Fusion Pharmaceuticals Initiates Multi-Dose Portion Of Phase 1 Trial Of FPI-1434 In Patients With Advanced Solid Tumors

Phase 1 Single-Dose Data Show Uptake Across Multiple Tumor Types; No Dose Limiting Toxicities or Treatment-Related Serious Adverse Events

HAMILTON, ON and BOSTON, Dec. 10, 2020 /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 multi-dose portion of the Phase 1 study evaluating [^{225}Ac]-FPI-1434 (FPI-1434) in patients with advanced solid tumors. FPI-1434 is a radioimmunoconjugate that utilizes Fusion's proprietary Fast-Clear™ linker to connect a humanized monoclonal antibody targeting the insulin-like growth factor 1 receptor (IGF-1R), with the alpha-emitting isotope actinium-225, creating a targeted alpha therapy (TAT).

The Phase 1, multi-center, open-label clinical trial is designed to investigate the safety, tolerability and pharmacokinetics of FPI-1434 in patients with solid tumors expressing IGF-1R. The trial is also designed to establish the maximum tolerated dose for FPI-1434 and the recommended Phase 2 dose. As part of the precision medicine approach, prior to receiving the therapeutic injection of FPI-1434, patients are administered an indium-111 imaging analogue, [^{111}In]-FPI-1547 (FPI-1547). The images collected are used to confirm the presence of tumor uptake and to ensure that estimated radiation doses to organs and tissues are below protocol-specified safety limits.

The multi-dose study follows completion of the single-dose portion of the Phase 1 study, which showed that FPI-1434 was generally well tolerated with no dose limiting toxicities or treatment-related serious adverse events reported to date. The multi-dose portion of the study is expected to enroll patients at sites in Canada, the United States and Australia. The initial patient cohort is being dosed with FPI-1434 at 75kBq/kg with repeat cycles every six weeks up to allowable limits.

"We are pleased with the results of the single-dose portion of our Phase 1 study of FPI-1434 which, following the evaluation of the Safety Review Committee, support initiating the multi-dosing portion of the study," said Chief Executive Officer John Valliant, Ph.D. "This is a critical next step in the FPI-1434 development program as data from the multi-dose portion of the study may provide important insights on potential anti-tumor activity. The multi-dosing trial will also inform the design of the Phase 2 program and assist in the selection of tumor indications to be pursued in planned expansion cohorts. This is especially important given the broad expression of IGF-1R across multiple tumor types."

For additional detail about the study, please visit https://clinicaltrials.gov/ct2/show/NCT03746431.

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.

Acknowledgement of US DOE and Actiunium-225 Supply

The actinium-225 used in this research was supplied by the United States Department of Energy Office of Science by the Isotope Program in the Office of Nuclear Physics.

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 antibodies and other targeting molecules in order to selectively deliver the alpha emitting payloads to tumors. Fusion's lead program, FPI-1434, is currently in a Phase 1 clinical trial.

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 development, the process of designing and conducting and clinical trials, , 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 quarter ended September 30, 2020 which is available on the Security and Exchange Commission's website at www.sec.gov and Fusion's website at www.fusionpharma.com.

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