Fusion Pharmaceuticals Provides Updates On FPI-1434 And FPI-1966 Clinical Programs

HAMILTON, ON and BOSTON, June 9, 2022 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN), a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines, today announced updates on its Phase 1 clinical trial evaluating FPI-1434 as a monotherapy for the treatment of solid tumors expressing IGF-1R and its Phase 1 clinical trial evaluating FPI-1966 for the treatment of solid tumors expressing FGFR3. In the FPI-1434 trial, the Company now expects to report Phase 1 safety, pharmacokinetics, and imaging data, including any evidence of anti-tumor activity, and details on the dosing regimen, in the first half of 2023, rather than in the second half of 2022. Fusion is also updating guidance for FPI-1966 and expects to dose the first patient in this study in the second half of 2022, rather than in the second quarter of 2022.

"Fusion is pioneering the development of next-generation, alpha-emitting radiopharmaceuticals, and we are working to identify the most effective dosing regimen that maximizes the therapeutic window in new these treatment paradigms," said Fusion Chief Executive Officer John Valliant, Ph.D. "To this end, we are evaluating two potential dosing regimens in our FPI-1434. Initial data from a sub-study of the "cold antibody" dosing regimen, to be presented in full next week at the Society of Nuclear Medicine and Medical Imaging (SNMMI) annual meeting, showed encouraging early results of the ability to maximize the therapeutic window and drive higher doses into the tumor. Following the protocol amendment to incorporate the cold antibody study arm, sites have been slow to initiate and, as a result, patient enrollment in this portion of the study is now lagging our prior forecasts, delaying the availability of the data from our original expectations. While our timelines are extended, we believe it is important to pursue optimization of this cold antibody dosing regimen and we look forward to presenting the full dataset in the first half of 2023.

Dr. Valliant continued: "We've experienced similar study site startup challenges in our Phase 1 trial of FPI-1966. As a result, we are updating guidance for timing of the first patient to be dosed, and now expect it to occur in the second half of this year. Delays are resulting from what we believe is a combination of staffing/resourcing shortages and administrative complications with various review boards for radiopharmaceuticals at the trial sites, and we have mitigation plans in place to address them. Importantly, our conviction in these programs and investigator enthusiasm remains strong, particularly given our pursuit of cancer types with high unmet medical need."

Overview of FPI-1434 Phase 1 Clinical Trial

- In the Phase 1 study, Fusion is exploring various dosing levels of FPI-1434 as well as two dosing regimens: one with FPI-1434 alone, and another in which a small dose of cold antibody (naked IGF-1R antibody without the isotope) is administered prior to each dose of FPI-1434.
- Data observed from a completed cold-antibody sub-study demonstrate the potential of pre-dosing cold antibody prior to FPI-1434 to increase the tumor to non-tumor distribution ratio of the radiopharmaceutical and thereby potentially improve the therapeutic window. As a result, Fusion initiated the dosing regimen evaluating pre-administration of cold antibody prior to FPI-1434 following a protocol amendment to the ongoing Phase 1 study of FPI-1434. Fusion expects to present more detailed data from the cold-antibody sub-study at the Society of Nuclear Medicine and Medical Imaging (SNMMI) 2022 Annual Meeting taking place in Vancouver, British Columbia from June 11-14, 2022.
- Given the protocol amendment to include the dosing regimen evaluating pre-administration of cold-antibody and the time required to generate sufficient data to be able to provide information on both dosing paradigms, as well as ongoing enrollment challenges relating to staffing and resourcing issues at trial sites, and additional review boards required at trial sites for novel alpha-emitting radiopharmaceuticals, Fusion now expects to report Phase 1 safety, pharmacokinetics, and imaging data, including any evidence of anti-tumor activity, and details on the dosing regimen, in the first half of 2023.

Overview of FPI-1966 Phase 1 Clinical Trial

- The Phase 1, non-randomized, open-label clinical trial of FPI-1966 in patients with solid tumors expressing FGFR3, intended to investigate safety, tolerability and pharmacokinetics and to establish the recommended Phase 2 dose, has been initiated.
- The first cohort in this study will comprise four sub-groups in which various doses of non-radiolabeled vofatamab (cold antibody) will be evaluated to assess the impact of pre-dosing on tumor uptake.
- As previously disclosed, Fusion experienced initial challenges with study site initiations and is further experiencing enrollment challenges similar to the FPI-1434 study, including study backlogs as COVID-19

headwinds ease, staffing shortages at trial sites, and additional review boards required at trial sites for novel alpha-emitting radiopharmaceuticals. As a result, Fusion now expects to dose the first patient in the FPI-1966 Phase 1 study in the second half of 2022. In addition, Fusion plans to provide updated guidance for preliminary pharmacokinetic, imaging and safety data from the first patient cohort once patient enrollment begins.

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 FPI-1966
FPI-1966 is a targeted alpha therapy designed to target and deliver an alpha emitting medical isotope, actinium-225, to cancer cells expressing FGFR3; a receptor that is overexpressed on several tumor types, including head and neck and bladder cancers. FPI-1966 utilizes Fusion's Fast-Clear™ linker to connect vofatamab, the human monoclonal antibody that targets FGFR3, with actinium-225. Vofatamab was previously evaluated as a therapeutic agent in a Phase 1b/2 trial and was reportedly well-tolerated.

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), advancing to 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. Fusion has an actinium supply agreement with the U.S. Department of Energy and a strategic partnership with TRIUMF, which provides preferential access to actinium supply.

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 ability to enroll patients in 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.

Contact:
Amanda Cray

Senior Director of Investor Relations & Corporate Communications
(617) 967-0207
cray@fusionpharma.com

SOURCE Fusion Pharmaceuticals Inc.

---

https://ir.fusionpharma.com/2022-06-09-Fusion-Pharmaceuticals-Provides-Updates-on-FPI-1434-and-FPI-1966-Clinical-Programs