



Clovis Oncology Announces 2018 Operating Results

- 2018 Rubraca® (rucaparib) U.S. sales totaled \$95.4M, including \$30.4M for the fourth quarter of 2018
- Rubraca EU approval granted January 2019 for ovarian cancer maintenance treatment indication; launch in Germany to initiate on this Friday, March 1
- Robust Clovis-sponsored Rubraca development program in place; enrollment ongoing for clinical studies in ovarian, prostate and bladder cancers
- Targeting late 2019 for supplemental NDA filing for BRCA-mutant advanced prostate cancer, pending data maturity; interim data update expected at Fall 2019 medical meeting
- Initial data from ATLAS advanced bladder study expected at a Fall 2019 medical meeting
- Three studies underway to evaluate Rubraca in combination with Opdivo® (nivolumab) as part of clinical collaboration with Bristol-Myers Squibb; enrollment ongoing or planned for ovarian, prostate and bladder studies; active discussions underway for additional tumor types and clinical studies
- Clinical collaboration with Bristol-Myers Squibb established for combination of lucitanib and Opdivo; Clovis-sponsored studies to begin in the first half of 2019
- \$520.1M in cash, cash equivalents and available for sale securities at December 31, 2018

BOULDER, Colo., February 26, 2019 – [Clovis Oncology](#), Inc. (NASDAQ:CLVS) reported financial results for the quarter and year ended December 31, 2018, and provided an update on the Company's [clinical development programs](#) and regulatory and commercial outlook for 2019.

"We are pleased to have renewed U.S. revenue growth in the fourth quarter, and with our maintenance treatment indication approved in the EU, we look forward to our initial European launch in Germany on March 1," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "In addition, we are targeting an sNDA filing for BRCA1/2-mutant metastatic castration-resistant prostate cancer (mCRPC) in late 2019, and we expect to present data from both the TRITON2 mCRPC study and the ATLAS study in advanced bladder cancer at a Fall 2019 medical meeting. We are also very pleased to further our clinical collaboration with Bristol-Myers Squibb to not only include a combination study of Opdivo and lucitanib, but also to discuss tumor types for potential additional combination studies with Rubraca."

Fourth Quarter and Year-End 2018 Financial Results

Clovis reported product revenue for Rubraca of \$30.4 million for the fourth quarter of 2018 and \$95.4 million for the year ended December 31, 2018. For both the fourth quarter and year, the supply of free drug distributed to eligible patients through the Rubraca patient assistance program was approximately 26 percent of overall commercial supply. This represented \$10.4 million in commercial value for the fourth quarter and \$33.4 million in commercial value for the full year. Net product revenue for the quarter and fiscal year ended December 31, 2017 was \$17.0 million and \$55.5 million. Rubraca was initially approved and launched in the ovarian cancer

treatment setting in the U.S. in December 2016 and in April 2018 the Rubraca label was expanded to include the broader and earlier-line maintenance treatment indication.

Clovis had \$520.1 million in cash, cash equivalents and available-for-sale securities as of December 31, 2018. Cash used in operating activities was \$82.7 million for the fourth quarter of 2018 and \$366.0 million for the year ended December 31, 2018, compared with \$65.6 million and \$260.9 million for the comparable periods of 2017. This includes product supply costs of \$22.7 million in the fourth quarter of 2018 and \$98.8 million for the year ended December 31, 2018, compared to \$12.0 million and \$53.5 million for the comparable periods in 2017. Clovis had approximately 52.8 million shares of common stock outstanding as of December 31, 2018. In April 2018, Clovis raised net proceeds of \$93.9 million through an offering of 1.8 million shares of common stock and \$290.9 million in proceeds on \$300 million aggregate principal amount of 1.25% convertible senior notes due 2025. The net proceeds from these offerings were \$384.8 million, after deducting underwriting discounts and commissions, and offering expenses.

Clovis reported a net loss for the fourth quarter of 2018 of \$99.3 million, or (\$1.88) per share, and \$368.0 million or (\$7.07) per share for the year ended December 31, 2018. The net loss for the fourth quarter of 2017 was \$51.9 million, or (\$1.04) per share and \$346.4 million, or (\$7.36) per share for the year ended December 31, 2017. Net loss for the fourth quarter of 2018 included share-based compensation expense of \$11.4 million and \$49.1 million for the full year 2018, respectively, compared to \$12.5 million and \$44.7 million for the comparable periods of 2017.

The net loss for the year ended December 31, 2018 includes a one-time charge of \$20 million related to a final settlement reached with the Securities and Exchange Commission which resolves their investigation related to rociletinib, and a charge of \$8.0 million related to a legal settlement. The net loss for the year ended December 31, 2017 included a charge of \$105.5 million related to the portion of a legal settlement that was paid in Clovis common stock. The adjusted net loss excluding these items was \$99.3 million or (\$1.88) per share for the fourth quarter and \$340.0 million or (\$6.53) per share for the fiscal year ended 2018 and \$63.4 million or (\$1.27) per share for the fourth quarter and \$240.9 million or (\$5.12) per share for the fiscal year ended 2017.

Research and development expenses totaled \$71.2 million for the fourth quarter of 2018, and \$231.3 million for the full year 2018, compared to \$38.0 million and \$142.5 million, respectively, for the comparable periods in 2017. The increase year over year is primarily due to higher research and development costs for rucaparib clinical trials, including increased enrollment in ongoing ovarian and prostate studies, increased costs related to initiating new ovarian and bladder studies during 2018, as well as additional headcount to support these increased rucaparib clinical trial activities.

Selling, general and administrative expenses totaled \$49.1 million for the fourth quarter of 2018, and \$175.8 million for the full year 2018, compared to \$38.5 million and \$138.9 million for the comparable periods in 2017. The increase year over year is primarily due to higher selling, general and administrative expenses related to the commercialization of Rubraca in the U.S. and the EU, including facility expenses and personnel expenses associated with establishing the EU infrastructure.

Key Milestones and Objectives for Rubraca

Recurrent Ovarian Cancer Maintenance Treatment Indication Approved in both U.S. and the EU

In April 2018, Rubraca was granted its second indication by the U.S. FDA as 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. This approval, in a broader and earlier-line indication, was based on positive data from the phase 3 ARIEL3 clinical trial. Biomarker testing is not required for patients to be prescribed Rubraca in this maintenance treatment indication.

In January 2019, the European Commission (EC) also approved the use of Rubraca for its second indication, 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. This approval expands rucaparib's indication beyond its initial marketing authorization in the EU granted in May 2018, and in this indication Rubraca is available to eligible patients regardless of their BRCA mutation status. Rucaparib was the first PARP inhibitor licensed for an ovarian cancer treatment indication in Europe and is the first to be available for both treatment and maintenance treatment among eligible patients. Clovis has established its EU organization to support its initial launch in Germany this Friday, March 1 and anticipates launching in other EU countries later in 2019 and 2020.

Regulatory Path for Supplemental NDA in BRCA-mutant Advanced Prostate Cancer Based on TRITON2 Dataset and Breakthrough Therapy Designation

Initial data from the Company's ongoing TRITON studies of Rubraca in advanced prostate cancer were presented at the ESMO 2018 Congress (European Society for Medical Oncology) in October 2018. The initial TRITON2 data showed a 44% confirmed objective response rate (ORR) by investigator assessment in 25 RECIST¹/PCWG3** response-evaluable patients with a *BRCA1/2* alteration, and results by independent assessment were consistent. The median duration of response in these patients had not yet been reached. In addition, a 51% confirmed prostate specific antigen (PSA) response rate was observed in 45 PSA response-evaluable patients with a *BRCA1/2* alteration. Preliminary safety data for Rubraca in men with mCRPC were consistent with those observed in patients with ovarian cancer and other solid tumors.

The TRITON2 results were the basis for Breakthrough Therapy designation for Rubraca as a monotherapy treatment of adult patients with *BRCA1/2* mutated mCRPC who have received at least one prior androgen receptor (AR)-directed therapy and taxane-based chemotherapy, which was granted on October 1, 2018 by the U.S. Food and Drug Administration (FDA). Both studies in the TRITON program, TRITON2 and TRITON3, continue to enroll patients.

Pending data maturity, Clovis is targeting the filing of a supplemental NDA (sNDA) for Rubraca in BRCA-mutant advanced prostate cancer in late 2019.

¹ Response Evaluation Criteria in Solid Tumors (RECIST) is a standardized methodology for determining therapeutic response to anticancer therapy using changes in lesion appearance on imaging studies.

** Prostate Cancer Working Group (PCWG3) is an international expert committee of prostate cancer clinical investigators who have recommended modifications to RECIST for use in the conduct of trials in metastatic castration-resistant prostate cancer (mCRPC) which were adopted in the TRITON2 protocol.

Rubraca Clinical Development

Clovis has a robust clinical development program underway in multiple tumor types, including Clovis-sponsored, partner-sponsored and investigator-initiated trials. The following clinical studies are open for enrollment or are anticipated to open during the next several months:

- The Clovis-sponsored ARIEL4 confirmatory study in the treatment setting is a Phase 3 multicenter, randomized study of Rubraca versus chemotherapy in relapsed ovarian cancer patients with BRCA mutations who have failed two prior lines of therapy. This study is currently enrolling patients.
- The Clovis-sponsored Phase 3 ATHENA study in advanced ovarian cancer in the first-line maintenance treatment setting evaluating Rubraca plus Opdivo[®] (PD-1 inhibitor), Rubraca, Opdivo and placebo in newly-diagnosed patients who have completed platinum-based chemotherapy. This study, as part of a broad clinical collaboration with Bristol-Myers Squibb, is currently enrolling patients.
- The Clovis-sponsored TRITON3 study, a Phase 3 comparative study in mCRPC enrolling BRCA-mutant and ATM-mutant (both inclusive of germline and somatic) patients who have progressed on androgen-receptor (AR)-targeted therapy and who have not yet received chemotherapy in the castration-resistant setting. TRITON3 compares Rubraca to physician's choice of AR-targeted therapy or chemotherapy in these patients. This study is currently enrolling patients.
- The Clovis-sponsored TRITON2 study in mCRPC, a Phase 2 single-arm study in patients with BRCA mutations (inclusive of germline and somatic) and is also enrolling patients with deleterious mutations of other homologous recombination (HR) repair genes. All patients will have progressed after receiving one line of taxane-based chemotherapy and one or two lines of AR-targeted therapy. This study is currently enrolling patients. Updated data from the ongoing TRITON2 study are anticipated at a Fall 2019 medical meeting.
- The Clovis-sponsored ATLAS study is a single-arm Phase 2 open-label monotherapy study of Rubraca in recurrent, metastatic bladder cancer. This study is currently enrolling patients, and initial data from the ongoing ATLAS study are anticipated at a Fall 2019 medical meeting.
- The Phase 1 RUCA-J study, sponsored by Clovis, has identified the 600mg BID dose of rucaparib as the recommended dose in Japanese patients; this will enable development of a bridging strategy and potential inclusion of Japanese sites in planned or ongoing global studies. This study is currently enrolling patients.
- The Phase 2, open-label, multi-cohort ARIES study evaluating the combination of Rubraca and Opdivo in patients with relapsed ovarian cancer and patients with locally advanced or metastatic bladder carcinoma. This study is sponsored by Clovis and is expected to begin enrolling patients in the first half of 2019.
- The Phase 1/2 combination study of sacituzumab govitecan and Rubraca for the treatment of advanced metastatic triple-negative breast cancer, relapsed platinum-resistant ovarian cancer and metastatic urothelial cancers is sponsored by Clovis and is expected to begin enrolling patients in 2019.
- The Phase 2 combination study of Opdivo with Rubraca for the treatment of mCRPC. This study, sponsored by Bristol-Myers Squibb, is being conducted as an arm in the CHECKMATE 9KD prostate cancer study, and is currently enrolling patients.

Exploratory studies in other tumor types are also underway, as well as active discussions with Bristol-Myers Squibb regarding additional potential combination studies.

Lucitanib Clinical Development

Lucitanib is an investigational, oral, potent inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors 1 through 3 (VEGFR1-3), platelet-derived growth factor receptors alpha and beta (PDGFR α/β)

and fibroblast growth factor receptors 1 through 3 (FGFR1-3), which was previously evaluated in breast and lung cancers in partnership with Servier. Clovis has global rights (excluding China) for lucitanib.

Recent data for a drug that inhibits these same three pathways - when combined with a PD-1 inhibitor - are extremely encouraging and represent a scientific rationale for the development of lucitanib in combination with a PD-1 inhibitor, and a Clovis-sponsored study of lucitanib in combination with Opdivo is planned in gynecologic cancers. Clovis also intends to initiate a study of lucitanib in combination with rucaparib in ovarian cancer, based on encouraging data of VEGF and PARP inhibitors in combination. Each of these Phase 1b/2 studies is expected to initiate during the first half of 2019.

Conference Call Details

Clovis will hold a conference call to discuss Q4/FY 2018 results this morning, February 26, at 8:30am ET. The conference call will be simultaneously webcast on the Company's web site at www.clovisoncology.com, and archived for future review. Dial-in numbers for the conference call are as follows: US participants 866.393.4306, International participants 734.385.2616, conference ID: **6675335**.

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 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.

In the EU, 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. This expands rucaparib's indication beyond its initial marketing authorization in the EU granted in May 2018 and with this label expansion, rucaparib is now available to patients regardless of their BRCA mutation status. Rubraca is also approved in the EU 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 an unlicensed medical product outside of the U.S. and the EU.

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 expectations for submission of regulatory filings, our plans to present final or interim data on ongoing clinical trials, the timing and pace of commencement of and enrollment in our clinical trials, including those being considered, planned or conducted in collaboration with partners, the potential results of such clinical trials, changes in drug supply timing and costs and other expenses and statements regarding our expectations of the supply of free drug distributed to 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 our approved drug, 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, whether future study results will be consistent with study findings to date and whether future study results will support continued development or regulatory approval, the corresponding development pathways of our companion diagnostics, the timing of availability of data from our clinical trials and the results, the initiation, enrollment, timing and results of our planned clinical trials, the risk that final results of ongoing trials may differ from initial or interim results as a result of factors such as final results from a larger patient population may be different from initial or interim results from a smaller patient population, 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, and other matters that could affect the development, 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.

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