Clovis Oncology Submits Investigational New Drug Applications for Novel Peptide-Targeted Radionuclide FAP-2286 for Therapeutic and Imaging Clinical Trial

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- Initiation of Phase 1/2 clinical study of novel peptide-targeted radionuclide therapy and imaging agent targeting fibroblast activation protein (FAP) expected 1H 2021
- Will be the first peptide-targeted radionuclide therapy targeting FAP to enter clinical development

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that the company has completed submission of two Investigational New Drug (IND) applications to the U.S. Food and Drug Administration (FDA) for FAP-2286, the lead compound in its peptide-targeted radionuclide therapy (PRTT) development program. Following clearance of the INDs by FDA, Clovis plans to initiate a Phase 1/2 clinical study of lutetium-177 labeled FAP-2286 (177Lu-FAP-2286) to determine the dose and tolerability of the FAP-targeting therapeutic agent (Phase 1), with expansion cohorts planned in multiple tumor types (Phase 2). FAP-2286 labelled with gallium-68 (68Ga-FAP-2286) will be utilized as a diagnostic to identify patients with fibroblast activation protein (FAP)-positive tumors appropriate for treatment with the therapeutic agent.

“Submission of these INDs is a very important milestone in the development of FAP-2286, the first clinical candidate from our PRTT platform,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “Targeted radiopharmaceuticals represent an emerging therapeutic class and an area of significant interest to the clinical community, and FAP is considered a target of particular interest given its high, selective expression in multiple solid tumors. We are enthusiastic about the opportunity to become a leader in the rapidly evolving field of PRTT, and the first to begin clinical development of a peptide-targeted radionuclide therapy targeting FAP.”

Fibroblast activation protein (FAP) is a cell-surface protein that is expressed in limited amounts by normal tissues, but highly expressed in cancer-associated fibroblasts (CAFs) present in the tumor microenvironment of many epithelial cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas.
Preclinical data demonstrate that 177Lu-FAP-2286 potently and selectively binds FAP on the surface of CAFs and tumor cells to deliver the beta-particle emitting radioisotope 177Lu, resulting in DNA damage and cell death. \textsuperscript{vi,iv} Compelling anti-tumor efficacy of 177Lu-FAP-2286 has been demonstrated in FAP-expressing preclinical tumor models.\textsuperscript{v}

Following clearance of the INDs by FDA, the Phase 1/2 study LuMIERE is planned to start in the first half of 2021 to determine the dose of 177Lu-FAP-2286 to be used in Phase 2 development. The FAP-targeting imaging agent, 68Ga-FAP-2286, will be used to identify patients with FAP-positive tumors eligible for treatment with 177Lu-FAP-2286 in the study. Once the Phase 2 dose is determined, expansion cohorts will evaluate 177Lu-FAP-2286 and 68Ga-FAP-2286 in multiple tumor types.

About Peptide-Targeted Radionuclide Therapy

Peptide-targeted radionuclide therapy (PTRT) is a form of targeted radiotherapy that is emerging as a new treatment option for patients with cancer.\textsuperscript{vi} These therapies consist of a small amount of a radioactive isotope, known as a radionuclide, linked to cell-targeting peptide that binds to a cancer specific protein which selectively directs the radionuclide to tumors.\textsuperscript{v} Following binding, the radionuclide warhead emits ionizing radiation causing DNA damage and cell death to neighboring tumor cells.\textsuperscript{vii}

About FAP-2286

FAP-2286 is a preclinical candidate under investigation as a peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein (FAP). FAP-2286 consists of two parts; a peptide that binds to FAP and a linker and site that can be used to attach radiation for imaging and therapeutic use. FAP is highly expressed in many epithelial cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas.\textsuperscript{iii} Clovis holds U.S. and global rights for FAP-2286 excluding Europe, Russia, Turkey and Israel. FAP-2286 is an unlicensed medical product.

About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the U.S., Europe and additional international markets. Clovis Oncology targets development programs at specific subsets of cancer populations, and simultaneously develops, with partners, for those indications that require them, diagnostic tools intended to direct a compound in development to the population that is most likely to benefit from its use. Clovis Oncology is headquartered in Boulder, Colorado, with additional office locations in the U.S. and Europe. Please visit \texttt{www.clovisoncology.com} for more information.
To the extent that statements contained in this press release are not descriptions of historical facts regarding Clovis Oncology, they are forward-looking statements reflecting the current beliefs and expectations of management. Examples of forward-looking statements contained in this press release include, among others, statements our intentions and expectations for our development and discovery programs, including the timing and pace of pre-clinical development, plans for clinical development, plans for additional applications of the FAP-2286 peptide, including combination trials, and regulatory plans with respect to FAP-2286. Such forward-looking statements involve substantial risks and uncertainties that could cause Clovis Oncology's actual 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 drug discovery and pre-clinical and clinical development, including the outcome of pre-clinical studies and clinical trials, whether initial results, findings or research will support future studies or development, whether future study results will be consistent with previous study findings or other results, including pre-clinical studies, results in named-patient or similar programs or clinical trials, whether additional studies not originally contemplated are determined to be necessary, the timing of initiation, enrollment and completion of planned studies and actions by the FDA, the EMA or other regulatory authorities regarding data required to support drug applications and whether to approve drug applications. Clovis Oncology 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 Clovis Oncology's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and its other reports filed with the Securities and Exchange Commission.


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