Clovis Oncology Announces Product Revenues for the Fourth Quarter and Full Year 2019

1/7/2020

- Estimated $38.3M - $39.3M in Rubraca ® sales for Q4 2019 and $142.0M-$143.0M for FY2019 consistent with guidance
- Q4/FY2019 Operating Results call planned for February 24, 2020
- sNDA for Rubraca in advanced prostate cancer submitted in mid-November 2019
- Company to present at J.P. Morgan Healthcare Conference on Monday, January 13

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ:CLVS) today announced its preliminary, unaudited revenues for the fourth quarter and full year ended December 31, 2019. The financial information presented in this news release may be adjusted as a result of completion of customary quarterly review and audit procedures.

Unaudited preliminary results include:

- $38.3-$39.3M in Rubraca ® product revenues for the fourth quarter of 2019 compared to $37.6M for Q3 2019 and $30.4M for Q4 2018
- $142.0-$143.0M in Rubraca product revenues for the FY2019 compared to $95.4M for FY2018

Clovis plans to discuss these results with investors this week at the 38th Annual J.P. Morgan Healthcare Conference in San Francisco.

"We are very pleased with our sales performance in the fourth quarter and the momentum it provides us going into this year," said Patrick J. Mahaffy, CEO and President of Clovis Oncology. "In mid-November 2019, we submitted the supplemental New Drug Application (sNDA) for Rubraca in BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer, and also during the quarter announced the first reported human experience of FAP-2286 and
launched Rubraca in England and Italy. With this progress, we are looking forward to an eventful 2020. Key milestones include additional EU country ovarian cancer launches for Rubraca, a potential U.S. Rubraca launch in prostate cancer, initial data for lucitanib combination studies, and a planned IND filing for FAP-2286 in the second half of the year.”

Clovis Oncology to Present at 38th Annual J.P. Morgan Healthcare Conference on January 13, 2019

Clovis’ President and CEO, Patrick J. Mahaffy, will present at the 38th Annual J.P. Morgan Healthcare Conference to be held at the Westin St. Francis hotel in San Francisco on Monday, January 13 at 10:00 a.m. PT. A live webcast of the presentation and Q&A session can be accessed through the investor relations section of the Company’s website at clovisoncology.com. Following the live presentations, replays of the webcasts will be available on the Company’s website for 30 days.

Fourth Quarter and Full Year 2019 Financial Results Release Planned for February 24, 2020

The Company plans to report financial results for the fourth quarter and full year ended December 31, 2019 on Monday, February 24, 2020, after the close of the U.S. financial markets. Clovis’ senior management will host a conference call and live audio webcast at 4:30 p.m. ET to discuss the Company’s results in greater detail.

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.

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 Lucitanib

Lucitanib is an 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 (PDGFRα/β) and fibroblast growth factor receptors 1 through 3 (FGFR1-3). Emerging clinical data support the combination of angiogenesis inhibitors and immunotherapy to increase effectiveness in multiple cancer indications. Angiogenic factors, such as vascular endothelial growth factor (VEGF), are frequently up-regulated in tumors and create an immunosuppressive tumor microenvironment. Use of antiangiogenic drugs reverses this immunosuppression and can augment response to immunotherapy.

Lucitanib is an unlicensed medical product.

About FAP-2286

FAP-2286 is a preclinical candidate discovered by 3B Pharmaceuticals under investigation as a peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein alpha (FAP). FAP is highly expressed in many epithelial cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas. Clovis will conduct the global clinical trials and holds U.S. and global rights, excluding Europe.

FAP-2286 is an unlicensed medical product.

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 the U.S. and Europe. 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. Examples of forward-looking statements contained in this press release include, among others, statements regarding our preliminary estimates of fourth quarter and fiscal year 2019 revenue, and our expectations for commercial launches, availability of study data and submission of regulatory filings. 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 or decisions by the FDA, the EMA or other regulatory authorities regarding whether to accept or approve drug applications that may be filed, including delays or denials of regulatory approvals, clearances or authorizations for applications, as well as their decisions regarding drug labeling, reimbursement and pricing. Furthermore, we are in the process of finalizing our financial results for the fourth quarter and fiscal year 2019, and therefore our finalized and audited results and final analysis of those results are not yet available. The preliminary expectations regarding 2019 revenue, free drug and year-end cash, cash equivalents and available for sale securities are subject to management's review and actual results could differ from management's expectations. The actual results are also subject to audit by our independent registered public accounting firm and no assurance is given by our independent registered public accounting firm on such preliminary expectations. You should not draw any conclusions as to any other financial results as of and for the year ended December 31, 2019 based on the foregoing estimates. These forward-looking statements speak only as of the date hereof. 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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Breanna Burkart
303.625.5023
bburkart@clovisoncology.com

Anna Sussman
303.625.5022
asussman@clovisoncology.com

Source: Clovis Oncology