Fusion Pharmaceuticals Announces FDA Clearance Of IND For FPI-1966, An Investigational Radiopharmaceutical For The Treatment Of Head And Neck And Bladder Cancers Expressing FGFR3

HAMILTON, ON and BOSTON, July 28, 2021 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN), a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) applications for [^{225}Ac]-FPI-1966 (FPI-1966) and imaging agent [^{111}In]-FPI-1967 (FPI-1967). FPI-1966 is a targeted alpha therapy (TAT) designed to use vofatamab, a human monoclonal antibody, to target and deliver actinium-225 to tumor sites expressing fibroblast growth factor 3 (FGFR3), a protein that is overexpressed in multiple tumor types, particularly head and neck and bladder cancers. FPI-1966 utilizes Fusion's Fast-Clear™ linker to connect vofatamab to actinium-225.

"Leveraging Fusion's platform and expertise developing targeted alpha therapies, we are excited to begin our second clinical program," said Chief Executive Officer John Valliant, Ph.D. "FGFR3 is an established and validated cancer target which is found in multiple tumor types with substantial unmet need, notably head and neck and bladder cancers. We have an opportunity to selectively deliver alpha particles to these tumors and use precision radiation therapy as a new treatment paradigm. While the currently approved pan-FGFR inhibitor for bladder cancer requires the presence of a specific mutation, our approach requires only over-expression of FGFR3. If successful, this could provide an opportunity to treat a larger population of patients."

Fusion plans to initiate a Phase 1, non-randomized, open-label clinical trial in patients with solid tumors expressing FGFR3 intended to investigate safety, tolerability and pharmacokinetics and to establish the recommended Phase 2 dose. The study employs a 3 + 3 dose escalation design to evaluate multiple ascending doses of FPI-1966. The first cohort will comprise four 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. As part of the screening process, patients will be administered an imaging analogue of FPI-1966, FPI-1967, and only those who meet predefined tumor uptake and safety criteria will go on to receive FPI-1966.

About FPI-1966
[^{225}Ac]-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 head and neck and bladder cancers. FPI-1966 utilizes Fusion's Fast-Clear™ linker to connect vofatamab, the 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. 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-1966. 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-Q for the quarter ended March 31, 2021 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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