



NEWS RELEASE

## Clovis Oncology Announces Completion of Target Enrollment in the ATHENA Trial, a Phase 3 Maintenance Treatment Study in Front-line, Newly-Diagnosed Advanced Ovarian Cancer

6/10/2020

- Topline data for Rubraca monotherapy arm vs placebo expected 2H 2021; intended to support a supplemental New Drug Application filing (sNDA)
- Topline data from Rubraca and Opdivo in combination vs Rubraca monotherapy expected one year or more later

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today the completion of target patient enrollment in the Clovis-sponsored Phase 3 ATHENA trial evaluating the combination of Clovis' Rubraca®(rucaparib), a poly (ADP ribose) polymerase inhibitor (PARP), and Bristol-Myers Squibb's PD-1 inhibitor, OPDIVO® (nivolumab), as front-line maintenance treatment of newly-diagnosed advanced ovarian cancer. ATHENA is the first front-line switch maintenance study designed to show PARP monotherapy and PARP/PD-1 combination therapy in one study design.

"The completion of target patient enrollment in the Phase 3 ATHENA trial is an important milestone for Clovis and a critical step toward developing additional therapeutic options for women with advanced ovarian cancer," said Patrick J. Mahaffy, President and Chief Executive Officer of Clovis Oncology. "This was a tremendous effort by trial investigators, our collaborators and our dedicated Clovis team to complete target enrollment in this 1,000-patient study in under two years. Most important, we are grateful to all of the patients who participated in this study."

ATHENA is a Phase 3, randomized, multinational, double-blind, placebo-controlled, four-arm trial evaluating Rubraca and Opdivo as maintenance treatment following response to front-line treatment in newly-diagnosed ovarian cancer patients. Response to treatment will be analyzed based on homologous recombination (HR) status of tumor samples. The primary endpoint is investigator assessed progression-free survival (PFS); secondary endpoints include overall survival (OS), objective response rate (ORR), duration of response (DOR), and safety.

Target enrollment for the ATHENA trial was 1,000 ovarian cancer patients. Patients were enrolled at clinical trial centers in 24 countries including North America, Europe and Asia.

Topline data for the Rubraca monotherapy versus placebo arm in all study populations is expected in the second half of 2021 and, if supportive, would serve as the basis of an sNDA for the maintenance treatment of front-line, newly-diagnosed, advanced ovarian cancer patients. Topline data for the combination of Rubraca and Opdivo versus Rubraca monotherapy in all study populations are expected a year or more later and, if supportive, would serve as the basis of an sNDA for the combination therapy in front-line, newly-diagnosed ovarian cancer. In each of these, the primary efficacy analysis will evaluate two prospectively defined molecular sub-groups in a step-down manner: first, HRD-positive patients, including BRCA-mutant patients; and the intent-to-treat population, or all patients treated in ATHENA.

## About Rubraca (rucaparib)

Rubraca is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in ovarian cancer as well as several additional solid tumor indications. Studies open for enrollment or under consideration include ovarian, prostate, breast, gastroesophageal, pancreatic, and lung cancers. Clovis holds worldwide rights for Rubraca.

In the United States, Rubraca is approved 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 also approved in the United States for the treatment of adult patients with 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 and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. Additionally, 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.

In Europe, Rubraca is approved 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. Rubraca is also approved in Europe for the 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. 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.

Rubraca is an unlicensed medical product outside of the U.S. and Europe.

## 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](http://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 made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Examples of forward-looking statements contained in this press release include, among others, our expectations regarding the timing and pace of conduct of our clinical trials, including those being planned or conducted in collaboration with partners, the potential results of such clinical trials, our plans for submission of regulatory filings, and our plans to present data on ongoing 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 impacts of the COVID-19 pandemic and disruption on our ability to continue our development activities, impacts on the conduct of our clinical trials, including with respect to availability of investigators and clinical trial sites or monitoring of data, whether our clinical development programs for our drug candidates and those of our partners can be completed on time or at all, the timing of availability of data from our clinical trials and the results, 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, their interpretations of our data and agreement with our regulatory approval strategies or components of our filings, including our clinical trial designs, conduct and methodologies, as well as their decisions regarding drug labeling, reimbursement and pricing, and other matters that could affect the development, approval, availability or commercial potential of our drug candidates or companion diagnostics. In particular, there are no guarantees that future study results and patient experience will be consistent with the study findings to date, that Rubraca will receive regulatory approval for any future indications, or that it will prove to be commercially successful. 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. All forward-looking statements are based on information currently available to the company, and Clovis Oncology does not undertake to update or revise any forward-looking statements

View source version on **businesswire.com**: <https://www.businesswire.com/news/home/20200610005746/en/>

#### Clovis Oncology Investor Contacts:

Anna Sussman, 303-625-5022

**asussman@clovisoncology.com**

or

Breanna Burkart, 303-625-5023

**bburkart@clovisoncology.com**

#### Clovis Oncology Media Contacts:

U.S.

Lisa Guiterman, 301-217-9353

**clovismedia@sambrown.com**

Europe

Jake Davis, +44 (0) 203.946.3538

**Jake.Davis@publicisresolute.com**

or

Joanna Sullivan, +44 (0) 207.173.4191

**Joanna.Sullivan@publicisresolute.com**

Source: Clovis Oncology