NEWS RELEASE

# Clovis Oncology Announces Rubraca®▼ (rucaparib) Now Available for Women with Relapsed Ovarian Cancer in England Through the Cancer Drugs Fund

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BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that the National Institute for Health and Care Excellence (NICE) has recommended that women with relapsed ovarian cancer in England have access to rucaparib through the Cancer Drugs Fund (CDF).1 Rucaparib is available for use within the CDF as an option for the maintenance treatment of relapsed, platinum-sensitive high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to platinum-based chemotherapy in adults, based on the conditions outlined in the managed access agreement.

"Ovacome welcomes the availability of rucaparib via the CDF as an option for maintenance treatment of platinum-sensitive relapsed high grade serous epithelial ovarian cancer regardless of BRCA status or line of treatment in the relapsed maintenance setting," said Victoria Clare, CEO of Ovacome, a United Kingdom ovarian cancer charity focused on providing support to anyone affected by ovarian cancer. "It is vital that the expansion of available maintenance options continues as maintenance treatments extend the time between chemotherapies. Many women with relapsed ovarian cancer know that they are facing a future of managing their disease as a chronic illness."

"For too long ovarian cancer treatment options beyond chemotherapy or surgery have been limited, and today's announcement means that women with ovarian cancer have more choice in their treatment than ever before," said Annwen Jones, Chief Executive of Target Ovarian Cancer, a United Kingdom ovarian cancer charity. "Target Ovarian Cancer has long campaigned for better treatment for women with ovarian cancer and we are delighted to see this latest development."

Approximately 6,400 women are diagnosed with ovarian cancer in the UK every year, which equates to roughly 17 every day.2 Despite advancements in treatment and care, more than 4,000 women still die each year from ovarian

cancer in the UK.2 Of those treated with surgery and first line chemotherapy, approximately 70% of patients will relapse within the first three years.3

“Inclusion of rucaparib in the CDF as an option for maintenance treatment for patients with recurrent ovarian cancer responding to platinum-based therapy regardless of BRCA mutation status or line of treatment in the relapsed maintenance setting represents a much-needed treatment option for women with recurrent ovarian cancer,” said Professor Jonathan Ledermann, MD, Professor of Medical Oncology, UCL Cancer Institute and UCL Hospitals, London, global Principal Investigator for non-US sites in the ARIEL3 study. “I am pleased that the CDF recommendation includes access for the broad patient population evaluated in the ARIEL3 trial which demonstrated rucaparib to be effective in eligible patients, regardless of their BRCA mutation status, providing a clinically-meaningful median progression-free survival of more than one year across the entire population studied by independent radiological review. This represents a significant step in the effective management of relapsed ovarian cancer in the NHS in England.”

The European Union (EU) conditional marketing authorization is based on data from the pivotal Phase 3 ARIEL3 clinical trial. ARIEL3 successfully achieved its primary endpoint of extending investigator-assessed PFS versus placebo in all patients treated (intention-to-treat, or ITT), population, regardless of BRCA status (median 10.8 months vs 5.4 months).4,5 In addition, it successfully achieved the key secondary endpoint of extending PFS by independent radiological review versus placebo in all patients treated (ITT), regardless of BRCA status (median 13.7 months vs 5.4 months).5 The overall safety profile of rucaparib is based on data from 937 patients with ovarian cancer treated with rucaparib monotherapy in clinical trials.5

“We welcome NICE’s recommendation to make rucaparib available through the CDF to all eligible women in England who may potentially benefit from this important therapeutic option,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “For women with recurrent ovarian cancer, access to new treatments that successfully demonstrate prolonged progression-free survival is essential in the fight against this deadly disease and central to Clovis Oncology’s mission to provide the right drug, to the right patient at the right time.”

## About Rubraca® (rucaparib)

Rubraca is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 that is being developed in multiple tumor types, including ovarian and metastatic castration-resistant prostate cancer (mCRPC), as monotherapy, and in combination with other anti-cancer agents. Exploratory studies in other tumor types are also underway.

## Rubraca® (rucaparib) European Union (EU) Conditional Marketing Authorization

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.

## Summary Warnings, Precautions and Safety

Efficacy of Rubraca as treatment for relapsed or progressive EOC, FTC, or 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.

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

The ≥ Grade 3 adverse reactions occurring in > 5% of patients were anaemia (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 anaemia (5%).

Adverse reactions that most commonly led to dose reduction or interruption were anaemia (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.

During treatment with rucaparib, events of myelosuppression (anaemia, neutropenia, thrombocytopenia) may be observed and are typically first observed after 8-10 weeks of treatment with rucaparib. 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 rucaparib and monthly thereafter, is advised. Patients should not start rucaparib until they have recovered from haematological toxicities caused by previous chemotherapy (≤ CTCAE Grade 1).

Myelodysplastic syndrome/acute myeloid leukaemia (MDS/AML), including cases with fatal outcome, have been

reported in patients who received rucaparib. The duration of therapy with rucaparib 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 haematologist for further investigations, including bone marrow analysis and blood sampling for cytogenetics. If, following investigation for prolonged haematological toxicity, MDS/AML is confirmed, rucaparib should be discontinued.

Further information should be obtained from the Rucaparib Summary of Product Characteristics (SmPC) found here: **https://www.medicines.org.uk/emc/product/10028/smpc**.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Side effects should be reported. See **https://yellowcard.mhra.gov.uk** for how to report side effects.

## 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 our plans to launch Rubraca in additional European countries, including the United Kingdom, 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.

## References


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2. World Health Organization. GLOBOCAN: estimated cancer incidence, mortality and prevalence worldwide in 2018. Available at **http://gco.iarc.fr/** Last accessed October 2019.
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4. 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;390:1949–61.
5. Summary of Product Characteristics Rubraca 200, 250, 300 mg film-coated tablets. Available at: **https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information_en.pdf**. Last accessed October 2019.


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