NEWS RELEASE

Clovis Oncology to Highlight Data for its Three Portfolio Compounds at the ESMO Virtual Congress 2020

9/9/2020

- Initial presentation of data from the Phase 1b part of the LIO-1 trial of lucitanib in combination with nivolumab in advanced metastatic solid tumors
- New data analyses for Rubraca® (rucaparib) from the Phase 2 TRITON2 and Phase 3 ARIEL3 studies in patients with metastatic castration-resistant prostate cancer (mCRPC) and recurrent ovarian cancer, respectively
- First presentation of preclinical data for FAP-2286, a novel peptide-targeted radionuclide therapy (PTRT) being developed for the treatment of a variety of cancers

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that six e-posters highlighting clinical data from the lucitanib and Rubraca® (rucaparib) clinical development programs, as well as preclinical data for FAP-2286, will be presented at the ESMO (European Society for Medical Oncology) Virtual Congress 2020, September 19 – September 21, 2020.

E-posters for presentation include the following:

- Initial data from the Phase 1b part of the LIO-1 study in patients with an advanced metastatic solid tumor, which aimed to determine the recommended Phase 2 starting dose of lucitanib in combination with nivolumab and to provide safety, pharmacokinetic and preliminary efficacy data for the combination.
- A Trials in Progress e-poster describing the design of the Phase 2 part of the LIO-1 study, which is now enrolling patients, and will evaluate the combination's safety and efficacy in patients with an advanced gynecological solid tumor, including ovarian, endometrial and cervical cancers.
- Analyses of pharmacokinetics and relationships between exposure and efficacy/safety in patients with metastatic castration-resistant prostate cancer (mCRPC) from the Phase 2 TRITON2 study of Rubraca, the primary analysis of which served as the pivotal data supporting FDA approval of Rubraca as the first poly-ADP

ribose polymerase (PARP) inhibitor for patients with advanced mCRPC associated with a BRCA mutation.
- New analysis of data from the Phase 3 ARIEL3 study evaluating the prevalence, timing, and duration of adverse events for Rubraca maintenance therapy in recurrent ovarian cancer.
- Initial data from the Phase 1b part of the Phase 1b/2 SEASTAR study arm evaluating Rubraca in combination with sacituzumab govitecan for the treatment of metastatic solid tumors, which aims to evaluate the tolerability and preliminary efficacy for the combination.
- The first presentation of preclinical data in in vivo and in vitro models for FAP-2286, a novel peptide-targeted radionucleotide therapy (PTRT) and imaging agent for which Clovis intends to file imaging and treatment Investigational New Drug applications to the FDA in late 2020.

“We have made significant progress in expanding the breadth and depth of our oncology development portfolio, including our pipeline compounds lucitanib and FAP-2286. We are excited to share new data and updates for all three compounds from our clinical and preclinical development programs at this year’s ESMO congress,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “We remain committed to developing targeted therapies to better serve patients, and believe delivering the right drug to the right patient at the right time represents the future of cancer therapy.”

The following abstracts will be available as e-posters for on-demand viewing on the ESMO website at 9:00 a.m. CEST on Thursday, September 17, 2020. The e-posters will also be available online at **www.clovisoncology.com/pipeline/scientific-presentations** once they are made available during the congress.

Lucitanib

E-poster Number 556P: Initial Clinical Experience of Lucitanib + Nivolumab in Advanced Metastatic Solid Tumours: Data From the Phase 1b/2 LIO-1 Study (CO-3810-101; NCT04042116)
Lead author: Dr. Erika Hamilton, Sarah Cannon Research Institute/Tennessee Oncology, Nashville, United States of America

E-poster Number 885TiP: LIO-1: A Phase 2 Study of Lucitanib + Nivolumab in Patients (pts) With Gynecological Tumours (CO-3810-101; NCT04042116; ENGOT-GYN3/AGO/LIO)
Lead author: Prof. Nicole Concin, Kliniken Essen-Mitte, Essen, Germany, and Medizinische Universität Innsbruck, Austria

Rucaparib

E-poster Number 659P: Rucaparib Population Pharmacokinetics (PPK) and Exposure-Response (ER) Analyses in Patients (pts) With Metastatic Castration-Resistant Prostate Cancer (mCRPC) in TRITON2

Lead author: Dr. Simon Chowdhury, Guy's Hospital, London and Sarah Cannon Research Institute, London, United Kingdom

E-poster Number 821P: Timing of Adverse Events During Maintenance Treatment With Rucaparib for Recurrent Ovarian Cancer in the Phase 3 ARIEL3 Study
Lead author: Dr. Andrew Dean, St John of God Subiaco Hospital, Subiaco, Australia

E-poster Number 547P: Rucaparib + Sacituzumab Govitecan (SG): Initial Data From the Phase 1b/2 SEASTAR Study (NCT03992131)
Lead author: Dr. Timothy A. Yap, The University of Texas MD Anderson Cancer Center, Houston, United States of America

FAP-2286

E-poster Number 571P: Preclinical Evaluation of FAP-2286, a Peptide-targeted Radionuclide Therapy (PTRT) to Fibroblast Activation Protein Alpha (FAP)
Lead author: Dr. Dirk Zboralski, 3B Pharmaceuticals GmbH, Berlin, Germany

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 (rucaparib) European Union (EU) authorized use and Important Safety Information

Rubraca 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.

Rubraca 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 ≥2 prior lines of platinum-based chemotherapy, and who are unable to tolerate further platinum-based chemotherapy.

Efficacy of Rubraca as treatment for relapsed or progressive epithelial ovarian cancer (EOC), fallopian tube cancer (FTC), or primary peritoneal cancer (PPC) has not been investigated in patients who have received prior treatment with a PARP inhibitor. Therefore, use in this patient population is not recommended.

Summary warnings and precautions:

Hematological toxicity

During treatment with Rubraca, events of myelosuppression (anemia, neutropenia, thrombocytopenia) may be observed and are typically first observed after 8–10 weeks of treatment with Rubraca. These reactions are manageable with routine medical treatment and/or dose adjustment for more severe cases. Complete blood count testing prior to starting treatment with Rubraca, and monthly thereafter, is advised. Patients should not start Rubraca treatment until they have recovered from hematological toxicities caused by previous chemotherapy (CTCAE grade ≥1).

Supportive care and institutional guidelines should be implemented for the management of low blood counts for the treatment of anemia and neutropenia. Rubraca should be interrupted or dose reduced according to Table 1 (see Posology and Method of Administration [4.2] of the Summary of Product Characteristics [SPC]) and blood counts monitored weekly until recovery. If the levels have not recovered to CTCAE grade 1 or better after 4 weeks, the patient should be referred to a hematologist for further investigations.

MDS/AML

MDS/AML, including cases with fatal outcome, have been reported in patients who received Rubraca. The duration of therapy with Rubraca in patients who developed MDS/AML varied from less than 1 month to approximately 28 months.

If MDS/AML is suspected, the patient should be referred to a hematologist for further investigations, including bone marrow analysis and blood sampling for cytogenetics. If, following investigation for prolonged hematological toxicity, MDS/AML is confirmed, Rubraca should be discontinued.

Photosensitivity

Photosensitivity has been observed in patients treated with Rubraca. Patients should avoid spending time in direct sunlight because they may burn more easily during Rubraca treatment; when outdoors, patients should wear a hat and protective clothing, and use sunscreen and lip balm with sun protection factor of 50 or greater.

Gastrointestinal toxicities

Gastrointestinal toxicities (nausea and vomiting) are frequently reported with Rubraca, and are generally low grade (CTCAE grade 1 or 2), and may be managed with dose reduction (refer to Posology and Method of Administration [4.2], Table 1 of the SPC) or interruption. Antiemetics, such as 5-HT3 antagonists, dexamethasone, aprepitant and fosaprepitant, can be used as treatment for nausea/vomiting and may also be considered for prophylactic (i.e. preventative) use prior to starting Rubraca. It is important to proactively manage these events to avoid prolonged or more severe events of nausea/vomiting which have the potential to lead to complications such as dehydration or hospitalization.

Embryofetal toxicity

Rubraca can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings from animal studies. In an animal reproduction study, administration of Rubraca to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity at exposures below those in patients receiving the recommended human dose of 600 mg twice daily (see Preclinical Safety Data [5.3] of the SPC).

Pregnancy/contraception

Pregnant women should be informed of the potential risk to a fetus. Women of reproductive potential should be advised to use effective contraception during treatment and for 6 months following the last dose of Rubraca (see section 4.6 of the SPC). A pregnancy test before initiating treatment is recommended in women of reproductive potential.

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

Rubraca U.S. FDA Approved Indications

Ovarian Cancer

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.

Prostate Cancer

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.

Select Important Safety Information

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML) occur 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 (≤ 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. For males on Rubraca treatment who have female partners of reproductive potential or who are pregnant, effective contraception should be used during treatment and for 3 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 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%).

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.

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 (PDFGRα/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 FAP-2286

FAP-2286 is a preclinical candidate discovered by 3B Pharmaceuticals under investigation as a PTRT and imaging agent targeting fibroblast activation protein alpha (FAP). FAP is highly expressed in many epithelial cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas. Clovis is planning to submit an investigational new drug application (IND) for FAP-2286 in the second half of 2020. Clovis will conduct the global clinical trials and holds U.S. and global rights, excluding Europe.

FAP-2286 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. 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 study results will be consistent with study findings to date and whether future study results will support continued development or regulatory approval. 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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