

Data From Pivotal Phase 2 RALLY Trial Show Marqibo Produced Compelling Single-Agent Anti-Leukemic Efficacy in Advanced Relapsed/Refractory Adult Ph(-) Acute Lymphoblastic Leukemia

SOUTH SAN FRANCISCO, Calif., Jun 7, 2010 (GlobeNewswire via COMTEX News Network) --

- Marqibo administered as third-, fourth-, fifth-, and sixth-line single-agent therapy
- 35% overall response rate with a predictable and manageable toxicity profile
- 20% complete response (CR) and CR with incomplete blood count recovery (CRi) rate
- 5.3 month median CR/CRi duration and 7.4 month median survival in responders

Hana Biosciences Inc., (OTCBB:HNAB), today announced complete data from its pivotal, Phase 2 RALLY clinical trial for Marqibo(R) (vincristine sulfate liposome injection) for the treatment of relapsed/refractory adult Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL). Results from the RALLY trial demonstrated compelling evidence of single-agent, anti-leukemic activity in an advanced, heavily pre-treated, adult ALL population.

An analysis of the 65 evaluable subjects demonstrated an overall response in 35 percent of the subjects and a complete response (CR) or CR with incomplete blood count recovery (CRi) in 20 percent of the subjects. The estimated median overall survival in complete responders was 7.4 months, with five patients having an overall survival greater than one year. The estimated median duration of CR/CRi was 5.3 months. Ten patients treated with Marqibo went on to receive a potentially life-saving stem cell transplant. There were no unexpected toxicities.

"We believe these data position Marqibo as an effective treatment for relapsed/refractory adult ALL patients with limited to no current options, as efficacy was demonstrated in second and third salvage settings, as third- through fifth-line therapy, and in both B- and T-lineage ALL," said Anne Hagey, M.D., Chief Medical Officer of Hana Biosciences. "Based upon these data, we are moving forward with our plan to initiate a rolling NDA submission with the hopes of bringing a much needed therapy to patients with no standard treatment options. In addition, the complete RALLY results reinforce our belief that Marqibo has the potential to be an important and useful stand-alone therapy in relapsed adult leukemia. We look forward to additional and continued development in combination therapy in leukemia and lymphomas."

"The results of the RALLY trial demonstrate a clinically meaningful benefit for patients who have relapsed multiple times or who have progressed following two or more prior lines of 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 historical data with single-agent therapy, one would have expected no more than a 4 percent CR/CRi rate in such an advanced leukemia population. Marqibo's CR/CRi rate of 20 percent would be an extremely important step forward in the treatment of adult ALL"

Phase 2 RALLY Clinical Trial Design and Results

The pivotal Phase 2 RALLY clinical trial enrolled a total of 65 evaluable patients at 22 sites in the United States, Canada, Germany, and Israel. The primary objective of the RALLY clinical trial was to assess the efficacy of single-agent, weekly Marqibo (2.25 mg/m² with no dose cap) as assessed by achievement of CR or CRi. Secondary objectives included assessments of duration of CR/CRi, overall survival (OS), safety and pharmacokinetics. Independent response assessment remains ongoing at the present time. Marqibo was dosed weekly based on actual body surface area without the dose capping applied to standard vincristine sulfate. The study population is defined as Philadelphia chromosome-negative adult patients in second or greater 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 23 of 65 subjects for an ORR of 35 percent, with 13 of 65

subjects (20 percent) experiencing a CR or CRI. Marqibo enabled successful stem cell transplantation in 10 patients after dosing. The median OS in the 65 subjects is estimated to be 4.6 months (range 0.1-21.6) using Kaplan-Meier methodology. The safety profile of Marqibo is predictable, manageable, and similar to standard vincristine sulfate. The early death rate, defined as death occurring within the first 14 days on study, was 4.6 percent (3 of 56 subjects) and occurred due to progressive ALL.

The Company anticipates locking the data base and commencing a rolling NDA submission in the near future.

ASCO Presentation

The complete data from the pivotal Phase 2 RALLY trial will be presented in an oral podium presentation by Susan O'Brien M.D. (Abstract #6507) at 11:45 am on Monday, June 7 at the American Society of Clinical Oncology (ASCO) Annual Meeting being held in Chicago, Illinois, June 4-8, 2010.

About Marqibo(R) (vincristine sulfate liposome 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 Hana's planned development and regulatory activities relating to Marqibo, including its proposed NDA filing and whether such filing will be accepted for review or approved by the FDA; statements regarding the potential of Marqibo to replace existing therapies and 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 even if an NDA for Marqibo is accepted by the FDA, that it will be approved; that the data of the clinical trials of Marqibo 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; that the results of the clinical trials of Marqibo will support Hana's claims or beliefs concerning Marqibo's safety and effectiveness; that its existing patent and other intellectual property rights will be adequate; and that Hana will be able to secure the additional capital necessary to fund the activities required to complete the proposed NDA submission and other clinical and regulatory activities relating to Marqibo. 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 Annual Report on Form 10-K for the year ended December 31, 2009 and in the Company's Form 10-Q for the three month period ended March 31, 2010. Hana assumes no obligation to update these statements, except as required by law.

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