



NEWS RELEASE

Clovis Oncology Highlights Rubraca® (rucaparib) and Lucitanib Data at 2021 ASCO Annual Meeting

5/19/2021

- New data analyses from the Phase 3 ARIEL3 and ARIEL4 trials further characterize Rubraca's efficacy and consistent safety profile in patients in the advanced ovarian cancer maintenance treatment and treatment settings

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that four abstracts featuring data from clinical studies evaluating Rubraca and/or lucitanib and one abstract on real world data of PARP inhibitor usage, will be presented during the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting to be held virtually, June 4-8, 2021.

"We remain committed to understanding how Rubraca and lucitanib may benefit patients with cancer, and the data presented at ASCO further enhance our understanding of their potential benefit in different patient populations and solid tumor types," said Patrick J. Mahaffy, President and CEO of Clovis Oncology.

The following Clovis-sponsored full abstracts are available as of May 19 at 5:00 pm ET on **ASCO's Meeting Library**. Clovis-sponsored posters and supplemental information will be available as of June 3 at 5:00 pm ET at <https://clovisoncology.com/pipeline/scientific-presentations/>.

Rubraca

Abstract #5517: Subgroup Analysis of Rucaparib Versus Chemotherapy as Treatment for BRCA-mutated, Advanced, Relapsed Ovarian Carcinoma: Effect of Platinum Sensitivity in the Randomized, Phase 3 Study ARIEL4

- Lead Author: Amit M. Oza, MD, Princess Margaret Cancer Centre, University Health Network, Toronto, Canada
- Poster Discussion Session: Gynecologic Cancer
- Date/Time: June 4 at 9:00 am ET

- Key Takeaways: Results from this exploratory subgroup analysis of the Phase 3 ARIEL4 trial demonstrate that patients treated with Rubraca had comparable or longer PFS vs. standard-of-care platinum-chemotherapy across all platinum status subgroups. Safety profiles for Rubraca and chemotherapy across the subgroups were consistent with known safety profiles of these agents. These results suggest that Rubraca is an effective treatment option for heavily pretreated patients with BRCA-mutated, advanced, relapsed ovarian cancer as compared to chemotherapy, regardless of their sensitivity to platinum-based therapy.

Abstract #5537: Clinical and Molecular Characteristics of ARIEL3 Patients Who Derived Exceptional Benefit from Rucaparib Maintenance Treatment for High-grade Ovarian Cancer (HGOC)

- Lead Author: Tanya Kwan, PhD, Clovis Oncology, Inc., Boulder, Colorado, USA
- Poster Session: Gynecologic Cancer
- Date/Time: June 4 at 9:00 am ET
- Key Takeaways: In the Phase 3 ARIEL3 trial, exceptional benefit (progression-free survival ≥ 2 years) was more common in, but not exclusive to, patients with favorable clinical characteristics and known mechanisms of PARP inhibitor sensitivity, including mutations of BRCA1/2 and RAD51C/D. These results suggest that rucaparib can deliver exceptional benefit to a diverse set of patients with high-grade ovarian cancer. In all, 21% (79/375) of patients in the rucaparib arm derived exceptional benefit versus only 2% (4/189) in the placebo arm of the trial. Among rucaparib-treated patients, incidence rates of the most common TEAEs were generally consistent between the exceptional benefit subgroup and the overall ARIEL3 patient population.

Rubraca in Combination with Lucitanib

Abstract #3102: Phase 1b/2 SEASTAR Trial: Safety, Pharmacokinetics, and Preliminary Efficacy of the Poly(ADP-ribose) Polymerase (PARP) Inhibitor Rucaparib and Angiogenesis Inhibitor Lucitanib in Patients with Advanced Solid Tumors

- Lead Author: Ecaterina E. Dumbrava, MD, The University of Texas MD Anderson Cancer Center, Houston, Texas, USA
- Poster Session: Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology
- Date/Time: June 4 at 9:00 am ET
- Key Takeaways: Initial findings suggest that rucaparib plus lucitanib has an acceptable safety profile, and there was some evidence of effect on tumor and disease stabilization among patients with measurable disease, with a 23.5% disease control rate. A maximum tolerated dose for the combination was not established, and no drug-drug interactions were observed. These data suggest the combination of a PARP inhibitor and an angiogenesis inhibitor is feasible and may merit further evaluation.

Lucitanib in Combination with Nivolumab

Abstract #5538: LIO-1: Lucitanib + Nivolumab in Patients with Advanced Solid Tumors—Updated Phase 1b Results and Initial Experience in Phase 2 Ovarian Cancer Cohort

- Lead Author: Erika Hamilton, MD, Sarah Cannon Research Institute/Tennessee Oncology, Nashville, Tennessee, USA
- Poster Session: Gynecologic Cancer
- Date/Time: June 4 at 9:00 am ET
- Key Takeaways: Data from the Phase 1b LIO-1 trial identified the Phase 2 starting dose of the combination and updated Phase 1b efficacy data suggest that lucitanib plus nivolumab has promising antitumor activity (47.1% disease control rate) with a manageable safety profile in patients with advanced solid tumors with no satisfactory treatment options. The Phase 2 study is currently assessing four cohorts of patients with advanced gynecologic malignancies. Interim results from one of these, non-clear cell ovarian cancer (OC) are reported here. 70.8% of patients had received at least 3 previous therapy lines, and 29.2% had primary platinum resistant disease. In 22 evaluable patients, the disease control rate was 31.8% including one confirmed PR. The safety profile of the combination was consistent with that reported in the Phase 1b portion of the study. In addition, the data support the individualized lucitanib dose-titration strategy. While evidence of clinical activity has been observed, Clovis does not believe that the interim efficacy data support further development in non-clear cell OC. Enrollment to the other cohorts continues.

HEOR

Abstract #e18702: Real-world Data Analysis of the Utilization of Second-Line Maintenance Therapy for Patients with Advanced Ovarian Cancer

- Lead Author: Robert Reid, MD, FACP, US Oncology, Virginia Cancer Specialists, Fairfax, Virginia, USA
- Accessible as e-publication only
- Key Takeaways: Real world data from the iKnowMed electronic database of the US Oncology Network (including >470 sites) found that fewer than half of eligible ovarian cancer patients receive second-line maintenance treatment, despite treatment guidelines recommending its usage. In addition, the proportion of patients receiving 2L PARPi maintenance increased from 17% in 2018 to 34% in 2019 but decreased to 22% in 2020.

About Rubraca (rucaparib)

Rucaparib 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.

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

Rubraca Ovarian Cancer U.S. FDA Approved Indications

Rubraca is indicated for the maintenance treatment of adult women 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 for the treatment of adult women with a 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. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca.

Select Important Safety Information

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML) have occurred in patients treated with Rubraca, and are potentially fatal adverse reactions. In 1146 treated patients, MDS/AML occurred in 20 patients (1.7%), including those in long term follow-up. Of these, 8 occurred during treatment or during the 28 day safety follow-up (0.7%). The duration of Rubraca treatment prior to the diagnosis of MDS/AML ranged from 1 month to approximately 53 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 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 for cytogenetics. 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 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%).

Co-administration of rucaparib 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.

Please [Click here](#) for full Prescribing Information for Rubraca.

You may also report side effects to Clovis Oncology, Inc. at 1-415-409-7220 (US toll) or 1-844-CLVS-ONC (1-844-258-7662; US toll-free).

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 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, 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 regarding the potential results of such clinical trials, our expectations regarding the suitability of Rubraca and lucitanib for certain patient populations or indications, and our plans to develop Rubraca and lucitanib in additional indications and tumor types, and our expectations regarding the outcomes of early studies or trials supporting further development, both non-clinical and clinical. 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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