Fusion Pharmaceuticals Announces First Patient Dosed In Phase 1/2 Study Of FPI-1966 In Patients With Advanced Solid Tumors Expressing FGFR3

HAMILTON, ON and BOSTON, Aug. 29, 2022 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN), a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines, today announced that the first patient has been dosed in the Phase 1/2 study evaluating [^{225}Ac]-FPI-1966 (FPI-1966) in patients with advanced solid tumors expressing fibroblast growth factor receptor three (FGFR3). FPI-1966 utilizes Fusion's Fast-Clear™ linker to connect vofatamab, a human monoclonal antibody that targets FGFR3, with actinium-225.

"Dosing of the first patient in this Phase 1/2 study of FPI-1966 demonstrates our continued ability to bring innovative targeted alpha therapies (TATs) into the clinic," said Chief Executive Officer John Valliant, Ph.D. "This study will evaluate FPI-1966 in patients with solid tumors expressing FGFR3, a validated cancer target found in multiple tumor types with substantial unmet need, notably bladder, ovarian and head and neck cancers. FPI-1966, and the growing number of TATs in our pipeline, are designed as next generation antibody drug conjugates (ADCs) in that they leverage the potency of actinium-225 and alpha particle radiation in place of chemical toxins to selectively eradicate cancer cells. Given the prevalence of the FGFR3 target, and the use of a precision medicine approach that employs an imaging analogue to enable patient selection, we believe FPI-1966 has the potential to become an important new treatment paradigm for cancer patients."

The Phase 1/2 multi-center, open-label clinical trial is designed to investigate the safety, tolerability, dosimetry, biodistribution, and pharmacokinetics of FPI-1966 in patients with FGFR3-expressing advanced, inoperable, metastatic, and/or recurrent solid tumors. The study employs a 3 + 3 dose escalation design to evaluate multiple ascending doses of FPI-1966. The first cohort will comprise 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 and pharmacokinetics. As part of the trial, patients will be administered an imaging analogue of FPI-1966, FPI-1967, and only those who upon imaging meet predefined tumor uptake will go on to receive FPI-1966. The Phase 2 portion of the study will consist of two tumor-specific cohorts and one basket cohort.

Fusion plans to provide guidance on timing for preliminary pharmacokinetic, imaging and safety data following initial experience with patient screening via imaging with FPI-1967, in order to more accurately predict the cadence of patient enrollment.

For additional detail about the study, please visit https://clinicaltrials.gov/ct2/show/NCT05363605?term=FPI-1966&draw=2&rank=1.

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 bladder, ovarian and head and neck cancers. FPI-1966 utilizes Fusion's Fast-Clear™ linker to connect vofatamab, a 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 first 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; and FPI-2059, a small molecule targeting neurotensin receptor 1 (NTSR1), which has received FDA investigational new drug (IND) clearance and will begin a Phase 1 study. 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. To support Fusion's growing pipeline of TATs, the company has signed strategic actinium supply agreements with TRIUMF and Niowave, Inc.

Forward-Looking Statements

This press release contains "forward-looking statements" for purposes of the safe harbor provisions of The Private Securities Litigation Reform Act of 1995, including but not limited to the statements regarding Fusion Pharmaceuticals Inc.'s (the "Company") future business and financial performance. For this purpose, any statements contained herein that are not statements of historical fact may be deemed forward-looking statements. Without limiting the foregoing, the words "expect," "plans," "anticipates," "intends," "will," and similar expressions are also intended to identify forward-looking statements, as are expressed or implied statements with respect to the Company's potential drug candidates, including any expressed or implied statements regarding the successful development of its product candidates. Actual results may differ materially from those indicated by such forward-looking statements as a result of risks and uncertainties, including but not limited to the following: there can be no guarantees that the Company will advance FPI-1966 in the clinic, through the regulatory process or to commercialization; management's expectations could be affected by unexpected patient recruitment delays or regulatory actions or delays; uncertainties relating to, or unsuccessful results of, clinical trials; the Company's ability to obtain additional funding required to conduct its business activities; and changes in the Company's business plan or objectives. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. These and other risks which may impact management's expectations are described in greater detail under the heading "Risk Factors" in the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2022, as filed with the SEC and in any subsequent periodic or current report that the Company files with the SEC. All forward-looking statements reflect the Company's estimates only as of the date of this release (unless another date is indicated) and should not be relied upon as reflecting the Company's views, expectations or beliefs at any date subsequent to the date of this release. While Fusion may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, even if the Company's estimates change.

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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