Fusion Pharmaceuticals Announces Presentation Of Interim Data From The Phase 2 TATCIST Clinical Trial Evaluating FPI-2265 At The AACR Annual Meeting 2024

Preliminary data demonstrate FPI-2265 is active in heavily pretreated patients with progressive metastatic castration-resistant prostate cancer (mCRPC), including those who received prior lutetium-based radioconjugates

HAMILTON, ON and BOSTON, April 9, 2024 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN), a clinical-stage oncology company focused on developing next-generation radioconjugates (RCs) as precision medicines, today announced the presentation of interim efficacy and safety data from the Phase 2 TATCIST open-label clinical trial evaluating FPI-2265, at the American Association for Cancer Research (AACR) Annual Meeting 2024 being held April 5-10 in San Diego, California. Results demonstrate that FPI-2265 is active in heavily pretreated patients with progressive metastatic castrate-resistant prostate cancer (mCRPC), including patients who received prior lutetium-based RCs. Safety, tolerability and clinical activity data were generally consistent with other published studies of small molecule-based ^{225}Ac-PSMA RCs.

"The interim results from the TATCIST trial underscore the potential of FPI-2265, the most advanced actinium-based prostate specific membrane antigen (PSMA) targeted radiotherapy in development, to improve treatment options for patients with mCRPC," said Fusion Chief Executive Officer John Valliant, Ph.D. "We believe the interim results represent compelling early clinical activity and tolerability data, validating the path to develop FPI-2265 in patients who progress on or after lutetium-based RCs. With our Phase 2 portion of the registrational program for FPI-2265 expected to initiate in the second quarter of 2024, and the expanding market for patients in the post-PLUVICTO™ setting, we believe FPI-2265 has the potential to meet the critical unmet needs of mCRPC patients."

The TATCIST trial is designed to evaluate patients with progressive mCRPC, including patients who are naïve to PSMA-targeted RCs and those who have been pre-treated with ^{177}Lu-based PSMA RCs such as PLUVICTO™.

Phase 2 TATCIST Clinical Trial Interim Results

The results are being presented at the AACR 2024 Annual Meeting in a poster presentation titled, "Preliminary efficacy and safety results from the TATCIST trial: A PSMA-directed targeted alpha therapy with FPI-2265 (^{225}Ac-PSMA-I&T) for the treatment of metastatic castration-resistant prostate cancer (mCRPC)."

As of the March 1, 2024 data cutoff, 35 patients received at least one dose of FPI-2265, with 25 patients having at least 12 weeks of follow-up. The analysis included 25 patients for safety evaluation and 20 patients for assessing prostate-specific antigen (PSA) response. Four participants were identified as superscan patients and were excluded from the efficacy analyses and reported separately in the safety analysis. One participant was not included in the efficacy analysis due to uninterpretable PSA response. Patients in the study were pretreated with a median of four prior lines of anticancer therapy, with 20 out of 25 (80%) receiving prior chemotherapy, including 10 patients who received at least two prior lines of taxanes. Nine out of 25 patients received a prior ^{177}Lu-based PSMA RC.

From the efficacy-evaluable patient population, PSA50 (≥50% decline in prostate-specific antigen by 12 weeks after first treatment) response was achieved in 10 out of 20 patients (50%) regardless of prior lutetium treatment. PSA50 was achieved in 61% of lutetium-naïve participants and 42% of lutetium-treated participants. In an exploratory subset analysis of 13 patients, including six patients who received prior ^{177}Lu-based PSMA RC treatment, with baseline PSMA Mean Standardized Uptake Value (SUV_{mean}) >6, PSA50 response was observed in nine patients (69%).

FPI-2265 demonstrated meaningful improvement in secondary endpoints which include maximum % PSA decline, and independent reviewer-assessed response rates based on RECIST v1.1 criteria, and the rate of disease progression in bone per Prostate Cancer Working Group 3 (PCWG3) criteria.

FPI-2265 was generally well tolerated and in line with prior published data, with predominantly Grade 1-2 treatment-related adverse events (TRAEs) observed, including xerostomia (dry mouth), thrombocytopenia, anemia, fatigue and dry eye. Xerostomia, the most common TRAE, was primarily Grade 1 with all incidences being Grade 1-2 (62% Grade 1 and 24% Grade 2). One treatment-related death due to cerebral hemorrhage

was reported in a superscan patient. Three out of 25 participants discontinued treatment due to TRAEs, including two participants in the superscan group, however there were no discontinuations due to xerostomia.

These findings underscore the potential of FPI-2265 to provide a viable therapeutic option for patients with progressive mCRPC, including those who have previously undergone prior treatment with lutetium-based RCs. Fusion will continue long term follow up in patients evaluated in the TATCIST trial and now intends to prioritize enrollment in the FPI-2265 Phase 2 portion of the registrational program.

FPI-2265 Phase 2/3 Development Program in mCRPC

Fusion is advancing a Phase 2/3 trial for FPI-2265 in patients with mCRPC with progressive disease who have previously been treated with a ^{177}Lu-based PSMA radiotherapy. The Phase 2 portion is expected to be initiated in the second quarter of 2024. A Phase 3 global registrational trial is expected to begin in 2025 following analysis of the Phase 2 data and an end of Phase 2 meeting to align with FDA on the recommended Phase 3 dosing regimen.

A copy of the poster presentation can be found at: https://fusionpharma.com/fusion-scientific-presentations/ following the conclusion of the AACR Annual Meeting.

About FPI-2265
FPI-2265 is an actinium-225 based PSMA targeting RC, for mCRPC, currently in a Phase 2 trial. Actinium-225 emits alpha particles and holds the promise of being a next-generation radioisotope in cancer treatment. By delivering a greater radiation dose over a shorter distance, alpha particles such as actinium-225 have the potential for more potent cancer cell killing, and targeted delivery, thereby minimizing damage to surrounding healthy tissue.

About Fusion
Fusion Pharmaceuticals is a clinical-stage oncology company focused on developing next-generation RCs 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 clinical-stage development portfolio includes lead program, FPI-2265, targeting PSMA for mCRPC and novel RCs targeting solid tumors.

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 the future business and financial performance of Fusion Pharmaceuticals Inc. (the "Company"). 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, including any expressed or implied statements regarding the successful development of FPI-2265. 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-2265 in the clinic, to 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, FPI-2265 clinical trials, including additional data relating to the ongoing and planned clinical trials evaluating FPI-2265; the Company's ability to obtain additional funding required to conduct its research, development and commercialization activities; changes in the Company's business plan or objectives; competition in general; the Company's ability to obtain, maintain and enforce patent and other intellectual property protection for FPI-2265; and the Company partners' ability to advance any technology relating to actinium-225 to development. 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 annual report on Form 10-K for the period ended December 31, 2023, as filed with the Securities and Exchange Commission (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.

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

SOURCE Fusion Pharmaceuticals
