Clovis Oncology Acquires Rights to FAP-Targeted Radiopharmaceutical Program from 3B Pharmaceuticals

Clovis to acquire rights to discovery program for three additional targets for radionuclide therapy

- *Clovis to pay approximately $12 million in upfront payments to 3B Pharmaceuticals*
- *Clovis currently planning to file an IND for FAP-targeted radiopharmaceutical therapy in 2H 2020*
- *FAP highly expressed in multiple tumor types; Clovis to pursue broad and accelerated clinical development program*

BOULDER, Colo. and BERLIN, Germany, September 23, 2019 – Clovis Oncology, Inc. (NASDAQ: CLVS) has entered into a global licensing and collaboration agreement with 3B Pharmaceuticals GmbH (3BP), a private German biotechnology company developing targeted radiopharmaceutical drugs and diagnostics for oncology indications with a high unmet medical need. The initial focus is on developing a peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein alpha (FAP). FAP is highly expressed in many epithelial cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas.[1] Clovis will conduct global clinical trials and has obtained U.S. and global rights, excluding Europe (inclusive of Russia, Turkey and Israel), where 3BP retains rights. The parties have also agreed to collaborate on a discovery program directed at three additional targets for radionuclide therapy, to which Clovis will have global rights.

Terms of the transactions include approximately $12 million in upfront payments to 3BP. Upon achievement of certain development and regulatory milestones, additional potential milestone payments and single- to low-double-digit commercial royalties would be paid to 3BP by Clovis. Clovis will be responsible for a limited number of 3BP full-time employees (FTEs) and external costs during the pre-clinical development. Research and development expense guidance provided by Clovis on its August 1 financial results call does not change as a result of today's announcement.

"We are extremely enthusiastic about the opportunity to develop this novel class of targeted radiopharmaceutical therapies, with an initial focus on fibroblast activation protein alpha. Targeted radiopharmaceutical therapy represents a next frontier in oncology drug development, with potential application across multiple tumor types. In particular, FAP represents a very compelling target given its overexpression across numerous tumor types and limited expression in healthy tissue," said Patrick J. Mahaffy, President and CEO of

[1] Rettig, 1993, Cancer Research

Clovis Oncology. “Additionally, as a result of our discovery collaboration, Clovis intends to further expand its pipeline with additional targeted radiopharmaceutical candidates that result from the discovery program using 3BP’s technology platform. We are delighted to work with 3BP given their leadership in the discovery and development of peptide-targeted radionuclide therapies.”

The collaboration is initially focused on the development of an FAP-targeted preclinical candidate identified by 3BP’s technology platform. FAP is highly expressed in cancer-associated fibroblasts (CAFs) which are found in the majority of cancer types and play an intricate role in driving tumor growth. Targeting CAFs with an FAP radiopharmaceutical is believed to have multiple modes of anti-tumor action, but principally relies on the induction of DNA damage in tumor cells by ionizing radiation emitted locally from neighboring CAFs targeted by the therapy.

Clovis and 3BP also announced their intention to enter into a collaboration for the discovery and development of radiopharmaceuticals for three additional targets using 3BP’s technology platform. 3BP will be responsible for discovery activities for the three targets. Once lead molecules have been identified, responsibilities will transition to Clovis for Investigational New Drug (IND)-enabling studies.

“We have focused for many years on developing a peptide technology platform for the discovery and development of innovative radiopharmaceuticals, which we believe represents the best means of selectively delivering potent radiation to tumors,” said Dr. Ulrich Reineke, Managing Director of 3BP. “As we are approaching clinical development, we are very enthusiastic about partnering with Clovis Oncology to move our FAP-targeted product forward and to collaborate further on building a portfolio of targeted radiopharmaceutical therapeutics. We believe this is an ideal partnership for the rapid clinical development of our radiopharmaceuticals for the benefit of patients with many different types of cancer.”

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 antitumor 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.

About 3B Pharmaceuticals
3B Pharmaceuticals is a German biotechnology company developing targeted radiopharmaceutical drugs and diagnostics for oncology indications with a high unmet medical need. As a leader in peptide discovery and optimization, 3B Pharmaceuticals has built a technology platform extending from hit identification to early clinical development. 3BP was founded in 2008 by a team of renowned experts in peptide drug discovery and nuclear medicine from Berlin, Bern and Basel. The company is owned by its founders and management. For more information on 3B Pharmaceuticals, visit www.3b-pharma.com.

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 regarding our future financial and operating performance, business plans or prospects, including expectations concerning our research and development expenses, our intentions regarding our development and discovery programs, including the expansion of our development pipeline, in connection with the collaboration with 3BP, the timing and pace of our pre-clinical development. 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 future study results will be consistent with previous study findings, including pre-clinical studies, 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.

# # #

Clovis Investor Contacts:
Anna Sussman, 303.625.5022
asussman@clovisoncology.com
or
Breanna Burkart, 303.625.5023
bburkart@clovisoncology.com

Clovis Media Contacts:
U.S.
Lisa Guiterman, 301.217.9353
clovismedia@sambrown.com
or
Christy Curran, 615.414.8668
clovismedia@sambrown.com

EU
Jake Davis, +44 (0) 20.3946.3538
Jake.Davis@publicisresolute.com

3B Pharmaceuticals Media Contact:
Dr. Jan Michel
Director Finance & Corporate Development
Tel.: +49 (30) 6392-4317
Fax.: +49 (30) 6392-4316
E-mail: jan.michel@3b-pharma.com