



NEWS RELEASE

Clovis Oncology Announces Presentations at 2019 AACR Annual Meeting

3/19/2019

Accepted abstracts highlight data from a phase 2 investigator-initiated trial of Rubraca® (rucaparib) in pancreatic cancer, clinical and nonclinical research of Rubraca in multiple solid tumor settings, and nonclinical research exploring lucitanib in multiple solid tumor models

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that six abstracts highlighting progress in the Rubraca clinical development and lucitanib preclinical research programs will be presented at the 2019 American Association for Cancer Research (AACR) Annual Meeting taking place March 29 – April 3 in Atlanta.

The accepted abstracts summarize multiple clinical trials and nonclinical research in which Rubraca is being studied as single agent and combination therapy in a variety of solid tumor types including pancreatic, ovarian, bladder and prostate. In addition, one abstract summarizes ongoing nonclinical research for lucitanib.

“We are actively evaluating the potential utility of Rubraca and lucitanib in a wide range of solid tumors,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “We know that many healthcare professionals and patients are hopeful about the role that these therapies may play in treating these cancers, and we are pleased to share our latest updates at this year’s AACR meeting.”

The five Clovis Oncology-sponsored presentations and one presentation of an investigator-initiated trial comprise:

Abstract CT234 - A Phase II, single arm study of maintenance rucaparib in patients with platinum-sensitive advanced pancreatic cancer and a pathogenic germline or somatic mutation in BRCA1, BRCA2 or PALB2

- Presenter: Kim A. Reiss Binder
- Session: CTMS03 Developmental Therapeutics: Clinical Results of Novel Agents

- Date/Time: April 2, 2019, 3:35 – 3:50 PM EDT
- Location: Marcus Auditorium- Bldg. A-GWCC

Abstract 727 (Poster 1) - Comprehensive genomic profiling of >1000 plasma and tumor tissue samples from metastatic castration-resistant prostate cancer (mCRPC) patients gives insight into targeted treatment strategies

- Presenter: Foad Green
- Session: Molecular and Cellular Biology/Genetics; Cancer Genomics 1
- Date/Time: Sunday, March 31, 2019 from 1:00 - 5:00 PM EDT
- Location: Exhibit Hall B, Section 33

Abstract 1214 (Poster 11) - Enhancement of anti-PD-1 antitumor efficacy in syngeneic preclinical models by the angiogenesis inhibitor lucitanib

- Presenter: Rachel L. Dusek
- Session: Experimental and Molecular Therapeutics; Cancer Immunotherapy
- Date/Time: Monday, Apr 1, 2019 8:00 AM - 12:00 PM EDT
- Location: Exhibit Hall B, Section 10

Abstract 3888 (Poster 8) - Intracranial evaluation of the in vivo pharmacokinetics, brain distribution, and efficacy of rucaparib in BRCA-mutant, triple-negative breast cancer

- Presenter: Minh Nguyen
- Session: Experimental and Molecular Therapeutics; Pharmacokinetics and Pharmacodynamics / Preclinical Toxicology
- Date/Time: Tuesday, Apr 2, 2019 1:00 - 5:00 PM
- Location: Exhibit Hall B, Section 13

Abstract CT158 (Poster 2) - ATHENA (GOG-3020/ENGOT-ov45): a randomized, double-blind, placebo-controlled, Phase III study of rucaparib + nivolumab following front-line platinum-based chemotherapy in ovarian cancer

- Presenter: Shannon N. Westin
- Session: Phase I-III Trials in Progress: Part 2

- Date/Time: Tuesday, Apr 2, 2019 8:00 AM - 12:00 PM EDT
- Location: Exhibit Hall B, Poster Section 17

Abstract CT179 (Poster 23) - ATLAS: A Phase II, open-label study of rucaparib in patients with locally advanced or metastatic urothelial carcinoma

- Presenter: Petros Grivas
- Session: Phase I-III Trials in Progress: Part 2
- Date/Time: Tuesday Apr 2, 2019 8:00 AM - 12:00 PM EDT
- Location: Exhibit Hall B, Poster Section 17

The five Clovis-sponsored posters will be available online at <http://clovisoncology.com/pipeline/scientific-presentations/> at once they are presented at the meeting.

About Rubraca (rucaparib)

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

Rubraca U.S. FDA Approved Indications

Rubraca is indicated as monotherapy 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 indicated as monotherapy for the treatment of adult patients with deleterious BRCA mutations (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.

Select Important Safety Information

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML) occur uncommonly in patients treated with Rubraca, and are potentially fatal adverse reactions. In approximately 1100 treated patients, MDS/AML occurred in 12 patients (1.1%), including those in long-term follow-up. Of these, five occurred during treatment or during the

28-day safety follow-up (0.5%). The duration of Rubraca treatment prior to the diagnosis of MDS/AML ranged from 1 month to approximately 28 months. The cases were typical of secondary MDS/cancer therapy-related AML; in all cases, patients had received previous platinum-containing regimens and/or other DNA-damaging agents. Do not start Rubraca until patients have recovered from hematological toxicity caused by previous chemotherapy (\leq Grade 1).

Monitor complete blood counts for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities (> 4 weeks), interrupt Rubraca or reduce dose (see Dosage and Administration [2.2] in full Prescribing Information) and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks, or if MDS/AML is suspected, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample cytogenetic analysis. If MDS/AML is confirmed, discontinue Rubraca.

Based on its mechanism of action and findings from animal studies, Rubraca can cause fetal harm when administered to a pregnant woman. Apprise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Rubraca.

Most common adverse reactions in ARIEL3 ($\geq 20\%$; Grade 1–4) were nausea (76%), fatigue/asthenia (73%), abdominal pain/distention (46%), rash (43%), dysgeusia (40%), anemia (39%), AST/ALT elevation (38%), constipation (37%), vomiting (37%), diarrhea (32%), thrombocytopenia (29%), nasopharyngitis/upper respiratory tract infection (29%), stomatitis (28%), decreased appetite (23%) and neutropenia (20%).

Most common laboratory abnormalities in ARIEL3 ($\geq 25\%$; Grade 1–4) were increase in creatinine (98%), decrease in hemoglobin (88%), increase in cholesterol (84%), increase in alanine aminotransferase (ALT) (73%), increase in aspartate aminotransferase (AST) (61%), decrease in platelets (44%), decrease in leukocytes (44%), decrease in neutrophils (38%), increase in alkaline phosphatase (37%) and decrease in lymphocytes (29%).

Most common adverse reactions in Study 10 and ARIEL2 ($\geq 20\%$; Grade 1–4) were nausea (77%), asthenia/fatigue (77%), vomiting (46%), anemia (44%), constipation (40%), dysgeusia (39%), decreased appetite (39%), diarrhea (34%), abdominal pain (32%), dyspnea (21%) and thrombocytopenia (21%).

Most common laboratory abnormalities in Study 10 and ARIEL2 ($\geq 35\%$; Grade 1–4) were increase in creatinine (92%), increase in alanine aminotransferase (ALT) (74%), increase in aspartate aminotransferase (AST) (73%), decrease in hemoglobin (67%), decrease in lymphocytes (45%), increase in cholesterol (40%), decrease in platelets (39%) and decrease in absolute neutrophil count (35%).

Co-administration of Rubraca can increase the systemic exposure of CYP1A2, CYP3A, CYP2C9, or CYP2C19 substrates, which may increase the risk of toxicities of these drugs. Adjust dosage of CYP1A2, CYP3A, CYP2C9, or CYP2C19 substrates, if clinically indicated. If co-administration with warfarin (a CYP2C9 substrate) cannot be avoided, consider increasing frequency of international normalized ratio (INR) monitoring. Because of the potential for serious adverse reactions in breast-fed children from Rubraca, advise lactating women not to breastfeed during treatment with Rubraca and for 2 weeks after the last dose. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Clovis Oncology, Inc. at 1-844-258-7662.

[Click here](#) or full Prescribing Information and additional Important Safety Information.

Rubraca® ▼ (rucaparib) EU Authorized Use and Important Safety Information

Rucaparib is indicated as monotherapy for the maintenance treatment of adult patients 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.

Rucaparib is indicated as monotherapy 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.

Summary warnings and precautions: Haematological toxicity: Patients should not start Rubraca until they have recovered from haematological toxicities caused by previous chemotherapy (\leq CTCAE Grade 1). Complete blood count testing prior to starting treatment with Rubraca and monthly thereafter is advised. Rubraca should be interrupted or dose reduced and blood counts monitored weekly until recovery for the management of low blood counts. Myelodysplastic syndrome/acute myeloid leukaemia (MDS/AML): If MDS/AML is suspected, the patient should be referred to a haematologist for further investigation. If MDS/AML is confirmed, Rubraca should be discontinued. Photosensitivity: Patients should avoid spending time in direct sunlight as they may burn more easily. When outdoors, patients should wear protective clothing and sunscreen with SPF of 50 or greater. Gastrointestinal toxicities: Low grade (CTCAE Grade 1 or 2) nausea and vomiting may be managed with dose reduction or interruption. Additionally, antiemetics may be considered for treatment or prophylaxis.

[Click here](#) to access the current Summary of Product Characteristics. Healthcare professionals should report any suspected adverse reactions via their national reporting systems.

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 α / β) 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, 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 for more information, including additional office locations in the U.S. and Europe.

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 evaluation of Rubraca and lucitanib, a candidate in development, 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, the risk that results of further trials may differ from initial or interim results, non-clinical or preclinical studies, or post-hoc analyses, as a result of many factors, including final results from a larger patient population differing from initial or interim results from a smaller patient population, and the uncertainties inherent in 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. 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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