Fusion Pharmaceuticals Announces First Patient Dosed In Phase 1 Study Of FPI-2059, A Targeted Alpha Therapy (TAT) For The Treatment Of Solid Tumors Expressing NTSR1

HAMILTON, ON and BOSTON, March 20, 2023 /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 study evaluating [^{225}Ac]-FPI-2059 (FPI-2059). FPI-2059 is a small molecule targeted alpha therapy (TAT) designed to deliver actinium-225 to tumor sites expressing neurotensin receptor 1 (NTSR1), a protein that is overexpressed in gastrointestinal, prostate, pancreatic ductal adenocarcinoma (PDAC) and multiple other cancers.

"Tremendous opportunity exists in the radiopharmaceutical field to look beyond the few established targets, particularly when using a potent payload like actinium-225. The initiation of the Phase 1 study of FPI-2059 marks an important milestone in this regard, bringing us a step closer to providing a differentiated therapy for patients," said Chief Executive Officer, John Valliant, Ph.D. "FPI-2059 is our fourth clinical program and the second small molecule-based TAT in our pipeline of radiopharmaceuticals, showcasing the potential for our platform technology to create TATs that treat a broad array of solid tumor types with high unmet need."

Fusion acquired [^{177}Lu]-IPN-1087 (IPN-1087), a lutetium-based beta-emitting radiopharmaceutical, from Ipsen in April 2021, and converted the compound to the alpha-emitting FPI-2059. In clinical studies, IPN-1087, also referred to as 3BP-227, showed promising early safety data, evidence of anti-tumor activity and uptake in multiple tumor types based on imaging of the distribution of the drug in patients. Fusion showed that in preclinical models, replacing the beta emitter with an alpha emitter resulted in responses at 1,500 times lower administered doses.

The Phase 1, multi-center, open-label clinical trial is designed to investigate the safety, tolerability, dosimetry, biodistribution, and pharmacokinetics of FPI-2059 as well as preliminary anti-tumor activity in participants with neurotensin receptor 1 (NTSR1) expressing advanced metastatic solid tumors. The study will employ a 3+3 dose escalation design to identify the recommended Phase 2 dose (RP2D) of FPI-2059 administered intravenously every 56 days for up to four cycles.

Fusion plans to provide guidance on timing for pharmacokinetic, imaging and safety data following early experience with FPI-2059 patient screening and enrollment.

About FPI-2059

FPI-2059 is a small molecule radiopharmaceutical targeting neurotensin receptor 1 (NTSR1) which is overexpressed in multiple solid tumors, including pancreatic ductal adenocarcinoma, colorectal, squamous cell carcinoma head & neck, gastric, Ewings sarcoma, and neuroendocrine differentiated prostate. FPI-2059 is based upon a compound previously referred to as IPN-1087 and 3BP-227 that had previously been studied in investigator sponsored studies and a Phase 1 clinical trial as a beta-emitting radiopharmaceutical. Fusion acquired the asset in 2021 and converted it to an alpha-emitting radiopharmaceutical using actinium-225. The diagnostic analogue which uses indium-111 in place of actinium-225 is referred to as FPI-2058.

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 to selectively deliver the alpha emitting payloads to tumors. Fusion's clinical portfolio includes: FPI-2265 targeting prostate specific membrane antigen (PSMA) for the treatment of metastatic castration resistant prostate cancer, currently in a Phase 2 trial; FPI-1434 targeting insulin-like growth factor 1 receptor, currently in a Phase 1 trial; FPI-1966 targeting the fibroblast growth factor receptor 3 (FGFR3), currently in a Phase 1 trial; and FPI-2059, a small molecule targeting neurotensin receptor 1 (NTSR1), currently in a Phase 1 trial. 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 Response 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, Niowave, Inc. and BWXT Medical.

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-2059 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; access to actinium-225 in order to manufacture FPI-2059; 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-K for the quarter ended December 31, 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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