Fusion Pharmaceuticals Presents Imaging Data From Cold Antibody Sub-Study In The Phase 1 Study Of FPI-1434

- Study evaluates pre-administration of cold antibody prior to administration of imaging agent

- Imaging shows favorable gain in tumor lesion uptake versus normal tissue when cold antibody is pre-administered

- Data presented at the SNMMI 2022 Annual Meeting

HAMILTON, ON and BOSTON, June 14, 2022 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN), a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines, today announced the presentation of imaging data from the "cold antibody sub-study" evaluating pre-administration of cold antibody (naked antibody without the isotope) prior to administration of the imaging agent (antibody with the isotope) in the Phase 1 study of FPI-1434 for the treatment of solid tumors expressing IGF-1R. Data were presented at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2022 Annual Meeting in a presentation titled "Impact of Pre-Administration of Anti-IGF-1R Antibody FPI-1175 on the Dosimetry, Tumor Uptake, and Pharmacokinetics of the IGF-1R Targeted Theranostic Imaging Agent [^{111}In]-FPI-1547 in Patients with Solid Tumors".

"Pre-administration of cold antibody has the potential to increase the therapeutic index of radiopharmaceuticals through multiple avenues, including adjusting the pharmacokinetics to increase drug circulation and drive increased binding to tumor targets, saturating natural sinks for antibodies and blocking endogenous antibody binding," said Chief Executive Officer John Valliant, Ph.D. "The positive trends observed in tumor lesion uptake when cold antibody is pre-administered validate our ongoing evaluation of additional cohorts using this dosing regimen in the Phase 1 trial of FPI-1434."

The cold antibody sub-study was conducted concurrently with the dose escalation portion of the Phase 1 study of FPI-1434 for the treatment of solid tumors. The sub-study was designed to determine the safety, tolerability, and effect of administration of varying doses of FPI-1175, the naked antibody without the isotope, or "cold antibody", on the biodistribution, dosimetry and tumor uptake of [^{111}In]-FPI-1547, the investigational imaging agent.

Imaging data from the study demonstrate a favorable gain in [^{111}In]-FPI-1547 tumor lesion uptake versus normal tissue when FPI-1175 was pre-administered and compared to dosing with FPI-1547 alone. Importantly, sites of improved tumor lesion uptake were independent of anatomic location of disease and included bone, lung, liver, and lymph nodes.

Administration of FPI-1547 with and without pre-administration of FPI-1175 was safe without any drug-related Serious Adverse Events or Dose Limiting Toxicities.

Dr. Valliant continued, "These data from the cold antibody sub-study strengthen our understanding of this dosing regimen and support further evaluation. In our ongoing Phase 1 study of FPI-1434, we are evaluating two dosing regimens, one with FPI-1434 alone, and one in which cold antibody is administered prior to FPI-1434, demonstrating our commitment to develop and potentially deliver the safest, most clinically meaningful treatment regimen possible to patients with solid tumors expressing IGF-1R."

Pre-administration of FPI-1175 at 0.5 mg/kg is currently being evaluated with increasing dose levels of FPI-1434 in the ongoing Phase 1 study.

Following the conclusion of the SNMMI Annual Meeting, copies of the presentations can be found at https://fusionpharma.com/fusion-scientific-presentations/.

About FPI-1434

FPI-1434 is a radioimmunoconjugate designed to target and deliver alpha emitting medical isotopes to cancer cells expressing IGF-1R, a receptor that is overexpressed on many tumor types. FPI-1434 utilizes Fusion's Fast-Clear linker to connect a human monoclonal antibody that targets IGF-1R with actinium-225, a powerful alpha-emitting isotope with desirable half-life and decay chain properties.

About Fusion

Fusion Pharmaceuticals is a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines. Fusion connects alpha particle emitting isotopes to various targeting molecules in order to selectively deliver the alpha emitting payloads to tumors. Fusion's lead program, FPI-1434 targeting insulin-like growth factor 1 receptor, is currently in a Phase 1 clinical trial. The pipeline includes FPI-1966, targeting the fibroblast growth factor receptor 3 (FGFR3), currently in a Phase 1 study following the investigational new drug (IND) clearance; and FPI-2059, a small molecule targeting neurotensin receptor 1 (NTSR1). In addition to a robust proprietary pipeline, Fusion has a collaboration with AstraZeneca to jointly develop novel targeted alpha therapies (TATs) and combination programs between Fusion's TATs and AstraZeneca's DNA Damage Repair Inhibitors (DDRis) and immuno-oncology agents. Fusion has also entered into a collaboration with Merck to evaluate FPI-1434 in combination with Merck's KEYTRUDA® (pembrolizumab) in patients with solid tumors expressing IGF-1R. Fusion and Hamilton, Ontario-based McMaster University are building a current Good Manufacturing Practice (GMP) compliant radiopharmaceutical manufacturing facility designed to support manufacturing of the Company's growing pipeline of TATs.

Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements can be identified by terms such as "believes," "expects," "plans," "potential," "would" or similar expressions and the negative of those terms. Such forward-looking statements involve substantial risks and uncertainties that could cause Fusion's research and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including Fusions' programs' early stage of clinical development, the ability to move in-licensed targets forward in the clinic, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products generally and radiopharmaceuticals specifically, Fusion's ability to successfully establish, protect and defend its intellectual property, risks relating to business interruptions resulting from the coronavirus (COVID-19) disease outbreak or similar public health crises and other matters that could affect the sufficiency of existing cash to fund operations. Fusion undertakes no obligation to update or revise any forward-looking statements. For a further 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 business of the company in general, see Fusion's quarterly report on Form 10-Q for the period ended March 31, 2022, which is available on the Securities and Exchange Commission's website at www.sec.gov and Fusion's website at www.fusionpharma.com.

Investors and others should note that Fusion communicates with its investors and the public using the Fusion website, www.fusionpharma.com, including, but not limited to, company disclosures, investor presentations, SEC filings, and press releases. The information that Fusion posts on this website could be deemed to be material information. As a result, Fusion encourages investors, media and others interested to review the information that Fusion posts there on a regular basis.

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