



NEWS RELEASE

Clovis Oncology Announces LuMIERE Clinical Trial Evaluating Novel Peptide-Targeted Radionuclide Therapy FAP-2286 Now Open for Enrollment

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- First clinical site for Phase 1/2 LuMIERE clinical study of novel peptide-targeted radionuclide therapy and imaging agent targeting fibroblast activation protein (FAP) now open for enrollment
- FAP-2286 is the first peptide-targeted radionuclide therapy targeting FAP to enter clinical development

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS), announced today that the first clinical site for the Phase 1/2 LuMIERE study of FAP-2286, its novel peptide-targeted radionuclide therapy and imaging agent targeting fibroblast activation protein (FAP), is now open at the O'Neal Comprehensive Cancer Center at The University of Alabama at Birmingham (UAB).

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20210623005235/en/>

Clovis Oncology is exploring FAP-2286 linked to Lutetium-177 as a therapeutic agent
(Graphic: Business Wire)

The O'Neal Comprehensive Cancer Center at UAB is among the nation's leading cancer research institutions and one of only 51 comprehensive cancer centers designated by the National Cancer Institute.

The Phase 1 portion of the LuMIERE study will evaluate the safety of the FAP-targeting investigational therapeutic agent and 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.

"I envision that targeted radionuclide therapy has the potential to transform how we diagnose and treat cancer and

I look forward to exploring this in the LuMIERE clinical trial,” said Thomas Hope, M.D., Director of Molecular Therapy in the Department of Radiology and Biomedical Imaging at the University of California, San Francisco and lead investigator of the LuMIERE trial.

“We are pleased to initiate sponsored clinical development of FAP-2286 with the LuMIERE study based on the clinical community’s enthusiasm to further explore the potential of targeted radionuclide therapy and FAP as a therapeutic target,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “Given FAP is highly expressed in many of the hardest-to-treat solid tumors, we look forward to exploring the potential of FAP-2286 to treat patients with cancer as our first entry into this emerging field of targeted radiotherapy. The O’Neal Comprehensive Cancer Center and each of the clinical trial sites expected to open for enrollment in the near future bring tremendous nuclear medicine and medical oncology expertise as well as passion for the program.”

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 solid tumors including breast, lung, colorectal and pancreatic carcinomas.^{i,ii,iii,iv} 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.^v Compelling anti-tumor efficacy of ¹⁷⁷Lu-FAP-2286 has been demonstrated in FAP-expressing preclinical tumor models.^{vi}

To learn more about targeted radiotherapy, FAP-2286 and Clovis’ targeted radionuclide development program, visit www.targetedradiotherapy.com.

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 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 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.

i Garin-Chesa P et al. Cell surface glycoprotein of reactive stromal fibroblasts as a potential antibody target in human epithelial cancers. Proc Natl Acad Sci U S A. 1990;87(18):7235-9.

ii Park JE et al. Fibroblast activation protein, a dual specificity serine protease expressed in reactive human tumor stromal fibroblasts. J Biol Chem. 1999;274(51):36505-12.

iii Rettig WJ et al. Regulation and Heteromeric Structure of the Fibroblast Activation Protein in Normal and Transformed Cells of Mesenchymal and Neuroectodermal Origin. Cancer Res. 1993;53:3327-3335.

iv Pure E et al. Pro-tumorigenic roles of fibroblast activation protein in cancer: back to the basics. Oncogene. 2018; 37:4343-57

vYong KJ et al. Mechanisms of Cell Killing Response from Low Linear Energy Transfer (LET) Radiation Originating from Lu Radioimmunotherapy Targeting Disseminated Intraperitoneal Tumor Xenografts. Int. J. of Mol.Sci. 2016; 17: 736.

vi Zboralski, D et al. Preclinical evaluation of FAP-2286, a peptide-targeted radionuclide therapy (PTRT) to fibroblast activation protein alpha (FAP). European Society for Medical Oncology (ESMO) Congress 2020. 18-22 September 2020. Madrid, Spain.

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