



NEWS RELEASE

## Clovis Oncology to Highlight Rubraca® (rucaparib) and Lucitanib Non-Clinical Data at the AACR Virtual Annual Meeting II 2020

6/17/2020

Findings explore the pharmacokinetics (PK), pharmacodynamics (PD), and antitumor activity of Rubraca and lucitanib alone and in combination with other agents in preclinical models and simulated patient populations

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that four abstracts showcasing non-clinical data from rucaparib and lucitanib development programs have been accepted for on-demand viewing and publication at the upcoming American Association for Cancer Research (AACR) Virtual Annual Meeting II, June 22 - 24, 2020.

The accepted abstracts summarize findings from pre-clinical studies evaluating the PK, PD and anti-tumor activity of rucaparib, an oral, small molecule PARP inhibitor in orthotopic and intracranial mouse models, and its synergy with CHK1 inhibition in tumor cell lines. Additional abstracts include findings from a study of the pharmacokinetics of lucitanib, an oral, potent inhibitor of tyrosine kinase activity, in a simulated patient population to inform dosing-regimen selection, and from a pre-clinical study evaluating the anti-tumor efficacy and mechanism of action of lucitanib in combination with a mouse ortholog of ALKS 4230, a selective agonist of the intermediate affinity IL-2 receptor, in a mouse colon cancer model. Lucitanib and ALKS 4230 are both development-stage compounds.

"Data from our ongoing non-clinical studies underscore our commitment to pursuing innovative research that advances novel therapies for cancer patients," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "In particular, we are pleased to present new, non-clinical data exploring the PK/PD of our PARP inhibitor Rubraca, evaluating the synergies of PARP and CHK1 inhibition in combination, as well as important data for lucitanib to understand optimal dosing and use in combination with other anticancer agents to treat solid tumors."

The following Clovis-sponsored, collaborator-sponsored and investigator-sponsored abstracts will be available as AACR 2020 Virtual Poster Session presentations. E-posters, and when available, accompanying audio descriptions,

will be available for on-demand viewing beginning 9:00 a.m. EDT Monday, June 22, and will remain available for viewing by registered attendees for at least three months after the virtual meeting.

**Abstract Number: 3026 / 14 - Evaluation of brain pharmacokinetics (PK) and tumor growth inhibition of PARP inhibitors in mouse xenograft models using semi-mechanistic PK/pharmacodynamic (PD) modeling**

- Presenting Author: Michelle Liao
- Session: Pharmacokinetics / Pharmacodynamics

**Abstract Number: 3027 / 15 - Application of machine learning and grid search approaches to minimize lucitanib pharmacokinetic variability following different dosing regimens**

- Presenting Author: Michelle Liao
- Session: Pharmacokinetics / Pharmacodynamics

**Abstract Number: 2202 / 7 - The combination of a mouse ortholog of ALKS 4230, a selective agonist of the intermediate affinity IL-2 receptor, and the angiogenesis inhibitor lucitanib enhances antitumor activity**

- Presenting Author: Jared E. Lopes
- Session: Combination Immunotherapies 2

In addition, the three previous posters will be available on the [Clovis Oncology website](#) once they become available on the AACR virtual meeting website.

**Abstract Number: 1375 / 11 - Investigating synergy between CHK1 and PARP inhibitors in BRCA2 mutant and restored cells**

- Presenting Author: Hannah L. Smith
- Session: Mechanisms of DNA Damaging Therapeutics

**About Rubraca (rucaparib)**

Rubraca is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in multiple tumor types, including ovarian and metastatic castration-resistant prostate cancers, as monotherapy, and in combination with other anti-cancer agents. Exploratory studies in other tumor types are also underway. Clovis holds worldwide rights for Rubraca.

In the United States, Rubraca is approved for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Rubraca is also approved in the United States for the treatment of adult patients with deleterious BRCA mutation (germline and/or somatic) associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. Additionally, Rubraca is indicated for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

In Europe, Rubraca is approved for the maintenance treatment of adults with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. Rubraca is also approved in Europe for the treatment of adult patients with platinum sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum-based chemotherapy, and who are unable to tolerate further platinum-based chemotherapy. Rubraca is indicated for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

Rubraca is an unlicensed medical product outside of the U.S. and Europe.

## 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 reverses this immunosuppression and can 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, 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](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. Examples of forward-looking statements contained in this press release include, among others, statements regarding our expectations for submission of regulatory filings, the timing and pace of commencement of and enrollment in our clinical trials, including those being planned or conducted in collaboration with partners, the potential results of such clinical trials, our expectations regarding the suitability of Rubraca for, and our plans to develop Rubraca in, additional indications and tumor types. 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, the uncertainties inherent in our clinical development programs for our drug candidates and those of our partners, whether future study results will be consistent with study findings to date, the timing of availability of data from our clinical trials and the initiation, enrollment, timing and results of our planned clinical trials and the corresponding development pathways, effectiveness and suitability of diagnostic tests, the risk that final results of ongoing trials may differ from initial or interim results as a result of factors such as final results from a larger patient population may be different from initial or interim results from a smaller patient population, the risk that additional pre-clinical or clinical studies may not support further development in certain additional indications or tumor types, 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 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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