Vidaza Significantly Extends Overall Survival by 74% in Phase 3 Trial in Myelodysplastic Syndromes (MDS)

Two year survival rate of 50.8 percent for Vidaza versus 26.2 for conventional care regimens
9.4 months median survival benefit for patients on Vidaza compared to conventional care regimens
Only agent to demonstrate survival benefit in MDS compared to conventional care regimens
Only epigenetic modifier to show survival benefit in cancer
Stratified log-rank p-value = 0.0001, Hazard ratio = 0.58
Largest study ever conducted in higher-risk MDS

BOULDER, Colo., Aug. 2 /PRNewswire-FirstCall/ -- Pharmion Corporation (Nasdaq: PHRM) today announced topline results from the multi-institutional, international, randomized, Phase 3 controlled trial of Vidaza(R) (azacitidine for injection) versus conventional care regimens (CCR) in the treatment of patients with higher-risk myelodysplastic syndromes (MDS). In the primary endpoint analysis, Vidaza treatment was associated with a median survival of 24.4 months versus 15 months for those receiving CCR treatment, an improvement of 9.4 months with a stratified log-rank p-value of 0.0001. The hazard ratio describing this treatment effect was 0.58 (95 percent confidence interval of 0.43 to 0.77). Two-year survival rates were 50.8 percent versus 26.2 percent for patients receiving Vidaza versus CCR ($p<0.0001$). Median number of treatment cycles was nine for Vidaza.

The survival benefits of Vidaza were consistent regardless of the CCR treatment option (best supportive care (BSC) alone, low-dose cytarabine plus BSC or standard chemotherapy plus BSC) utilized in the control arm.

"These landmark results, showing a significant improvement in survival in the most advanced MDS patients, validate the benefit Vidaza can provide patients with this extremely difficult to treat disease," said Dr. Lewis R. Silverman, Associate Professor of Medicine, Division of Hematology and Medical Oncology, Mount Sinai School of Medicine. "Building on the established data from our earlier clinical studies, which showed that Vidaza offers transfusion independence to many patients with MDS, we now see that Vidaza not only improves a patient's life, but extends it as well."

"With these very exciting results for Vidaza, survival should now be the standard by which we evaluate treatment options for higher-risk MDS," said Dr. Alan F. List, Chief, Malignant Hematology Division and Deputy Physician in Chief, H. Lee Moffitt Cancer Center and Research Institute. "Importantly, as the first and only epigenetic therapy to have demonstrated a survival benefit in any cancer, these findings should accelerate exploration of Vidaza in other malignancies where hypermethylation is believed to play a key role in tumor development and progression."

"We are extremely gratified with the results from the Vidaza Survival Study, which for the first time bring the hope of prolonged survival for patients with higher-risk MDS," said Patrick J. Mahaffy, Pharmion's chief executive officer and president. "As the only therapy to have ever

demonstrated a survival advantage in MDS, and especially to have demonstrated an improvement of this magnitude, Vidaza is unique in the treatment for this disease."

Pharmion expects to present full study results at an upcoming medical meeting. Based on these results, Pharmion intends to file a Marketing Authorization Application (MAA) in the European Union (EU) for Vidaza for the treatment of higher-risk MDS before the end of this year and will shortly thereafter submit additional international regulatory submissions. The Company will also file a supplemental New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) to include these data in the prescribing information in the U.S.

Pharmion is also developing a next generation product, oral Azacitidine, for the treatment of MDS and other cancers where demethylation can provide an anti-tumor effect. Oral Azacitidine is the subject of a Phase 1 multi-center, open label dose escalation trial that will assess the maximum tolerated dose, dose limiting toxicities and safety of a seven day, multi-cycle oral dosing regimen of oral Azacitidine in patients with MDS and AML. In addition, the trial will examine pharmacokinetics and pharmacodynamic effects of orally administered Azacitidine, as compared with parenteral Vidaza.

Pharmion will hold a conference call to discuss these results later this morning, August 2, at 9:00 a.m. ET. The conference call will be simultaneously webcast on the Company's web site at www.pharmion.com, and archived for future review. Dial-in numbers for the conference call for institutional investors and analysts are as follows: participants from the U.S. 866.314.5232, International participants 617.213.8052, passcode: 71992680.

About the Trial Design

This was the largest randomized study ever conducted in higher-risk MDS. The study was a multi-center, randomized, open-label, parallel-group, Phase 3 trial of subcutaneous (SC) Vidaza (administered at 75/mg/m2/day SC for seven consecutive days every 28 days) plus best supportive care versus CCR plus best supportive care for the treatment of MDS. CCR consisted of one of three physician selected regimens: best supportive care alone, low-dose cytarabine plus best supportive care or standard chemotherapy plus best supportive care. EPO and prophylactic G-CSF use was not permitted. The CCR represented standard of care within the territories where the trial was conducted. The study evaluated 358 higher-risk MDS patients at sites in the U.S., Europe and Australia. Patients were randomized on a 1:1 ratio to either Vidaza of the CCR with stratification by FAB subtypes (RAEB or RAEB-T) and IPSS subgroups (INT-2 or HIGH). Investigators selected the CCR option for each individual patient prior to randomization. The primary objective of the trial was to demonstrate superiority in survival of Vidaza plus best supportive care versus CCR plus best supportive care in higher-risk MDS patients. Secondary objectives of the trial included transfusion independence, hematologic status, hematologic response and hematologic improvement, episodes of infections requiring intravenous antibiotics, time to relapse after complete response (CR) or partial response (PR), time to disease progression, time to transformation to AML, time to transformation or death from any cause, safety and toxicity and pharmacoeconomics.

About Vidaza

In May 2004, Vidaza became the first drug approved by the FDA for the treatment of patients with Myelodysplastic Syndromes (MDS). The FDA approved Vidaza, the first in a new class of drugs called demethylation agents, for treatment of all five MDS subtypes, which include both low-risk and high-risk patients. These subtypes include: refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS) if accompanied by neutropenia or thrombocytopenia or requiring transfusions; refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and chronic myelomonocytic leukemia (CMMoL).

Vidaza is believed to exert its antineoplastic effects by causing hypomethylation of DNA and direct cytotoxicity on abnormal hematopoietic cells in the bone marrow. The concentration of Vidaza required for maximum inhibition of DNA methylation in vitro does not cause major suppression of DNA synthesis. Hypomethylation may restore normal function to genes that are critical for differentiation and proliferation. The cytotoxic effects of Vidaza cause the death of rapidly dividing cells, including cancer cells that are no longer responsive to normal growth control mechanisms. Non- proliferating cells are relatively insensitive to Vidaza. Vidaza was approved for IV administration in January 2007.

About Epigenetics

Vidaza is the first of a new class of anti-cancer compounds known as epigenetic therapies. Epigenetics refers to changes in the regulation of gene expression, and DNA methylation and histone deacetylation are two of the more studied epigenetic regulators of gene expression. Epigenetic changes can silence gene expression and, unlike DNA mutations, may be reversed by targeting the mechanisms involved. The silencing of key cell cycle control genes and tumor suppressor genes through these two mechanisms of epigenetic regulation has been demonstrated in vitro and in vivo in hematological malignancies and in solid tumors. These key growth control genes can be re- expressed in cancer cells when DNA hypermethylation is reversed by Vidaza. The epigenetic approach to cancer therapy is that rather than using molecules that kill both normal, and tumor cells, the silenced genes are reactivated through targeted epigenetic therapy, re-establishing the cancer cell's natural mechanisms to control abnormal growth.

About MDS

Myelodysplastic syndromes, or MDS, are a group of diseases in which the bone marrow does not function normally, resulting in the production of malformed or immature blood cells. MDS affects approximately 40,000-50,000 people in the United States and 75,000-85,000 patients in Europe. The majority of patients with higher-risk MDS eventually experience bone marrow failure. Up to 50 percent of MDS patients succumb to complications, such as infection or bleeding, before progressing to acute myeloid leukemia (AML). MDS patients have a median survival of four months to five years depending on risk stratification. Higher-risk patients have a median survival of five to 14 months. Alleviation of disease-related complications, including transfusion requirements and hematologic improvement are key treatment goals in lower-risk MDS. Altering the natural history of disease is one of the most important treatment goals in higher-risk MDS.

Important Safety Information

Vidaza is contraindicated in patients with a known hypersensitivity to Vidaza or mannitol and in patients with advanced malignant hepatic tumors.

In clinical studies, the most commonly occurring adverse reactions by SC route were nausea (70.5%), anemia (69.5%), thrombocytopenia (65.5%), vomiting (54.1%), pyrexia (51.8%), leukopenia (48.2%), diarrhea (36.4%), fatigue (35.9%), injection site erythema (35.0%), constipation (33.6%), neutropenia (32.3%) and ecchymosis (30.5%). Other adverse reactions included dizziness (18.6%), chest pain (16.4%), febrile neutropenia (16.4%), myalgia (15.9%), injection site reaction (13.6%), aggravated fatigue (12.7%) and malaise (10.9%). The most common adverse reactions by IV route also included petechiae (45.8%), rigors (35.4%), weakness (35.4%) and hypokalemia (31.3%).

Because treatment with Vidaza is associated with neutropenia and thrombocytopenia, complete blood counts should be performed as needed to monitor response and toxicity, but at a minimum, prior to each dosing cycle.

Because Vidaza is potentially hepatotoxic in patients with severe pre- existing hepatic impairment, caution is needed in patients with liver disease. In addition, Vidaza and its metabolites are substantially excreted by the kidneys and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, it may be useful to monitor renal function.

Vidaza may cause fetal harm. While receiving treatment with Vidaza, women of childbearing potential should avoid becoming pregnant, and men should avoid fathering a child. In addition, women treated with Vidaza should not nurse.

About Pharmion

Pharmion is a biopharmaceutical company focused on acquiring, developing and commercializing innovative products for the treatment of hematology and oncology patients in the U.S., Europe and additional international markets. Pharmion has a number of products on the market including the world's first approved epigenetic drug, Vidaza(R), a DNA demethylating agent. For additional information about Pharmion, please visit the company's website at www.pharmion.com.

Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995: This press release contains forward-looking statements, including summary statements relating to top line results of the Vidaza Survival Study and summary statements relating to the potential efficacy of Vidaza based on those results. Such statements are based on current expectations and beliefs only and are subject to risks and uncertainties, many of which are beyond our control, that could cause the final results to differ significantly from the results summarized by such statements. Actual results could differ materially depending on a number of factors, and we caution investors not to place undue reliance on the forward-looking statements contained in this press release. In particular, there can be no guarantee that topline results from the clinical trial discussed in this

press release will be confirmed upon full analysis of the results of the Vidaza Survival Study and additional information relating to the safety, efficacy or tolerability of Vidaza may be discovered upon further analysis of data from the Vidaza Survival Study or analysis of additional data from other ongoing Vidaza clinical trials. Furthermore, even if these topline results are confirmed upon full analysis of the study, we cannot guarantee that Vidaza will be approved for marketing in a timely manner, if at all, by regulatory authorities in the EU or that information from the study will be included in the approved prescribing information in the U.S. Additional risks and uncertainties relating to Pharmion and its business can be found in the "Risk Factors" section of Pharmion's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2007, its Annual Report on Form 10-K for the year ended December 31, 2006 and in Pharmion's other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and Pharmion undertakes no obligation to update these forward-looking statements, even if new information becomes available in the future.

The scientific information discussed in this press release is preliminary and investigative. Vidaza has not yet been approved by the EMEA in the EU and the results described in this press release have not been approved for inclusion in the prescribing information for Vidaza by the FDA in the U.S. or any other regulatory authority.

SOURCE Pharmion Corporation
08/02/2007
CONTACT: Breanna Burkart or Anna Sussman, Directors, Investor Relations and Corporate Communications of Pharmion Corporation, +1-720-564-9150
Web site: http://www.pharmion.com
(PHRM)
CO: Pharmion Corporation
ST: Colorado
IN: HEA BIO MTC
SU: TRI CCA DE
-- LATH092 --
5652 08/02/2007 08:26 EDT http://www.prnewswire.com

Subject Codes: PT/lang.en, PC/ticker, IN/HEA, IN/BIO, IN/MTC, SU/TRI, SU/CCA, RE/Colorado, PC/priority.r, PC/category.f
Company Codes: NASDAQ-NMS:PHRM