



NEWS RELEASE

Initial Clinical Experience Reported from FAP-2286 Named-Patient Use at ICPO Symposium

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- Presented at the International Symposium on Theranostics/Precision Oncology (ICPO)
- FAP-targeted images consistent with those of PET and CT scans
- Encouraging tumor accumulation and retention in initial named-patient experience

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that Professor Dr. Richard P. Baum reported his initial independent clinical experience with FAP-2286 in named-patient use at the International Centers for Precision Oncology (ICPO) Foundation Symposium in Bad Berka, Germany. At Prof. Dr. Baum's clinic, FAP-2286 was linked to Gallium-68 as a tumor-imaging compound using PET/CT and to Lutetium-177 as a therapeutic agent.

In the first named-patient experience with FAP-2286, Prof. Dr. Baum imaged 10 patients with advanced solid tumors, including breast, pancreatic, colorectal and ovarian cancers, with PET/CT using FAP-2286 linked to the commonly used imaging agent Gallium-68 for PET/CT imaging. In each case, Prof. Dr. Baum found that the FAP-PET/CT showed consistency with standard of care 18F-FDG-PET/CT scans for the same patients, including identification of both primary and metastatic lesions in liver, lung, bones, lymph nodes and other sites. Prof. Dr. Baum did not observe accumulation of FAP-2286 in healthy tissues of these 10 patients, except, as anticipated in the kidneys where FAP-2286 is excreted.

In addition, Prof. Dr. Baum treated 10 patients with FAP-2286 linked with Lutetium-177. Lutetium-177 is a radionuclide approved for use with somatostatin receptor targeting agents and is in development for use with other compounds. The initial single dose administration showed significant, specific accumulation in primary tumors and metastatic lesions. In this first-in-human experience, patients received a relatively low dose of Lutetium-177. Prof. Dr. Baum reported a lack of significant adverse effects within the first two months of follow-up and an absence of myelosuppression or damage to any other tissue, including the kidneys. Prof. Dr. Baum intends

to administer a second dose of FAP-2286 linked with Lutetium-177 this month.

“I’m extremely pleased with our experience thus far with FAP-2286,” said Prof. Dr. Baum, Chairman and Clinical Director, Theranostics Center for Radiomolecular Precision Oncology at Zentralklinik, Bad Berka, Germany. “As an imaging agent alone, it appears consistent with 18FDG-PET/CT scanning on a schedule that is much more convenient for patients. In addition, while obviously early, when linked to Lutetium-177, FAP-2286 was very well-tolerated, showed encouraging residence time in the tumor lesions, and appears to have, after only one low dose, provided symptomatic relief in several of the patients treated. I believe that FAP as a target and FAP-2286 as a drug candidate represent a very exciting new area of research in molecular targeted radiotherapy.”

“While these examples from named-patient use do not represent a clinical study, we are pleased that the initial imaging and treatment experience with FAP-2286 are consistent with the preclinical data that led to our enthusiasm for FAP as a target and for FAP-2286 as a highly differentiated targeted radionuclide therapy,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “We look forward to completing the pre-clinical work in order to file our IND for FAP-2286 in the second half of 2020 and to initiating formal clinical development for this very promising compound.”

Physicians in Germany and certain other countries may treat patients suffering from a life-threatening disease or a disease leading to severe disability with experimental drugs if no other appropriate options are available under named-patient and similar programs. A physician may initiate treatment for specific patients until there is commercial product available and patients are encouraged to enroll in clinical trials where possible. Named-patient programs are not clinical trials and the treating physician is solely responsible for all decisions, including dose and assessment of efficacy and safety, and the drug sponsor has no role in decisions.

About FAP-2286

FAP-2286 is a preclinical candidate discovered by 3B Pharmaceuticals under investigation as a peptide-targeted radionuclide therapy (PRT) and imaging agent targeting fibroblast activation protein alpha (FAP). FAP is highly expressed in cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas. Clovis is planning to file an investigational new drug application (IND) for FAP-2286 in the second half of 2020. Clovis will conduct the global clinical trials and holds U.S. and global rights, excluding Europe.

FAP-2286 is an unlicensed medical product.

About Fibroblast Activation Protein Alpha (FAP)

Fibroblast activation protein alpha, or FAP, is highly expressed in cancer-associated fibroblasts (CAFs) which are

found in the majority of cancer types, potentially making it a suitable target across a wide array of solid tumors. FAP is highly expressed in many epithelial cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas.¹ CAFs are highly prevalent in the tumor microenvironment of many cancers and persist through all malignant stages of a tumor, from primary tumor to metastasis. FAP has limited expression on normal fibroblasts, reducing the potential for effects in normal tissue.

About Peptide-Targeted Radionuclide Therapy (PTRT)

Peptide-targeted radionuclide therapy involves a small amount of radioactive material (radionuclide) that is combined with a cell-targeting moiety peptide for the treatment of cancer; PTRT is considered a form of radiopharmaceuticals. The targeting peptide is able to recognize and bind to specific features of tumors, such as antigens and cell receptors. When injected into the patient's bloodstream, the peptide attaches to cancer cells or cancer-associated stromal cells, delivering a high dose of radiation to the tumor while sparing normal tissues.

About FAP-Targeted Radiopharmaceuticals

Clinical studies of small molecule imaging agents targeting FAP have validated this target in a diverse number of cancer indications and support the further evaluation of peptide-targeted radionuclide therapy. FAP-targeted radiopharmaceuticals have at least two potential modes of anti-tumor activity: radiation crossfire, in which tumor cells are irradiated due to their close proximity to CAFs; and depletion of CAFs, disrupting the communication between the tumor cells and the tumor stroma. In addition, in certain tumor types, such as sarcoma and mesothelioma, FAP is expressed on the tumor cells themselves, and in those tumors, FAP-targeted radiopharmaceuticals may have a direct effect.

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 our intentions and expectations for our development and discovery programs, including the timing and pace of pre-

clinical development 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, 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 or results in named-patient or similar programs, whether additional studies not originally contemplated are determined to be necessary, the timing of initiation, enrollment and completion of planned studies. 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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