



Clovis Oncology Initiates Early Access Program for Rucaparib as Treatment and as Maintenance Therapy in Recurrent Ovarian Cancer in Europe

March 23, 2018

BOULDER, Colo.--(BUSINESS WIRE)--Mar. 23, 2018-- Clovis Oncology, Inc. (NASDAQ:CLVS) today announced the initiation of an early access program in Europe for rucaparib for treatment and as maintenance therapy in recurrent ovarian cancer. The program will be overseen and implemented by Caligor Coghlan, which specializes in early access to medicines.

The program, to be known as the Rucaparib Access Program (RAP), will enable participation from certain countries in Europe, where permitted by applicable rules, procedures and regulatory authorities. The RAP protocol allows for rucaparib treatment of an individual patient with third-line or greater BRCA mutant epithelial, fallopian tube, or primary peritoneal ovarian cancer who has platinum-sensitive disease and is unable to tolerate further platinum-based chemotherapy or has platinum-resistant disease and needs treatment with single agent rucaparib. The RAP protocol will also provide access to rucaparib for maintenance therapy of an individual patient with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who has received at least two prior platinum-based treatment regimens, has platinum-sensitive disease, and is in a complete or partial response to the most recent platinum-based regimen. In all cases, the patient must have a special clinical need that cannot be met by current licensed available medicines. Patients must be ineligible for Clovis' ARIEL4 clinical trial or unable to access a participating ARIEL4 site to qualify for Clovis' early access program.

Questions or inquiries regarding the RAP should be directed to rucaparibaccessEU@caligorr.com.

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, lung and bladder cancers. Clovis holds worldwide rights for Rubraca.

In the United States, Rubraca is approved on an accelerated basis as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer, who have been treated with two or more chemotherapies, and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. In December 2017, the U.S. Food and Drug Administration (FDA) accepted the Company's supplemental New Drug Application (sNDA) for Rubraca for a second-line or later maintenance treatment indication in ovarian cancer based on the ARIEL3 data. The FDA granted Priority Review status to the application with a Prescription Drug User Fee Act (PDUFA) date of April 6, 2018.

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

About Early Access Programs

Early Access Programs provide companies with a way to allow ethical access to their pre-license/unlicensed medicines to help patients with unmet medical needs. Access is provided in response to physician requests, in a fully compliant manner, where no alternative treatment options are available.

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, and has additional offices in San Francisco, California and Cambridge, UK. Please visit 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, statements regarding our expectation of timing for European Commission approval of rucaparib for the treatment indication and the filing of a variation to the MA for a maintenance indication for rucaparib. 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 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.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20180323005344/en/>

Source: Clovis Oncology, Inc.

Clovis Oncology, Inc.
Breanna Burkart
303.625.5023
bburkart@clovisoncology.com

or
Anna Sussman
303.625.5022
asussman@clovisoncology.com