NEWS RELEASE

Clovis Oncology Announces European Commission Authorization of Rubraca®▼ (rucaparib) Tablets as Maintenance Treatment for Women with Relapsed Ovarian Cancer

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- Rubraca ® (rucaparib) offers a new monotherapy option in Europe 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, regardless of BRCA status
- Positive data from the phase 3 ARIEL3 clinical trial supported this expanded indication making Rubraca available to a larger patient population in an earlier line of therapy
- Rucaparib provided statistically-significant improvement in progression-free survival versus placebo in all patients studied (median 10.8 mos vs 5.4 mos) by investigator assessment
- Most common Grade ≥3 adverse reaction was anemia; the only serious adverse reaction occurring in >2% was anemia
- Clovis Oncology plans its initial launch of rucaparib as a maintenance therapy in Germany in Q1 2019

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that the European Commission (EC) has approved the use of Rubraca® (rucaparib) for a second indication, as monotherapy 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. This expands rucaparib's indication beyond its initial marketing authorization in Europe granted in May 2018 and with this label expansion, rucaparib is now available to patients regardless of their BRCA mutation status. Rucaparib was the first PARP inhibitor licensed for an ovarian cancer treatment indication in the EU and is now the first to be available for both treatment and maintenance treatment among eligible patients.

The EC authorization is based on data from the phase 3 ARIEL3 clinical trial, which found that rucaparib significantly improved progression-free survival in all ovarian cancer patient populations studied.i

For the full European approved prescribing information, please refer to the Rubraca (rucaparib) Summary of Product Characteristics on the **European Medicines Agency website**.

Ovarian cancer is the sixth deadliest cancer among women in Europe, where more than 65,000 women are diagnosed annually.ii Moreover, the 80 to 85 percent of women diagnosed in the later stages of the disease (III and IV) have particularly poor outcomes.iii Ovarian cancer is challenging to treat, and most women will relapse after surgery and chemotherapy. Multiple studies, including the rucaparib ARIEL3 clinical trial, have demonstrated that maintenance treatment with a PARP inhibitor significantly extends median progression free survival (mPFS) as compared to observation (i.e., "watch and wait" or placebo).i

"This EC authorization of rucaparib is an important step in ensuring that it is available to all women who may potentially benefit, regardless of their BRCA status," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We believe that access to maintenance treatment is extremely important for women with relapsed platinum-sensitive ovarian cancer, and we are pleased that rucaparib can now be an option for these women. As the only PARP inhibitor that has shown further tumor shrinkage as well as prolonged progression-free survival in this maintenance setting, we believe Rubraca represents an important step forward for women with advanced ovarian cancer."

The ARIEL3 trial was a double-blind, placebo-controlled clinical trial of rucaparib that enrolled 564 women with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer in complete or partial response to platinum-based chemotherapy. Patients were randomized (2:1) to receive rucaparib tablets 600mg twice daily (n=375) or placebo (n=189).

ARIEL3 successfully achieved its primary endpoint, of extending investigator-assessed progression-free survival (PFS) versus placebo in all patients treated (intention-to-treat [ITT]), population, regardless of BRCA status; the key secondary endpoint of extending PFS as assessed by independent radiological review (IRR) was also achieved.

Parameter	Investigator assessment		IRR	
	Rucaparib	Placebo	Rucaparib	Placebo
All patients				
Patients, n	375	189	375	189
PFS events, n (%)	234 (62)	167 (88)	165 (44)	133 (70)
PFS, median in months (95% CI)	10.8 (8.3, 11.4)	5.4 (5.3, 5.5)	13.7 (11.0, 19.1)	5.4 (5.1, 5.5)
HR (95% CI)	0.36 (0.30, 0.45)		0.35 (0.28, 0.45)	
p-value	<0.0001		<0.0001	
tBRCA Group				
Patients, n	130	66	130	66
PFS events, n (%)	67 (52)	56 (85)	42 (32)	42 (64)
PFS, median in months (95% CI)	16.6 (13.4, 22.9)	5.4 (3.4, 6.7)	26.8 (19.2, NA)	5.4 (4.9, 8.1)
HR (95% CI)	0.23 (0.16, 0.34)		0.20 (0.13, 0.32)	
p-value	<0.0001		<0.0001	

An exploratory analysis of patients in the ITT population with measurable disease at baseline showed a tumor response was reported in 18% (95% CI 12%–26%) of patients (n=26) on rucaparib compared to 8% (95% CI 3% – 17%) of patients (n=5) on placebo (p value = 0.0069), including 10 patients (7%) in the rucaparib group who achieved a complete remission.

The overall safety profile of rucaparib is based on data from 937 patients with ovarian cancer treated with rucaparib monotherapy in clinical trials. Adverse reactions occurring in ≥20% of patients were nausea, fatigue/asthenia, vomiting, anaemia, abdominal pain, dysgeusia, alanine aminotransferase (ALT) elevations, aspartate aminotransferase (AST) elevations, decreased appetite, diarrhoea, thrombocytopenia and creatinine elevations. The majority of adverse reactions were mild to moderate (Grade 1 or 2).

Grade ≥3 adverse reactions occurring in >5% of patients were anemia (23%), ALT elevations (10%), fatigue/asthenia (10%), neutropenia (8%), thrombocytopenia (6%), and nausea (5%). The only serious adverse reaction occurring in > 2% of patients was anemia (5%).

Adverse reactions that most commonly led to dose reduction or interruption were anemia (20%), fatigue/asthenia (18%), nausea (16%), thrombocytopenia (15%), and AST/ALT elevations (10%). Adverse reactions leading to permanent discontinuation occurred in 10% of patients, with thrombocytopenia, nausea, anaemia, and fatigue/asthenia being the most frequent adverse reactions leading to permanent discontinuation.

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.

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

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 (≤ 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 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 **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 expectation of future development plans and the timing and pace of commencement of and enrollment in our 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 corresponding development pathways of our companion diagnostics, the initiation, enrollment and timing of our planned clinical trials and the results of our clinical trials, actions by the FDA, the EMA or other regulatory authorities regarding whether to approve drug applications that may be filed, as well as their decisions that may affect drug labeling, pricing and reimbursement, and other matters that could affect the availability or commercial potential of our drug candidates or companion diagnostics. 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.

i Coleman RL et al. Rucaparib maintenance treatment for recurrent ovarian carcinoma after response to platinum therapy (ARIEL3): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet 2017;390:1949-1961.
ii World Health Organization. Globocan 2012: estimated cancer incidence, mortality and prevalence worldwide in 2012. Accessed 23 February 2018.
iii American Cancer Society. Survival rates for ovarian cancer, by stage. **https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/survival-rates.html**

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