Fusion Pharmaceuticals Announces Preliminary Safety And Dosimetry Results From Its Single-Dose Portion Of The Phase 1 Study Of FPI-1434

Product candidate FPI-1434, administered at three different dose levels, demonstrated a favorable safety profile with no drug-related serious adverse events or dose-limiting toxicity

Imaging shows drug uptake across multiple tumor types

Enrollment in multi-dosing cohorts continues

Fusion also reported preclinical data showing the combination of FPI-1434 with olaparib resulting in synergistic efficacy against colorectal and lung cancer xenografts, and combination with immune checkpoint inhibitors demonstrated enhanced efficacy in colorectal cancer models

Data featured in oral sessions and posters at the SNMMI 2021 Virtual Annual Meeting

HAMILTON, Ontario and BOSTON, June 14, 2021 /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 preliminary Phase 1 data from the single-dose portion of the study at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Virtual Annual Meeting. The presentations and posters highlight the potential of Fusion's targeted alpha therapies (TATs) to enable delivery of alpha particle emitting isotopes (^{225}Ac) to targeted tumor cells.

"The data from our ongoing clinical study of FPI-1434 presented at SNMMI demonstrated that treatment with our actinium-based targeted alpha therapy was well tolerated, and imaging shows uptake of the drug across multiple tumor types," said Chief Executive Officer John Valliant, Ph.D. "Importantly, these data supported our ability to initiate the multi-dosing portion of the study, in which we would expect to begin reaching total cumulative levels of radiation necessary to demonstrate anti-tumor activity."

In both the oral session and the poster titled, "Preliminary Dosimetry Results from a First-in-Human Phase 1 Study Evaluating the Efficacy and Safety of [^{225}Ac]-FPI-1434 in Patients with IGF-1R Expressing Solid Tumors," results from the first three patient cohorts (n=12) demonstrated a favorable safety profile for [^{225}Ac]-FPI-1434. No drug-related serious adverse events and/or dose limiting toxicity were reported in administered activity up to 40 kBq/kg body weight and dosimetric results were within normal organ radiation tolerability limits. The single dose escalation portion of the study has concluded, while enrollment into the multi-dosing cohorts are ongoing.

Preclinical Results Combining FPI-1434 with DNA Damage Response Inhibitor (DDRi) and Immune Checkpoint Inhibitors
In separate oral and poster presentations, Fusion presented preclinical data demonstrating synergistic efficacy against olaparib-resistant colorectal and radioresistant lung cancer xenografts when combining FPI-1434 with olaparib.

The combination of the two therapeutics, using doses that were non-effective as single agents, resulted in anti-tumor efficacy against colorectal and non-small cell lung cancer tumor models. The strongest combination effect appeared to occur at the lowest single agent doses, as FPI-1434's efficacy dominated at higher dose levels.

Fusion also presented preclinical data showing that treatment with FPI-1434 in combination with immune checkpoint inhibitors resulted in complete tumor eradication. Additionally, an increase in antigen-specific CD8 positive T cells and a strong "vaccine" effect were observed with the combination of IGF-1R TAT and immune checkpoint inhibitors, as noted by the prevention of tumor growth in animals that were reinoculated with the same tumor cells.

Dr. Valliant continued, "We are excited by our preclinical data that show the power of combining a potent TAT with the latest generation of cancer therapies, such as checkpoint inhibitors and DDRis. We view these combinations as an opportunity to bring these next-generation radiopharmaceuticals into earlier lines of therapy for patients, and we look forward to initiating combination studies in human once we have achieved the recommended Phase 2 dose for FPI-1434 monotherapy. Our previously announced collaborations with both

Merck and AstraZeneca provide us with multiple opportunities to explore these exciting combination therapies."

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. Employing a proprietary Fast-Clear™ linker technology, 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) and FPI-2059, a small molecule recently acquired from Ipsen, targeting neurotensin receptor 1 (NTSR1). In addition to a robust proprietary pipeline, Fusion has a collaboration with AstraZeneca to jointly develop up to three novel targeted alpha therapies (TATs) and explore up to five combination programs between Fusion's TATs and AstraZeneca's DNA Damage Repair Inhibitors (DDRis) and immuno-oncology agents. Fusion also recently 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.

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 product candidate FPI-1434; and the likelihood of success of any ongoing or future clinical trials involving product candidate FPI-1434. 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 any clinical product candidate or other component of its potential pipeline to the clinic, to the regulatory process or to commercialization; management's expectations could be affected by unexpected regulatory actions or delays; uncertainties relating to, or unsuccessful results of, clinical trials, including additional data relating to the ongoing clinical trials evaluating its product candidates; 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; the ability of the Company to attract and retain qualified personnel; competition in general; and the Company's ability to obtain, maintain and enforce patent and other intellectual property protection for its product candidates and its discoveries. 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, 2020 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.

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