



NEWS RELEASE

## Pan-Cancer Analysis Suggests Fibroblast Activation Protein (FAP) is an Attractive Target for Peptide-Targeted Radionuclide Therapy with FAP-2286

10/7/2021

- High expression of FAP, the target of radionuclide therapeutic development candidate FAP-2286, was observed across multiple tumor types and correlated with FAP-2286 binding
- Clovis Oncology's clinical development of FAP-2286 is underway with the Phase 1/2 LuMIERE clinical trial now enrolling patients with FAP-positive solid tumors

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced that nonclinical data describing the expression of fibroblast activating protein (FAP) in a variety of solid tumor types will be presented during the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics, taking place October 7-10, 2021. The analysis, conducted with its partner 3B Pharmaceuticals GmbH, measured FAP expression in multiple tumor types using immunohistochemistry (IHC) as well as the correlation between FAP expression by IHC and in vitro binding of FAP-2286, Clovis' peptide-targeted radionuclide therapy (PTRT) clinical development candidate that targets FAP.

"We believe these findings across multiple solid tumor types demonstrate the importance of FAP as a cancer target and underscore the potential for <sup>177</sup>Lu-FAP-2286 to treat patients with FAP-expressing tumors," said Dr. Thomas Harding, Executive Vice President and Chief Scientific Officer of Clovis Oncology. "These provide additional validation for our ongoing **Phase 1/2 LuMIERE clinical trial of FAP-2286**, the first peptide-targeted radionuclide therapeutic in clinical development targeting FAP, and support investigation of FAP-2286 in a broad number of cancer indications. This is representative of our commitment to emerge as a leader in targeted radionuclide therapy by developing innovative radiotherapies such as FAP-2286 for patients with hard-to-treat cancers."

To determine FAP protein expression in different tumor types, a pan-tumor IHC screen was performed that included 360 samples representing 16 different tumor types. For this analysis, high FAP expression was defined as

an overall H-score  $\geq 30$  in more than 30% of the samples analyzed in a given tumor type. The IHC screen showed high FAP expression in nine of the 16 solid tumor types evaluated, including pancreatic ductal adenocarcinoma, cancer of unknown primary, salivary gland, mesothelioma, colon, bladder, sarcoma, squamous non-small cell lung, and squamous head and neck cancers. High FAP expression was detected in both primary and metastatic tumor samples and was independent of tumor stage or grade.

The analysis also demonstrated that in most tumor types, FAP expression was predominantly localized to the stroma surrounding the tumor cells within the tumor microenvironment. FAP expression in tumor cells was also observed: in cancers of mesenchymal origin, such as sarcoma and mesothelioma, tumor-cell expression was common, consistent, and strong; in cancers of epithelial origin, tumor-cell FAP expression was rare and, when present, appeared weaker than in the adjacent stroma.

A significant correlation was seen between FAP expression observed by IHC and in vitro FAP-2286 binding as determined by autoradiography, suggesting that FAP is an attractive target for PTRT in a wide array of tumor types.

Following are details of the Clovis-sponsored presentation:

Poster Number: LBA032 - Pan-Cancer Analysis of Fibroblast Activation Protein Alpha (FAP) Expression to Guide Tumor Selection for the Peptide-Targeted Radionuclide Therapy FAP-2286

Lead author: Tanya T. Kwan, PhD

Category: Radiotherapeutics

Date/Time: Thursday, October 7 at 9:00 am ET

The presentation and accompanying poster can also be viewed at: <https://clovisoncology.com/pipeline/scientific-presentations/>

For more information about FAP-2286, Targeted Radionuclide Therapy (TRT), or Clovis' TRT development program [CLICK HERE](#).

## 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. High

FAP expression has been shown in pancreatic ductal adenocarcinoma, cancer of unknown primary, salivary gland, mesothelioma, colon, bladder, sarcoma, squamous non-small cell lung, and squamous head and neck cancers. High FAP expression was detected in both primary and metastatic tumor samples and was independent of tumor stage or grade. Clovis holds US 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 (**NCT04939610**). 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 US, 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 US and Europe. Please visit [www.clovisoncology.com](http://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 made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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 potential indications, tumor types and 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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