



NEWS RELEASE

## Clovis Oncology Announces First Patient Enrolled in the Phase 2 Portion of the LIO-1 Trial Evaluating the Combination of Lucitanib and Opdivo in Gynecologic Cancers

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- Initial Phase 1b data from LIO-1 to be presented at the ESMO Virtual Congress 2020
- The LIO-1 trial is part of Clovis Oncology's broad clinical collaboration with Bristol Myers Squibb

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today treatment of the first patient in the Phase 2 portion of the LIO-1 trial evaluating the combination of lucitanib, Clovis' investigational angiogenesis inhibitor, including vascular endothelial growth factor receptors 1 through 3 (VEGFR1-3), and Opdivo® (nivolumab), Bristol Myers Squibb's PD-1 inhibitor, for the treatment of gynecologic cancers. The LIO-1 trial is sponsored by Clovis as part of its broad clinical collaboration with Bristol Myers Squibb.

"The Phase 2 part of the LIO-1 trial will advance our scientific understanding of the potential for an inhibitor of multiple tyrosine kinases, including VEGF, such as lucitanib, to be combined with a PD-1 inhibitor for the treatment of gynecologic cancers," said Dr. Erika Hamilton, Director of the Breast and Gynecologic Research Program, Sarah Cannon Research Institute at Tennessee Oncology. "It is estimated that nearly 100,000 women will be diagnosed with a gynecologic cancer in the U.S. this year alone, and it is vital that we identify new treatment options, in particular new combinations, for these women."

The Phase 2 part of LIO-1 is an open-label study to evaluate the safety and efficacy of lucitanib and Opdivo in patients with advanced gynecological solid tumors, including a broad spectrum of ovarian and endometrial subtypes including clear cell disease and patients with cervical cancer. The primary endpoint is confirmed best overall response rate based on investigator assessment according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. The study will be conducted in the U.S. and Europe, in collaboration with the European Network for

Gynaecological Oncological Trial groups (ENGOT) for European study sites.

The Phase 2 dosing regimen for the LIO-1 study is based on results from the recently completed Phase 1b dose-escalation portion of the LIO-1 study. Abstracts describing the initial results of the Phase 1b portion of the LIO-1 study, as well as a trials-in-progress description of the Phase 2 study design of LIO-1, have been accepted as ePosters at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 in September.

“The initiation of the Phase 2 stage of the LIO-1 clinical trial is an important milestone for the lucitanib development program, and I am grateful to our team and our investigators for their commitment to initiating this study safely and expeditiously in this new COVID-19 era,” said Patrick J. Mahaffy, President and Chief Executive Officer of Clovis Oncology. “Importantly, we look forward to sharing initial Phase 1b data from LIO-1 at the upcoming virtual ESMO Congress, as well as data for each of our commercial and development-stage products. We are committed to pursue innovative clinical studies, both monotherapy and in combination, that are supported by a strong scientific rationale and offer the potential to provide additional treatment options with meaningful clinical benefit to a broad group of cancer patients.”

More information about the LIO-1 trial (NCT04042116) is available [here](#).

## About Lucitanib

Lucitanib is an oral, potent inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors 1 through 3 (VEGFR1-3), platelet-derived growth factor receptors alpha and beta (PDGFR $\alpha$ / $\beta$ ) and fibroblast growth factor receptors 1 through 3 (FGFR1-3). Emerging clinical data support the combination of angiogenesis inhibitors and immunotherapy to increase effectiveness in multiple cancer indications. Angiogenic factors, such as vascular endothelial growth factor (VEGF), are frequently up-regulated in tumors and create an immunosuppressive tumor microenvironment. Use of antiangiogenic drugs may reverse this immunosuppression and augment response to immunotherapy.

Lucitanib is an unlicensed medical product.

## 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, 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; please visit [www.clovisoncology.com](http://www.clovisoncology.com) for more

information, including additional office locations in the U.S. and Europe.

## Clovis Oncology Forward-Looking Statement

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 the potential benefit of our drug candidate lucitanib in combination with nivolumab and expanding treatment options for a broader set of patient populations. Such forward-looking statements involve substantial risks and uncertainties that could cause our future results, performance or achievements to differ significantly from that expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, whether future pre-clinical or clinical study results will support continued development or regulatory approval, whether our clinical development programs for our drug candidates and those of our partners can be completed on time or at all, whether future study results will be consistent with study findings to date, and actions by the FDA, the EMA or other regulatory authorities regarding data required to support drug applications and whether to accept or approve drug applications that may be filed, as well as their decisions regarding drug labeling, reimbursement and pricing, and other matters that could affect the development, approval, availability or commercial potential of our drug candidates. Clovis Oncology does not undertake to update or revise any forward-looking statements. A further description of risks and uncertainties can be found in Clovis Oncology's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its reports on Form 10-Q and Form 8-K.

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