

First-in-human Study of Precision Immune Stimulant PIN-2 Demonstrated Pharmacologic Activity and Safety in Patients with Advanced Solid Tumors

(New York, NY) January 2, 2019—PIN Pharma, Inc., today announced final results of a first-in-human clinical trial of its novel immunomodulating agent PIN-2 in subjects with advanced solid tumors.

This was an open-label, repeat-dose study with a primary objective to assess the pharmacodynamic activity of PIN-2. Pharmacodynamic biomarkers that signal changes in the human immune system were used to assess the immunomodulatory potential of PIN-2. Biomarkers evaluated as part of the primary end point were the following: tumor necrosis factor alpha (TNF- α), interferon gamma (IFN- γ), and interleukin-12 (IL-12). The secondary end points were the following: characterization of the safety profile of PIN-2, its plasma pharmacokinetics, and its immunogenicity.

The study, conducted in Australia by PIN Pharma's wholly owned Australian subsidiary, PIN Pharma Pty Ltd, included 8 patients who received a dose of 300 μ g of PIN-2 intravenously, 3 times per week for 2 weeks, followed by a 1-week rest period. A second cycle of treatment was offered according to patient and investigator preference.

There was a rapid onset of action as evidenced by a marked increase in circulating TNF- α 6 hours post PIN-2 injection, which returned to baseline. A similar but more pronounced finding was observed during a second cycle of treatment. This finding demonstrated proof-of-mechanism for the immunomodulatory effect of PIN-2 and corroborated results observed in human monocytes in vitro. No clear changes were observed in the other biomarkers.

PIN-2 was generally safe and well tolerated, with grade 2 infusion-related reactions seen in 3 patients, who responded promptly to standard therapy. The drug was rapidly cleared from plasma. Anti-drug antibodies that did not impact the pharmacodynamic end point developed in 2 patients.

Colin Bier, PhD, CEO, said, "We are pleased that, in patients with advanced malignancy who failed to respond to multiple therapeutic regimens, PIN-2 demonstrated a signal indicating induction of innate immune activation as evidenced by the rapid rise in TNF- α , which is a key early mediator of the immune response. This is a result we predicted on the basis of previously reported transcriptomic studies. These study findings clearly support additional clinical trials to assess the clinical efficacy and safety profile of our novel immunomodulating agent. We plan to present complete results of the trial at an oncology congress in 2019."

About PIN-2

PIN-2 is a novel immunomodulatory peptide with a unique mechanism of action in that it links the innate and adaptive immune systems, resulting in an enhanced immune response. In vitro and in vivo preclinical studies have shown that PIN-2 rapidly and preferentially penetrates monocytes, modifies the mRNAs involved in the induction of innate immune activation (with an attendant link to the adaptive immune system), and promotes endogenous cytotoxic T lymphocytes infiltration at the tumor site. PIN-2 acts upstream of other immune-based treatment modalities.

In a validated, highly aggressive breast cancer mouse model, PIN-2 was shown to impact tumor progression and increase survival (in combination with cyclophosphamide), override tumor-mediated immune resistance, and reduce distant site metastasis (in combination with a checkpoint inhibitor.)

Given its unique, upstream immunomodulatory activity, its extensive preclinical body of evidence, and its first-in-human study results, PIN-2 holds the potential to be a new strategy in the fight against cancer and cancer-mediated immunosuppression. Further clinical research is warranted to evaluate the full potential of PIN-2 in cancer care.

About PIN Pharma, Inc.

PIN Pharma is a clinical stage, biopharmaceutical company dedicated to the development of PINs (precision immune stimulants)—immunomodulatory peptides that link the innate and adaptive immune systems to enhance the body's ability to fight cancer. Although the company is currently focusing on immune oncology, PINs have potential application in other therapeutic areas.

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