Clovis Oncology to Highlight Results from Rubraca® (rucaparib) TRITON Prostate Program at ESMO 2018 Congress

10/3/2018

- First presentation of initial data from Rubraca Phase 2 TRITON2 trial in advanced metastatic castration-resistant prostate cancer (mCRPC)
- First presentation of genomic profiling data based on tumor tissue and plasma cell free circulating tumor DNA (cfDNA) samples from the TRITON clinical program
- Additional posters include a subset analysis of the ARIEL3 trial in advanced ovarian cancer and a trial in progress (TIP) poster of the ATLAS trial in advanced bladder cancer

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that four posters featuring data and highlighting studies from the Rubraca clinical development program will be presented at the ESMO 2018 Congress (European Society for Medical Oncology), 19-23 October, 2018, in Munich, Germany. These posters include the first presentation of initial results from the Phase 2 TRITON2 clinical trial of Rubraca, an oral, small molecule PARP inhibitor, in advanced mCRPC, as well as genomic profiling data based on tumor tissue and plasma cfDNA samples from patients who were screened following progression on prior therapy for enrollment in TRITON2 or the Phase 3 TRITON3 clinical study. Both datasets from the TRITON clinical program have been selected for inclusion in a poster discussion session that will be led by invited discussant Dr. Joaquín Mateo, of the Prostate Cancer Translational Research Group, Vall d'Hebron Institute of Oncology (VHIO), Barcelona, Spain.

TRITON2 is an international, multicenter, open-label, Phase 2 study of Rubraca in men with advanced prostate cancer with BRCA gene mutations (germline or somatic) or other deleterious mutations in other homologous recombination (HR) repair genes in the metastatic castration-resistant setting. The study is currently recruiting at approximately 100 sites worldwide. On October 2, 2018, Clovis announced that the U.S. Food and Drug Administration granted Breakthrough Therapy designation for Rubraca for the treatment of adult patients with BRCA1/2-mutated mCRPC who have received at least one prior androgen receptor (AR)-directed therapy and
taxane-based chemotherapy. The FDA granted this designation based on the initial efficacy and safety results from TRITON2 that will be shared at the ESMO 2018 Congress.

“We look forward to presenting a first look at the TRITON2 prostate cancer data at ESMO, with a primary focus on the BRCA mutant population,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “The data and updates we will share at ESMO emphasize our commitment to developing Rubraca beyond its initial ovarian cancer indications.”

The four Rubraca abstracts from Clovis Oncology that have been accepted for poster presentation at the ESMO 2018 Congress are:

Title: ARIEL3: Subgroup analysis of rucaparib in platinum-sensitive recurrent ovarian carcinoma: effect of prior chemotherapy regimens (abstract 947P)
Presenter: Dr. Domenica Lorusso, Unità di Ginecologia Oncologica, Fondazione IRCCS Istituto Nazionale dei Tumori and MITO, Milan, Italy
Session: Poster session
Date/Time: Saturday, 20 October, 12:30–13:30 CEST
Location: Hall A3

Title: Preliminary results from TRITON2: a phase 2 study of rucaparib in patients with metastatic castration-resistant prostate cancer (mCRPC) associated with homologous recombination repair (HRR) gene alterations (abstract 793PD)
Presenter: Dr. Wassim Abida, Memorial Sloan Kettering Cancer Center, New York, NY, USA
Session: Poster discussion session, genitourinary tumors, prostate
Date/Time: Sunday, 21 October, 09:15–10:30 CEST
Location: Room 14b
As the subject of a poster discussion session, this poster will be on display for the duration of the congress beginning at 9:00 CEST on Saturday, 20 October 2018.

Title: TRITON: Genomic profiling of circulating tumour DNA (ctDNA) and tumour tissue for the evaluation of rucaparib in metastatic castration-resistant prostate cancer (mCRPC) (abstract 795PD)
Presenter: Dr. Simon Chowdhury, Guy’s Hospital & Sarah Cannon Research Institute, London, UK
Session: Poster discussion session, genitourinary tumours, prostate
Date/Time: Sunday, 21 October, 09:15–10:30 CEST
Location: Room 14b
As the subject of a poster discussion session, this poster will be on display for the duration of
the congress beginning at 9:00 CEST on Saturday, 20 October 2018.

Title: ATLAS: a phase 2, open-label study of rucaparib in patients with locally advanced (unresectable) or metastatic urothelial carcinoma (abstract 928TIP)
Presenter: Dr. Simon Chowdhury, Guy’s Hospital & Sarah Cannon Research Institute, London, UK
Session: Poster session
Date/Time: Monday, 22 October, 13:15–14:15 CEST
Location: Hall A3

Specific program times and locations are subject to change by ESMO.

Clovis’ Rubraca poster presentations will be available online at clovisoncology.com at 07:30 CEST on Saturday, 20 October, 2018.

About Rubraca ® (rucaparib)

Rubraca 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. Clovis holds worldwide rights for Rubraca. Rubraca is an unlicensed medical product outside of the U.S. and Europe.

Rubraca EU Authorized Use

Rubraca is licensed for 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.

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

Rubraca U.S. FDA Approved Indications and Important Safety Information

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, 5 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 (≤ 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 (≥ 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 (≥ 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 (≥ 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 (≥ 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 for full Prescribing Information and additional Important Safety Information.

About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the US, 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, and has additional offices in San Francisco and Oakland, California and Cambridge, UK. Please visit clovisoncology.com for more information.

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 timing and pace of commencement of and enrollment in our clinical trials, including those being planned or conducted in collaboration with partners, and the potential results of such clinical trials. 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, the initiation, enrollment, timing and results of our planned clinical trials, and the risk that final results of trials may differ from initial or interim results. 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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Source: Clovis Oncology, Inc.