

Hana Biosciences Announces Positive Data From Pivotal rALLY Clinical Trial of Marqibo(R) in Acute Lymphoblastic Leukemia at 51st American Society of Hematology Annual Meeting

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--36% Overall Response Rate and 21% Complete Remission Rate--

--Median Overall Survival of 7.3 Months in Complete Responders--

SOUTH SAN FRANCISCO, Calif., Dec. 7, 2009 (GLOBE NEWSWIRE) -- Hana Biosciences (OTCBB:HNAB), a biopharmaceutical company focused on strengthening the foundation of cancer care, today announced data from its pivotal Phase 2 rALLY clinical trial for Marqibo(R) (vincristine sulfate liposomes injection) for the treatment of adult acute lymphoblastic leukemia (ALL) in second relapse. Results from the rALLY trial demonstrated compelling evidence of single-agent, anti-leukemic activity in a relapsed/refractory, heavily pre-treated, adult population of ALL patients, with a universal history of prior exposure to the standard formulation of vincristine sulfate.

The analysis of the first 56 evaluable subjects demonstrated an overall response in 36 percent of the subjects and a complete remission (CR) or CR with incomplete hematologic recovery (CRi) in 21 percent of the subjects. The estimated median overall survival in complete responders was 7.3 months. Fifty percent of the complete responders were able to receive a potentially life-saving stem cell transplant. Fifty percent of the complete responders had remission durations longer than the duration of their prior remission. In addition, Marqibo was generally well-tolerated with a low incidence of early death.

"We are excited by the rALLY trial results for Marqibo in adult ALL that demonstrate an ability to induce meaningful remissions in patients without approved treatment options," said Anne Hagey, M.D., Chief Medical Officer of Hana Biosciences. "Based on the rALLY trial data, other published Marqibo data in adult ALL, and supportive data in lymphomas and solid tumors, we plan to submit a New Drug Application seeking accelerated approval for Marqibo in 2010."

"This important clinical trial adds significantly to our understanding of adult ALL patients in need of effective second salvage therapy," said Susan O'Brien, M.D., Professor of Medicine in the Leukemia Department at the University of Texas, MD Anderson Cancer Center and rALLY study lead investigator. "Based on the rALLY trial data, Marqibo provides clinical benefit and could be a valuable weapon in the fight against leukemia."

Final data on all 65 subjects enrolled and dosed in the Phase 2 rALLY trial will be presented in 2010.

Phase 2 rALLY Clinical Trial Design and Results

The pivotal Phase 2 rALLY clinical trial enrolled a total of 65 patients at 22 sites in the United States, Canada, Germany, and Israel. The study achieved its enrollment target of 56 subjects in August 2009, but additional subjects were enrolled to obtain target population pharmacokinetic data. The primary objective of the rALLY clinical trial was to assess the efficacy of single-agent, weekly Marqibo (2.25 mg/m²) as assessed by achievement of CR or CRi. Secondary objectives included duration of CR/CRi, overall survival (OS), safety and tolerability. Marqibo was dosed weekly based on actual body surface area without the dose capping applied to standard vincristine. The study population is defined as Philadelphia chromosome-negative adult patients in second relapse, or those patients who relapsed following two lines of anti-leukemia chemotherapy, including those who have previously undergone stem cell transplantation.

An overall response rate (ORR) as determined by CR, CRi, partial remission, and bone marrow blast count normalization without blood count recovery was reported by investigators in 20 of 56 subjects for an ORR of 36 percent, with 12 of 56 subjects (21 percent) experiencing a CR or CRi. Seven subjects underwent allogeneic stem cell transplant after receiving Marqibo. The median OS in the 56 subjects is estimated to be 4.6 months (range 0.1-15.9) using Kaplan-Meier methodology. The safety profile of Marqibo is predictable, manageable, and similar to vincristine sulfate. Adverse events occurring in greater than 30 percent of subjects include neuropathy, nausea, constipation, pyrexia, decreased appetite, and febrile neutropenia. The early death rate, defined as death occurring within the first 14 days on study, was 5.4 percent (3 of 56 subjects) and

occurred due to progressive ALL.

About Marqibo(R) (vincristine sulfate liposomes injection)

Marqibo is a novel, targeted, Optisome(TM) encapsulated formulation of vincristine sulfate, a widely-used chemotherapy, which has shown promising anti-cancer activity in patients with ALL, non-Hodgkin's lymphoma, Hodgkin's disease, and melanoma in several clinical trials. Marqibo is designed to enhance the penetration and concentration of vincristine sulfate at sites of active cancer and facilitate dose-intensification compared to standard vincristine formulations. Unlike standard vincristine, Marqibo is dosed based on actual patient body surface area without the need for dose-capping.

Hana Biosciences has received orphan drug and fast track designations for Marqibo for the treatment of adult ALL from the U.S. Food and Drug Administration. Marqibo has also received orphan drug designation in adult ALL from the European Medicines Evaluation Agency.

About Hana Biosciences, Inc.

Hana Biosciences, Inc. is a biopharmaceutical company dedicated to developing and commercializing new, differentiated cancer therapies designed to improve and enable current standards of care. The Company's lead product candidate, Marqibo (R), potentially treats acute lymphoblastic leukemia and lymphomas. The Company has additional pipeline opportunities some of which, like Marqibo, improve delivery and enhance the therapeutic benefits of well characterized, proven chemotherapies and enable high potency dosing without increased toxicity. Additional information on Hana Biosciences can be found at www.hanabiosciences.com.

The Hana Biosciences, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=3290>

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are often, but not always, made through the use of words or phrases such as "anticipates," "expects," "plans," "believes," "intends," and similar words or phrases. These forward-looking statements include without limitation, statements regarding, the timing, progress and anticipated results of regulatory processes, including potential NDA filings and other regulatory submissions relating to Marqibo, and clinical development of Marqibo; and statements regarding the expected benefits Marqibo may have for patients with relapsed ALL compared to existing therapies. Such statements involve risks and uncertainties that could cause Hana's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Among other things, there can be no assurances that any of Hana's clinical and regulatory development efforts relating to Marqibo will be successful; that the data of the rALLY trial will be sufficient to support approval by the FDA of an NDA for Marqibo; that Hana will have completed all other activities necessary for the filing of an NDA or other submission with the FDA; and that the results of the rALLY trial and other clinical trials of Marqibo will support Hana's claims or beliefs concerning Marqibo's safety and effectiveness. Additional risks that may affect such forward-looking statements include Hana's need to raise additional capital to fund its product development programs, including Marqibo, to completion, Hana's reliance on third-party researchers to develop its product candidates, and its lack of experience in developing and commercializing pharmaceutical products. Additional risks are described in the company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 16, 2009. Hana assumes no obligation to update these statements, except as required by law.

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