



Clovis Oncology and Immunomedics Announce Planned Clinical Collaboration to Study Combination Therapies in Metastatic Triple-Negative Breast and Urothelial Cancers

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Companies to Start Phase 1/2 Study to Evaluate the Combination of Rubraca® (Rucaparib) and Sacituzumab Govitecan in Patients with Metastatic Triple-negative Breast Cancer and Metastatic Urothelial Cancer

BOULDER, Colo. and MORRIS PLAINS, N.J. , June 03, 2018 (GLOBE NEWSWIRE) -- **Clovis Oncology, Inc.** (NASDAQ:[CLVS](#)) and **Immunomedics, Inc.**, (NASDAQ:[IMMU](#)) today announced their intent to enter into a clinical collaboration to investigate the combination of Clovis' Rubraca® (rucaparib), a poly (ADP ribose) polymerase inhibitor (PARPi), and Immunomedics' lead antibody-drug conjugate (ADC) product candidate, sacituzumab govitecan, as a treatment of patients with metastatic triple-negative breast cancer (mTNBC) and metastatic urothelial cancer (mUC). The planned phase 1/2 study will include an initial safety cohort followed by expansion cohorts in each of mTNBC and mUC.

"We look forward to entering this important co-development partnership with Clovis, one of the leading innovative biotech companies, to fully leverage the scientific expertise of both companies and expand the potential for two very active agents," said Usama Malik, Chief Business Officer of Immunomedics. "There is synergy between PARPi and sacituzumab govitecan in preclinical models regardless of BRCA mutation status. This partnership will hopefully provide clinical validation for this exciting concept and bring new treatment options to disease settings with high unmet medical need."

"We are very pleased to partner with Immunomedics and are very enthusiastic about the potential synergy between rucaparib and sacituzumab govitecan," said Patrick J. Mahaffy, President and Chief Executive Officer of Clovis Oncology. "Our plan to initiate new combination studies with Immunomedics further expands our clinical development efforts in both advanced breast and bladder cancers, where there is tremendous need for new treatment options."

In preclinical studies, the combination of sacituzumab govitecan and rucaparib in TNBC cell lines *in vitro* resulted in synergistic growth inhibition regardless of BRCA1/2 status. In addition, the combination of sacituzumab govitecan and a PARPi also demonstrated significant antitumor effects above that observed with monotherapy in BRCA wild-type and mutant animal models of TNBC.¹

"There is an opportunity to develop new treatment options for patients in the mTNBC and mUC space through our planned collaboration with Clovis Oncology, as well as potentially pursuing other indications in the future," stated Dr. Robert Iannone, Head of Research & Development and Chief Medical Officer of Immunomedics. "We are excited by the prospect that our unique ADC in combination with rucaparib could help fill a gap in treatment for cancer patients who have few available options."

Reference

1. Cardillo TM, Sharkey RM, Rossi DL, et al. Synthetic lethality exploitation by an anti-Trop-2-SN-38 antibody-drug conjugate, IMMU-132, plus PARP inhibitors in BRCA1/2-wild-type triple-negative breast cancer. *Clin Cancer Res.* 2017 Jul 1;23(13):3405-3415.

About Sacituzumab Govitecan

Sacituzumab govitecan, Immunomedics' most advanced product candidate, is a novel, first-in-class antibody-drug conjugate (ADC). It is currently under review by the U.S. Food and Drug Administration for accelerated approval as a treatment of patients with triple-negative breast cancer who previously received at least two prior therapies for metastatic disease. If approved, sacituzumab govitecan would be the first and only ADC approved for the treatment of metastatic triple negative breast cancer.

About Rubraca

Rubraca is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in multiple tumor types, including ovarian, metastatic castration-resistant prostate, and bladder cancers, as monotherapy, and in combination with other anti-cancer agents. Exploratory studies in other tumor types are also underway. Clovis holds worldwide rights for Rubraca. Rubraca is an unlicensed medical product outside of the U.S. and EU.

Rubraca U.S. FDA Approved Indications and Important Safety Information

Rubraca is indicated as monotherapy 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 indicated as monotherapy 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.

Select Important Safety Information

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML) occur uncommonly in patients treated with Rubraca, and are potentially fatal adverse reactions. In approximately 1100 treated patients, MDS/AML occurred in 12 patients (1.1%), including those in long term follow-up. Of these, 5 occurred during treatment or during the 28 day safety follow-up (0.5%). The duration of Rubraca treatment prior to the diagnosis of MDS/AML ranged from 1 month to approximately 28 months. The cases were typical of secondary MDS/cancer therapy-related AML; in all cases, patients had received previous platinum-containing regimens and/or other DNA damaging agents.

Do not start Rubraca until patients have recovered from hematological toxicity caused by previous chemotherapy (\leq Grade 1).

Monitor complete blood counts for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities (> 4 weeks), interrupt Rubraca or reduce dose (see Dosage and Administration (2.2) in full Prescribing Information) and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks or if MDS/AML is suspected, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue Rubraca.

Based on its mechanism of action and findings from animal studies, Rubraca can cause fetal harm when administered to a pregnant woman. Apprise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Rubraca.

Most common adverse reactions in ARIEL3 ($\geq 20\%$; Grade 1-4) were nausea (76%), fatigue/asthenia (73%), abdominal pain/distention (46%), rash (43%), dysgeusia (40%), anemia (39%), AST/ALT elevation (38%), constipation (37%), vomiting (37%), diarrhea (32%), thrombocytopenia (29%), nasopharyngitis/upper respiratory tract infection (29%), stomatitis (28%), decreased appetite (23%), and neutropenia (20%).

Most common laboratory abnormalities in ARIEL3 ($\geq 25\%$; Grade 1-4) were increase in creatinine (98%), decrease in hemoglobin (88%), increase in cholesterol (84%), increase in alanine aminotransferase (ALT) (73%), increase in aspartate aminotransferase (AST) (61%), decrease in platelets (44%), decrease in leukocytes (44%), decrease in neutrophils (38%), increase in alkaline phosphatase (37%), and decrease in lymphocytes (29%).

Most common adverse reactions in Study 10 and ARIEL2 ($\geq 20\%$; Grade 1-4) were nausea (77%), asthenia/fatigue (77%), vomiting (46%), anemia (44%), constipation (40%), dysgeusia (39%), decreased appetite (39%), diarrhea (34%), abdominal pain (32%), dyspnea (21%), and thrombocytopenia (21%).

Most common laboratory abnormalities in Study 10 and ARIEL2 ($\geq 35\%$; Grade 1-4) were increase in creatinine (92%), increase in alanine aminotransferase (ALT) (74%), increase in aspartate aminotransferase (AST) (73%), decrease in hemoglobin (67%), decrease in lymphocytes (45%), increase in cholesterol (40%), decrease in platelets (39%), and decrease in absolute neutrophil count (35%).

Co-administration of rucaparib can increase the systemic exposure of CYP1A2, CYP3A, CYP2C9, or CYP2C19 substrates, which may increase the risk of toxicities of these drugs. Adjust dosage of CYP1A2, CYP3A, CYP2C9, or CYP2C19 substrates, if clinically indicated. If co-administration with warfarin (a CYP2C9 substrate) cannot be avoided, consider increasing frequency of international normalized ratio (INR) monitoring.

Because of the potential for serious adverse reactions in breast-fed children from Rubraca, advise lactating women not to breastfeed during treatment with Rubraca and for 2 weeks after the last dose.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Clovis Oncology, Inc. at 1-844-258-7662.

[Click here](#) for full Prescribing Information and additional Important Safety Information.

About Immunomedics

Immunomedics is a clinical-stage biopharmaceutical company developing monoclonal antibody-based products for the targeted treatment of cancer and other serious diseases. Immunomedics' corporate objective is to become a fully-integrated biopharmaceutical company and a leader in the field of antibody-drug conjugates. For additional information on the Company, please visit its website at <https://immunomedics.com/>. The information on its website does not, however, form a part of this press release.

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.

Immunomedics cautionary note regarding forward-looking statements

This release, in addition to historical information, may contain forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Such statements, including statements regarding clinical trials (including the funding therefor, anticipated patient enrollment, trial outcomes, timing or associated costs), regulatory applications and related timelines, including the filing and approval timelines for BLAs and BLA supplements, out-licensing arrangements, forecasts of future operating results, potential collaborations, capital raising activities, and the timing for bringing any product candidate to market, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. Factors that could cause such differences include, but are not limited to, Immunomedics' dependence on business collaborations or availability of required financing from capital markets, or other sources on acceptable terms, if at all, in order to further develop our products and finance our operations, new product development (including clinical trials outcome and regulatory requirements/actions), the risk that we or any of our collaborators may be unable to secure regulatory approval of and market our drug candidates, risks associated with the outcome of pending litigation and competitive risks to marketed products, and Immunomedics' ability to repay its outstanding indebtedness, if and when required, as well as the risks discussed in Immunomedics' filings with the Securities and Exchange Commission. Immunomedics is not under any obligation, and Immunomedics expressly disclaims any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise.

Clovis Oncology Forward-Looking Statement

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 plans or intentions to enter into clinical collaborations and/or co-development programs with partners, our expectations regarding potential of pre-clinical data and the timing and pace of commencement of and enrollment in our clinical trials, including those being planned or conducted in collaboration with partners. 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 clinical development, including the outcome of clinical trials, whether future study

results will be consistent with previous study findings, including pre-clinical studies, the timing of initiation, enrollment and completion of planned clinical trials and the availability of data and results, actions by regulatory authorities regarding whether to approve drug applications that may be filed, as well as their decisions that may affect drug labeling and other matters that could affect the availability or commercial potential of our drug candidates. 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.

For More Information:

For Investor Inquiries:

Dr. Chau Cheng

Senior Director, Investor Relations & Corporate Secretary

(973) 605-8200, extension 123

ccheng@immunomedics.com

Clovis Investor Contacts:

Anna Sussman, 303-625-5022

asussman@clovisoncology.com

or

Breanna Burkart, 303-625-5023

bburkart@clovisoncology.com

For Media Inquiries:

media@immunomedics.com

Clovis Media Contacts: U.S.

Lisa Guiterman, 301-217-9353

clovismedia@sambrown.com

or

Christy Curran, 615-414-8668

clovismedia@sambrown.com

Clovis Media Contact: EU

Ann Hughes, +44 (0) 7956 700 790

Ann.Hughes@publicisresolute.com