



NEWS RELEASE

Clovis Oncology Announces Availability of Rubraca® ▼ (rucaparib) Tablets for Women with Relapsed Ovarian Cancer in Germany

3/4/2019

- Rubraca® (rucaparib) offers a new monotherapy maintenance treatment option for eligible women with platinum-sensitive relapsed ovarian cancer, regardless of BRCA status
- Rucaparib provided statistically significant improvement in progression-free survival (PFS) versus placebo in all ovarian cancer patients studied
- Some patients with residual disease at ARIEL3 study entry who were treated with rucaparib showed further reduction in tumor burden, including complete responses
- Most common Grade ≥3 adverse reaction was anemia; the only serious adverse reaction occurring in >2% was anemia
- Rucaparib is the first PARP inhibitor to be approved for both treatment and maintenance treatment among eligible women with ovarian cancer in Europe
- Clovis Oncology intends to launch Rubraca in other European countries to follow in 2019 and 2020

BOULDER, Colo. & MUNICH--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that Rubraca® (rucaparib) is now available by prescription in Germany 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. In addition, 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 two or more prior lines of platinum-based chemotherapy, and who are unable to tolerate further platinum-based chemotherapy.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20190304005368/en/>

On January 24, 2019, the European Commission (EC) expanded rucaparib's indication beyond its

initial marketing authorization in Europe for the treatment of advanced ovarian cancer in selected patients granted in May 2018. With this label expansion, rucaparib is now approved as maintenance treatment for eligible patients regardless of their BRCA-mutation status. Rucaparib is 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.

"I have been treating women with relapsed ovarian cancer under the Rucaparib Access Program and I am confident that rucaparib represents an important treatment option for women here in Germany," said Professor Jalid Sehouli, Gynecologic Oncologist and head of the Charité European Competence Center for Ovarian Cancer at the University of Berlin. "There has been a significant need for additional treatment options for women with relapsed ovarian cancer, and rucaparib's approval in the maintenance setting provides another option for these patients."

"With this milestone approval in Germany, we are one step closer to ensuring that Rubraca is available to all eligible women who may potentially benefit," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "Rubraca has shown further tumor shrinkage as well as prolonged progression-free survival in this maintenance setting, therefore Rubraca represents an important step forward for women with advanced ovarian cancer, regardless of their BRCA status."

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

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).ⁱ

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 (median 10.8 mos vs 5.4 mos); the key secondary endpoint of extending PFS as assessed by independent radiological review (IRR) was also achieved (median 13.7 mos vs 5.4 mos).ⁱⁱ

In a prespecified exploratory analysis of patients in the ITT population with measurable disease at baseline showed a tumor response was reported in 18 percent of patients (n=26) on rucaparib compared to eight percent of patients (n=5) on placebo, including seven percent (n=10) in the rucaparib group who achieved a complete remission.ⁱ

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 $\geq 20\%$ of patients were nausea, fatigue/asthenia, vomiting, anemia, abdominal pain, dysgeusia, alanine aminotransferase (ALT) elevations, aspartate aminotransferase (AST) elevations, decreased appetite, diarrhea, thrombocytopenia and creatinine elevations. The majority of adverse reactions were mild to moderate (Grade 1 or 2). ii

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%). ii

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, anemia, and fatigue/asthenia being the most frequent adverse reactions leading to permanent discontinuation.ii

This release is only being distributed to members of the press and those health care practitioners allowed to receive prescription drug promotion.

About Ovarian Cancer in Europe and Germany

In 2018, ovarian cancer was the sixth most common cancer among women in Europe, with an estimated 68,000 women diagnosed and the fifth leading cause of cancer deaths among women, with an estimated 45,000 deaths annually. After initial therapy, many women's disease will still recur, and approximately 70% of patients with ovarian cancer will relapse within the first three years following initial treatment. Germany has the highest incidence of new cases and deaths caused by ovarian cancer in Europe. The World Health Organization estimates that in 2018 there were approximately 6,800 new cases of ovarian cancer and 5,400 ovarian cancer-related deaths in the country.

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 the EU.

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 rucaparib until they have recovered from haematological toxicities caused by previous chemotherapy (\leq CTCAE Grade 1). Complete blood count testing prior to starting treatment with rucaparib and monthly thereafter is advised. Rucaparib 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, rucaparib 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 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 plans to launch Rubraca in additional European countries and to make Rubraca available to additional eligible patients. 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 the market potential of Rubraca, including the performance of our sales and marketing efforts and the success of competing drugs and therapeutic approaches, the performance of our third-party manufacturers, our clinical development programs for our drug candidates and those of our partners, and 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.

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.

li Summary of Product Characteristics Rubraca 200, 250, 300 mg film-coated tablets. Clovis Oncology Inc. Last updated February 2019.

View source version on **businesswire.com**: <https://www.businesswire.com/news/home/20190304005368/en/>

Clovis Investor Contacts:

Anna Sussman, 303.625.5022
asussman@clovisoncology.com

Breanna Burkart, 303.625.5023
bburkart@clovisoncology.com

Clovis Media Contacts:

U.S.
Lisa Guiterman, 301.217.9353
clovismedia@sambrown.com

Christy Curran, 615.414.8668
clovismedia@sambrown.com

EU

Ann Hughes, +44 (0) 7956 700 790

Ann.Hughes@publicisresolute.com

Germany

Martin Kuegelgen +49 696 612 456 8332

Martin.Kuegelgen@mslgroup.com

Source: Clovis Oncology, Inc.