Clovis Oncology Announces Rucaparib Data Presentations at ESMO 2016 Congress

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- *Data for rucaparib in the treatment of advanced ovarian cancer to be highlighted in oral presentation*
- *U.S. Food and Drug Administration (FDA) accepted accelerated approval application for review and granted priority review status*
- *Prescription Drug User Fee Act (PDUFA) date is February 23, 2017*
- *European Marketing Authorization Application (MAA) planned in Q4 2016*

BOULDER, Colo.--(BUSINESS WIRE)--Sep. 28, 2016-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that data from its rucaparib program in ovarian cancer will be presented at the annual European Society for Medical Oncology (ESMO) 2016 Congress. ESMO will take place October 7-11, 2016 in Copenhagen, Denmark. The data being presented comprise the primary efficacy and safety data included in the New Drug Application (NDA) currently under priority review with the FDA.

Rucaparib is the Company's oral, potent, small molecule inhibitor of PARP1, PARP2 and PARP3 currently being developed for the treatment of advanced ovarian cancer, specifically in patients with tumors with BRCA mutations and other DNA repair deficiencies beyond BRCA (commonly referred to as homologous recombination deficiencies, or HRD). Data from rucaparib studies are the subject of one oral and one poster presentation at the conference:

Abstract 856O – *Clinical activity of the poly(ADP-ribose) polymerase (PARP) inhibitor rucaparib in patients (pts) with high grade ovarian carcinoma (HGOC) and a BRCA mutation (BRCAmut): Analysis of pooled data from Study 10 (parts 1, 2a, and 3) and ARIEL2 (parts 1 and 2)*

- Rebecca S. Kristeleit, PhD, The University College London, Cancer Institute, London, United Kingdom
- Friday, October 7 from 2:45pm-3:00pm CEST
- Location: Oslo

Abstract 219TiP – *Window study of the PARP inhibitor rucaparib in patients with primary triple negative or BRCA1/2 related breast cancer (RIO)*

- Christy Toms, PhD, The Institute of Cancer Research, Sutton, United Kingdom
- Monday, October 10 from 1:00pm-2:00pm CEST
- Location: Hall E, Poster Board #219

About Rucaparib

Rucaparib is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed for advanced ovarian cancer.

Specifically, Clovis is developing rucaparib as monotherapy treatment of advanced ovarian cancer in patients with deleterious BRCA-mutated tumors inclusive of both germline and somatic BRCA mutations (as detected by an FDA-approved test) who have been treated with two or more chemotherapies. Rucaparib was granted Breakthrough Therapy Designation for this proposed indication by the FDA in April 2015. In August 2016, the FDA accepted Clovis' New Drug Application (NDA) submission for accelerated approval of rucaparib and granted priority review status to the application with a PDUFA date of February 23, 2017; and in September 2016, the FDA notified Clovis that the Agency is not planning to hold an advisory committee meeting to discuss the Company's NDA for rucaparib. The Company's Marketing Authorization Application (MAA) to the European Medicines Agency for the proposed treatment indication for rucaparib is planned for Q4 2016.

Additionally, Clovis is developing rucaparib as maintenance therapy in the ARIEL3 trial for ovarian cancer patients with tumors with BRCA mutations and other DNA repair deficiencies beyond BRCA (commonly referred to as homologous

recombination deficiencies, or HRD). Data from ARIEL3 are expected in Q4 2017, which is expected to be followed by the submission of a supplemental NDA for a second-line or later maintenance indication.

Rucaparib is also being explored in other solid tumor types with BRCA and HRD populations, including breast, prostate and gastroesophageal cancers.

Clovis holds worldwide rights for rucaparib.

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 aimed at specific subsets of cancer populations, and simultaneously develops diagnostic tools that direct a compound in development to the population that is most likely to benefit from its use. Clovis Oncology is headquartered in Boulder, Colorado.

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. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those 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, the corresponding development pathways of our companion diagnostics, 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 regarding drug labeling, and other matters that could affect the availability or commercial potential of our drug candidates or companion diagnostics, including competitive developments. 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.

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Source: Clovis Oncology, Inc.

Clovis Oncology, Inc.
Breanna Burkart, 303-625-5023
bburkart@clovisoncology.com
or
Anna Sussman, 303-625-5022
asussman@clovisoncology.com