



Cleave Therapeutics Announces Preclinical Research Collaboration with Jazz Pharmaceuticals in Acute Myeloid Leukemia (AML)

Preclinical Combination Studies Planned with CB-5339 and Vyxeos®

San Francisco, CA— September 9, 2020 - Cleave Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on VCP/p97 as a novel target in oncology, announced that it has entered into a preclinical research collaboration with Jazz Pharmaceuticals, a global biopharmaceutical company developing life-changing medicines for people with serious diseases.

Under the terms of the agreement, Cleave will conduct preclinical research studies evaluating CB-5339, its second-generation, small molecule VCP/p97 inhibitor, in combination with Vyxeos® (daunorubicin and cytarabine) liposome for injection, approved in the U.S. and Europe for newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

CB-5339 plays a key role in DNA damage repair and has demonstrated impressive preclinical activity and synergy in combination with DNA-damaging agents. Vyxeos, a unique liposomal formulation of daunorubicin and cytarabine at a fixed 1:5 molar ratio, has been shown to have synergistic effects at killing leukemia cells *in vitro* and in murine models.

“With 75,000 newly diagnosed AML patients worldwide each year, there is an urgent need to advance new treatment options,” said Amy Burroughs, president and chief executive officer of Cleave Therapeutics. “As we evaluate CB-5339 as a single agent in human Phase 1 studies, we are excited to collaborate with Jazz Pharmaceuticals on preclinical studies to explore the potential of CB-5339 in combination with Vyxeos.”

About Vyxeos® (daunorubicin and cytarabine)

In the U.S., Vyxeos® (daunorubicin and cytarabine) is a liposomal formulation of a fixed combination of daunorubicin and cytarabine for intravenous infusion that represents the first, only and most proven chemotherapy treatment option specifically for two types of high-risk, secondary acute myeloid leukemia (AML): newly diagnosed therapy-related AML (t-AML) and AML with myelodysplasia-related changes (AML-MRC). In Europe, Vyxeos® Liposomal (daunorubicin/cytarabine) is indicated for the treatment of adults with newly diagnosed, therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC). Vyxeos is currently approved in more than 30 countries. Through a robust clinical development program, Vyxeos is being evaluated across multiple AML populations.

About Cleave Therapeutics and CB-5339

Cleave Therapeutics is a clinical-stage biopharmaceutical company focused on VCP/p97 as a novel target in protein homeostasis and cellular stress pathways for therapeutic use in cancer. The privately held company, based in San Francisco, is studying CB-5339, its second-generation, small molecule VCP/p97 inhibitor, in a Phase 1 clinical trial in acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), while the National Cancer Institute (NCI) is sponsoring and evaluating CB-5339 in a Phase 1 clinical trial of patients with solid tumors and lymphomas. Cleave investors include 5AM Ventures, Bristol-Myers Squibb, Orbimed, U.S. Venture Partners (USVP), Arcus Ventures, Astellas Venture Management, and Osage University Partners. For additional information, visit www.cleavetherapeutics.com.

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