Clovis Oncology Announces Notice of Allowance for Rucaparib High Dosage Strength Tablet Patent with Expiration in 2035

March 8, 2018

• Claims to be issued cover all commercial dosage strengths of Rubraca®
• This will be the 10th Orange Book-listed patent for Rubraca

BOULDER, Colo.--(BUSINESS WIRE)--Mar. 8, 2018-- Clovis Oncology, Inc. (NASDAQ:CLVS) announced today that the Company has received a Notice of Allowance from the United States Patent and Trademark Office in United States Patent Application 14/828,065 with claims directed to high dosage strength rucaparib camsylate formulations. The patent is expected to issue shortly with claims that cover the commercial Rubraca product, including all commercial dosing strengths (200, 250 and 300mg). Upon issuance, the high dosage strength rucaparib formulation patent will expire in 2035, and will have the longest term of the multiple patents directed to rucaparib, rucaparib camsylate, and methods of treatment. This will be the 10th Orange Book-listed patent for rucaparib.

“Our development team has done a tremendous job developing high dosage strength tablets to help ensure that patients eligible for rucaparib are able to adhere to their daily dose in a straightforward manner,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “The Notice of Allowance recognizes that work and we expect will soon result in issuance of a patent that will not expire until 2035, complementing our already issued camsylate salt patents that expire in 2031. This is relevant not only to our current indication in ovarian cancer, but also to multiple tumor types based on our ongoing and substantial clinical development programs.”

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 not a licensed medicinal product in countries outside the US.

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 the ultimate issuance of the patent that is subject of the Notice of Allowance and the timing for such issuance, and the expiration of patents in our portfolio. 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 actions by the United States Patent and Trademark Office regarding final approval and issuance of such patent, and third-party challenges to the validity, enforceability or scope of our patents. 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.


Source: Clovis Oncology, Inc.

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