase 2 trial, and the expansion cohort of the trial in patients with metastatic urothelial cancer. Such forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause Principia’s actual results, performance, or achievements to be materially different from those expressed or implied by the forward-looking statements. For a description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the Principia’s business in general, see the risk factors set forth in Principia’s reports filed with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Principia specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Investor Contact
Christopher Chai, CFO
ir@principiabio.com

Media Contact
Paul Laland, VP of Corporate Communications
paul.laland@principiabio.com
415.519.6610

Source: Principia Biopharma Inc.