**Clovis Oncology Announces 2016 Operating Results**

February 22, 2017 4:06 PM ET

- *Rubraca™ (rucaparib) approved and launched in the U.S. on December 19, 2016 for the treatment of advanced BRCA-mutant ovarian cancer*
- *$266.2M in cash, cash equivalents and available for sale securities at December 31, 2016*
- *$487.4M in adjusted cash, cash equivalents and available for sale securities at December 31, 2016 as adjusted for the January 2017 financing proceeds of $221.2 million*
- *Rucaparib MAA submission accepted and under review; CHMP opinion anticipated Q4 2017*
- *Establishing EU commercial organization*
- *Data from ARIEL3 pivotal rucaparib maintenance study expected mid-2017*
- *Robust rucaparib development plan in place; clinical studies in ovarian, prostate, breast and gastroesophageal cancers open for enrollment or initiating this quarter*

BOULDER, Colo.--(BUSINESS WIRE)--Feb. 22, 2017-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for the quarter and year ended December 31, 2016, and provided an update on the Company's clinical development programs and regulatory outlook for 2017.

"We are extremely pleased with the Rubraca launch to date; our commercial team hit the ground running and we are committed to the successful launch of this new therapeutic option for the treatment of advanced ovarian cancer," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We are preparing for a potential approval in the EU in late 2017 or early 2018, and are aggressively building our European organization. We continue to anticipate the ARIEL3 read out in mid-2017, and we look forward to expanding the TRITON program into earlier line castrate-resistant prostate cancer. We will provide additional details on this study and other clinical development plans to develop rucaparib in other indications as well as in combination with an immuno-oncology agent over the course of this year."

**Fourth Quarter and Year-End 2016 Financial Results**

Clovis had $266.2 million in cash, cash equivalents and available-for-sale securities as of December 31, 2016. Cash used in operating activities was $54.7 million for the fourth quarter of 2016 and $266.7 million for the year ended December 31, 2016. Clovis had approximately 38.7 million shares of common stock outstanding as of December 31, 2016. In January 2017, the Company raised net proceeds of $221.2 million through an offering of 5.75 million shares of common stock.

Clovis reported a net loss for the fourth quarter of 2016 of $70.7 million, or ($1.83) per share, and $349.1 million or ($9.07) per share for the year ended December 31, 2016. The net loss for the fourth quarter of 2015 was $119.5 million or ($3.12) per share and $352.9 million or ($9.79) per share for the year ended December 31, 2015. Net loss for the fourth quarter of 2016 included share-based compensation expense of $10.1 million and $39.8 million for the full year 2016, respectively, compared to $10.9 million and $40.4 million for the comparable periods of 2015. Net product revenue for the quarter and the year was $78 thousand, following the approval and launch of Rubraca on December 19, 2016.

The net loss for the year ended December 31, 2016 includes a net expense non-cash impact of $50.6 million relating to the lucitanib product rights recorded in 2013 in connection with the Company's acquisition of Ethical Oncology Science S.p.A. (EOS), comprised of a $104.5 million non-cash expense for the impairment of the intangible asset, a $25.5 million non-cash expense credit for the reduction in the fair value of the contingent purchase consideration liability and a $28.4 million related non-cash income tax benefit. The non-GAAP adjusted net loss excluding these items was $298.6 million or ($7.76) per share for the full year 2016.

Research and development expenses totaled $54.5 million for the fourth quarter of 2016, and $251.1 million for the full year 2016, compared to $76.0 million and $269.3 million, respectively, for the comparable periods in 2015. The decrease year over year is primarily due to decreased development activities for the rociletinib program and to a lesser extent,

expenses related to the commercialization of Rubraca, which had been classified as research and development prior to FDA approval, partially offset by higher expenses related to the rucaparib program.

Selling, general and administrative expenses totaled $12.2 million for the fourth quarter of 2016, and $40.7 million for the full year 2016, compared to $8.2 million and $30.5 million for the comparable periods in 2015. The increase year over year is primarily due to higher legal costs; selling, general and administrative expenses related to the commercialization of Rubraca, which had been classified as research and development prior to FDA approval; and to a lesser extent, higher personnel costs.

**Key Milestones and Objectives for Rucaparib**

On December 19, 2016, the U.S. Food and Drug Administration (FDA) approved Rubraca (rucaparib) tablets 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. The indication for Rubraca is approved under the FDA's accelerated approval program, and is based on objective response rate and duration of response results from two multicenter, single-arm, open-label clinical trials, Study 10 and ARIEL2 Parts 1 and 2. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The ARIEL3 maintenance confirmatory study has completed enrollment and the ARIEL4 treatment confirmatory study is open for enrollment.

The ARIEL3 pivotal study is a randomized, double-blind study comparing the effects of rucaparib against placebo to evaluate whether rucaparib given as a maintenance therapy to platinum-sensitive patients can extend the period of time for which the disease is controlled after a positive outcome with platinum-based chemotherapy. Patients who have high-grade serous ovarian cancer and have had at least two prior lines of platinum-based chemotherapies are randomized to receive either placebo or rucaparib and the primary endpoint of the study is progression free survival, or PFS.

The primary efficacy analysis will evaluate, in a step-down process, BRCA-mutant patients, all patients with a homologous recombination deficiency, or HRD, signature (including BRCA and non-BRCA), followed by all patients. In addition, a pre-specified subgroup analysis is planned to evaluate patients with low volume or no residual disease at baseline, to determine the impact of disease burden on PFS. Importantly, this analysis will also identify the size of the population with meaningful disease still present after a partial response to second-line platinum therapy.

Target enrollment in ARIEL3 was completed during the second quarter of 2016. Data from ARIEL3 are expected mid-2017. Clovis has not yet been notified by the independent statistician that the required 70 percent of events in the mutant BRCA population has been reached, which will trigger the final analysis of the data. Pending positive data from ARIEL3, Clovis intends to follow up with a supplemental NDA for second-line maintenance therapy in women with ovarian cancer who have responded to platinum-based therapy.

The ARIEL4 confirmatory study, which is open for enrollment, is a Phase 3 multicenter, randomized study of rucaparib versus chemotherapy in relapsed ovarian cancer patients with BRCA mutations (inclusive of germline and/or somatic) who have failed two prior lines of therapy. The primary endpoint of the study is PFS.

Also during the quarter, the Company submitted an MAA for rucaparib to the European Medicines Agency for the same ovarian cancer treatment indication that was submitted to the U.S. FDA. Clovis anticipates an opinion from the Committee for Medicinal Products for Human Use (CHMP) in late 2017, and, pending a favorable opinion from CHMP, an approval would follow shortly thereafter.

In October, in support of the anticipated U.S. commercial launch of rucaparib, Clovis entered into a long-term manufacturing and supply agreement with Lonza, the manufacturer of the active pharmaceutical ingredient (API) for rucaparib. This new agreement for a dedicated manufacturing line is expected to provide security of supply and reduce cost of goods over time.

In February, Clovis entered into an agreement with Strata Oncology to accelerate patient identification and enrollment in the TRITON prostate cancer development program. The Strata trial is an observational study that provides no-cost tumor sequencing to patients at participating clinical sites, and under this agreement, match BRCA and ATM mutated advanced prostate cancer patients to Clovis' TRITON studies. Strata has agreed not to provide similar matching services on behalf of any other Strata collaborator for any other metastatic castrate-resistant prostate cancer (mCRPC) clinical trial with respect to patients having those same genetic mutations.

**Rucaparib Clinical Development**

In addition to ARIEL3 and ARIEL4 mentioned above, Clovis has a robust clinical development program underway in multiple tumor types, including both Clovis-sponsored and investigator-initiated trials. Several clinical studies are open for enrollment or are anticipated to open during 2017:

- The Clovis-sponsored TRITON2 (**T**rial of **R**ucapar**i**b in Pros**t**ate Indicati**on**s) study in mCRPC, a Phase 2 single-arm study enrolling patients with BRCA mutations and ATM mutations (both inclusive of germline and somatic) or other deleterious mutations in other homologous recombination (HR) repair genes and all patients will have progressed after receiving one line of taxane-based chemotherapy and one or two lines of androgen-receptor (AR) targeted therapy.
- 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 AR-targeted therapy and who have not yet received chemotherapy in the castrate-resistant setting is also open for enrollment. TRITON3 will compare rucaparib to physician's choice of AR-targeted therapy or chemotherapy in these patients.
- The cooperative group-sponsored MITO-25 study evaluating rucaparib and bevacizumab in combination as a first-line maintenance therapy for advanced ovarian cancer; and
- The investigator-initiated RUBY study in women with breast cancer whose tumors have a somatic BRCA mutation or homologous recombination deficient (HRD) signature other than a known germline BRCA mutation; and
- The investigator-initiated PLATFORM study in gastroesophageal cancer in the first-line maintenance setting and
- The Phase 1b combination study of Genentech's cancer immunotherapy Tecentriq (atezolizumab; anti-PDL1) and rucaparib for the treatment of gynecological cancers, with a focus on ovarian cancer.

**Conference Call Details**

Clovis will hold a conference call to discuss fourth quarter 2016 results this afternoon, February 22, at 4:30pm 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 866.489.9022, International participants 678.509.7575, conference ID: **68475508.**

**About Rubraca™ (rucaparib)**

Rubraca is a PARP inhibitor indicated 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. The indication for Rubraca is approved under the FDA's accelerated approval program based on objective response rate and duration of response, and is based on results from two multicenter, single-arm, open-label clinical trials. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Please visit rubraca.com for more information.

**About Rucaparib**

Rucaparib is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in ovarian cancer as well as several additional solid tumor indications. The MAA submission in Europe for an ovarian cancer treatment indication was submitted and accepted during the fourth quarter of 2016. Additionally, rucaparib is being developed as maintenance

therapy for ovarian cancer in the ARIEL3 trial for patients with tumors with BRCA mutations and other DNA repair deficiencies beyond BRCA, as well as biomarker negative patients. Data from ARIEL3 are expected in mid-2017, which, pending positive data, is expected to be followed by the submission of a sNDA for a second line or later maintenance indication. Rucaparib is also being developed in patients with mutant BRCA tumors and other DNA repair deficiencies beyond BRCA – commonly referred to as homologous recombination deficiencies, or HRD. Studies open for enrollment or under consideration include prostate, breast, pancreatic, gastroesophageal, bladder and lung 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 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. 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, the performance of our third-party manufacturers, 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. 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.*

**CLOVIS ONCOLOGY, INC**
**CONSOLIDATED FINANCIAL RESULTS**
(in thousands, except per share amounts)

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | **2016** | **2015** | **2016** | **2015** |
| Revenues: | | | | |
| Product revenue, net | $78 | $- | $78 | $- |
| License and milestone revenue | - | - | - | - |
| Total revenues | 78 | - | 78 | - |
| | | | | |
| Operating expenses: | | | | |
| Cost of sales - product | 70 | - | 70 | - |
| Research and development | 54,454 | 75,995 | 251,129 | 269,251 |
| Selling, general and administrative | 12,190 | 8,238 | 40,731 | 30,524 |
| Acquired in-process research and development | 500 | - | 1,300 | 12,000 |

| | | | | |
|---|---|---|---|---|
| Impairment of intangible asset | - | 89,557 | 104,517 | 89,557 |
| Change in fair value of contingent purchase consideration | - | (26,882) | (24,936) | (24,611) |
| Total expenses | 67,214 | 146,908 | 372,811 | 376,721 |
| | | | | |
| Operating loss | (67,136) | (146,908) | (372,733) | (376,721) |
| | | | | |
| Other income (expense): | | | | |
| Interest expense | (2,173) | (2,101) | (8,491) | (8,372) |
| Foreign currency gains (losses) | (146) | 736 | (580) | 2,740 |
| Other income | 160 | 164 | 633 | 416 |
| Other expense, net | (2,159) | (1,201) | (8,438) | (5,216) |
| | | | | |
| Loss before income taxes | (69,295) | (148,109) | (381,171) | (381,937) |
| Income tax benefit (expense) | (1,433) | 28,568 | 32,034 | 29,076 |
| Net loss | $(70,728) | $(119,541) | $(349,137) | $(352,861) |
| | | | | |
| Basic and diluted net loss per common share | $(1.83) | $(3.12) | $(9.07) | $(9.79) |
| | | | | |
| Basic and diluted weighted average common shares outstanding | 38,624 | 38,321 | 38,478 | 36,026 |

**RECONCILIATION OF GAAP TO NON-GAAP**
**NET LOSS AND NET LOSS PER SHARE**
(in thousands, except per share amounts)

| | **Three Months Ended December 31,** | | **Twelve Months Ended December 31,** | |
|---|---|---|---|---|
| | **2016** | **2015** | **2016** | **2015** |
| GAAP net loss | $(70,728) | $(119,541) | $ (349,137) | $(352,861) |
| Adjustments: | | | | |
| Impairment of intangible asset (1) | - | 89,557 | 104,517 | 89,557 |
| Change in fair value of contingent purchase consideration (2) | - | (26,882) | (25,452) | (26,882) |
| Income tax benefit (1) | - | (28,568) | (28,497) | (28,568) |
| | | | | |
| Non-GAAP net loss | $(70,728) | $(85,434) | $ (298,569) | $(318,754) |
| | | | | |
| GAAP net loss per common share | $(1.83) | $(3.12) | $ (9.07) | $(9.79) |
| | | | | |
| Non-GAAP net loss per common share | $(1.83) | $(2.23) | $ (7.76) | $(8.85) |

| | **December 31, 2016** |
|---|---|
| Cash, cash equivalents and available for sale securities | $ 266,183 |

| | |
|---|---|
| January 2017 financing proceeds | 221,237 |
| Adjusted cash | $ 487,420 |

*The Company prepares its consolidated financial statements in accordance with U.S. GAAP. This press release also contains non-GAAP measurements of net loss, net loss per common share and adjusted cash that the Company believes provide useful supplemental information relating to operating performance and trends and facilitates comparisons with other periods. These non-GAAP financial measures should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP.*

Explanation of adjustments:
(1) During the three months ended June 30, 2016, the Company recorded a $104.5 million non-cash impairment charge to the intangible asset related to the lucitanib product rights initially recorded in 2013 in connection with the acquisition of Ethical Oncology Science, S.p.A. (EOS). The Company also recorded a $28.4 million tax benefit associated with this charge. During the three months ended December 31, 2015, the Company recorded an $89.6 million non-cash impairment charge to the intangible asset associated with the Company's acquisition of EOS. The Company also recorded a $28.6 million tax benefit associated with this charge. These adjustments remove the net of tax effect of these charges from our net loss.

(2) During the three months ended June 30, 2016, the Company recorded a $25.5 million non-cash credit to operating expenses to reflect the reduction in the fair value of the contingent purchase consideration liability, also associated with the Company's acquisition of EOS. During the three months ended December 31, 2015, the Company recorded a $26.9 million non-cash credit to operating expenses to reflect the reduction in the fair value of the contingent purchase consideration liability associated with the Company's acquisition of EOS. These adjustments, which exclude the normal accretion of the liability, remove the effect of these expense credits from our net loss.

**CONSOLIDATED BALANCE SHEET DATA**
(in thousands)

| | December 31, 2016 | December 31, 2015 |
|---|---|---|
| Cash and cash equivalents | $ 216,186 | $ 278,756 |
| Available-for-sale securities | 49,997 | 249,832 |
| Working capital | 213,813 | 464,125 |
| Total assets | 364,557 | 713,386 |
| Convertible senior notes | 281,126 | 279,885 |
| Common stock and additional paid-in capital | 1,174,989 | 1,130,016 |
| Total stockholders' (deficit) equity | (3,634) | 300,650 |

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Source: Clovis Oncology, Inc.

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