



NEWS RELEASE

Initial Clinical Experience of FAP-2286 in Independent Named Patient Use Published in The Journal of Nuclear Medicine

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- FAP-2286 is an investigational targeted radionuclide therapeutic and imaging agent targeting fibroblast activation protein (FAP)
- Clovis Oncology initiated sponsored clinical development of FAP-2286 with the Phase 1/2 LuMIERE clinical trial in patients with FAP-positive solid tumors which is now enrolling

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS), announced today that Professor Dr. Richard P. Baum and Dr. Harshad R. Kulkarni, in conjunction with 3B Pharmaceuticals (Clovis' licensing partner and discoverer of FAP-2286), published a retrospective report of their independent experience with FAP-2286 in named-patient use in **The Journal of Nuclear Medicine**. In the first named-patient experience of the investigational compound conducted at Zentralklinik, Bad Berka, Germany, patients were treated with the FAP-targeted radiotherapy FAP-2286 linked to the radionuclide lutetium-177 (¹⁷⁷Lu) as a therapeutic agent after prior confirmation of tumor FAP-positivity in patients by PET/CT imaging.

In this palliative use setting, FAP-2286 was administered on a named-patient basis to 11 patients with progressive and metastatic adenocarcinoma of the pancreas, breast, rectum, and ovary after prior confirmation of FAP expression. According to the authors, administration of ¹⁷⁷Lu-FAP-2286 demonstrated high uptake and long retention in primary and metastatic tumor lesions and an acceptable toxicity profile. The report concludes that the data warrant further investigation of ¹⁷⁷Lu-FAP-2286 in clinical studies to systematically evaluate its safety and efficacy, and to define the patient population who would benefit most from treatment.

The Clovis Oncology-sponsored Phase 1/2 LuMIERE study of ¹⁷⁷Lu-FAP-2286 is evaluating the compound in patients with advanced solid tumors. FAP-2286 labeled with gallium-68 (⁶⁸Ga-FAP-2286) will be utilized as an investigational imaging agent to identify patients appropriate for treatment in LuMIERE.

"We believe the early clinical experience from named-patient use validates our plans to further investigate FAP-

2286 as a therapeutic and imaging agent across a variety of solid tumor types,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “We are very pleased to move FAP-2286 into formal clinical development with the recent initiation of the Phase 1/2 LuMIERE study of FAP-2286, a novel peptide-targeted radionuclide therapy in patients with solid tumors.”

About FAP-2286

FAP-2286 is a clinical candidate under investigation as a peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein (FAP). FAP-2286 consists of two functional elements; a targeting peptide that binds to FAP and a site that can be used to attach radioactive isotopes 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. Clovis holds U.S. and global rights for FAP-2286 excluding Europe, Russia, Turkey, and Israel.

FAP-2286 is an unlicensed medical product.

About Targeted Radionuclide Therapy

Targeted radionuclide therapy is an emerging class of cancer therapeutics, which seeks to deliver radiation directly to the tumor while minimizing delivery of radiation to normal tissue. Targeted radionuclides are created by linking radioactive isotopes, also known as radionuclides, to targeting molecules (e.g., peptides, antibodies, small molecules) that can bind specifically to tumor cells or other cells in the tumor environment. Based on the radioactive isotope selected, the resulting agent can be used to image and/or treat certain types of cancer. Agents that can be adapted for both therapeutic and imaging use are known as “theranostics.” Clovis, together with licensing partner 3B Pharmaceuticals, is developing a pipeline of novel, targeted radiotherapies for cancer treatment and imaging, including its lead candidate, FAP-2286, an investigational peptide-targeted radionuclide therapeutic (PTRT) and imaging agent, as well as three additional discovery-stage compounds.

About the LuMIERE Clinical Study

LuMIERE is a Phase 1/2 study evaluating FAP-2286 as a peptide-targeted radionuclide therapy (PTRT) targeting fibroblast activation protein, or FAP, in patients with advanced solid tumors. The Phase 1 portion of the LuMIERE study is evaluating the safety of the investigational therapeutic agent and will identify the recommended Phase 2 dose and schedule of lutetium-177 labeled FAP-2286 (¹⁷⁷Lu-FAP-2286). FAP-2286 labeled with gallium-68 (⁶⁸Ga-FAP-2286) will be utilized as an investigational imaging agent to identify patients with FAP-positive tumors appropriate for treatment with the therapeutic agent. Once the Phase 2 dose is determined, Phase 2 expansion cohorts are planned in multiple tumor types.

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 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 of 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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