

**FINAL – for release at 7am Eastern on Wednesday, August 29**

## **Pharmion's Oral Azacitidine Granted Fast Track Status for Myelodysplastic Syndromes**

**BOULDER, Colo.**, August 29, 2007 – Pharmion Corporation (NASDAQ: PHRM) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for oral Azacitidine in the treatment of Myelodysplastic Syndromes (MDS).

Fast Track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track emphasizes the critical nature of close, early communication between the FDA and sponsors. The benefits of Fast Track include scheduled meetings to seek FDA input into development plans, and the option of submitting a New Drug Application in sections rather than all components simultaneously. These meetings can help the FDA and sponsors reach early agreement on design of the clinical efficacy studies that will be needed to support approval.

The FDA stated that Fast Track designation was granted for oral Azacitidine for MDS because Azacitidine is approved to treat all subtypes of MDS, and because it will potentially provide a safer, more comfortable, more convenient and more efficient route of administration of Azacitidine.

“We are extremely enthusiastic about working closely with Pharmion to drive the development of oral Azacitidine,” said Dr. Hagop Kantarjian, chair of the department of leukemia at the University of Texas M.D. Anderson Cancer Center. “Vidaza has now demonstrated a unique and profound survival benefit in higher-risk MDS, and we think oral Azacitidine may provide significant benefit in treating lower risk forms of MDS as well. We are delighted that the FDA shares our view that its development should be expedited. The opportunity to explore the biological and clinical consequences of continuous oral dosing of Azacitidine is particularly exciting, since we know that DNA methylation occurs between cycles of intermittent parenteral therapy. Effects of continuous Azacitidine dosing on tumor RNA, another potential azacitidine target, will also be explored for the first time.”

Pharmion currently markets the parenteral formulation of azacitidine, known as Vidaza<sup>®</sup> (azacitidine for injection) for the treatment of patients with Myelodysplastic Syndromes (MDS). In January 2007 the FDA approved a new drug application supplement to add intravenous use as a new route of administration to instructions in the prescribing information for Vidaza. Earlier this month, Pharmion announced topline results from the largest study ever conducted in higher-risk MDS, which demonstrated a significant improvement in survival for patients treated with Vidaza. In the primary endpoint analysis, Vidaza treatment was associated with a median survival of 24.4 months versus 15 months for those receiving conventional care regimens, an improvement of 9.4 months ( $p < 0.0001$ ).

Pharmion is exploring oral Azacitidine's utility in the treatment of MDS and other cancers where demethylation may 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.

An oral dosage formulation of Azacitidine, in addition to the more desirable and convenient route of administration, would enable the evaluation of a low-dose regimen that could maximize demethylation and gene re-expression, as well as the evaluation of long-term or maintenance therapy.

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### **About Vidaza**

Vidaza was the first drug approved for the treatment of all five subtypes of myelodysplastic syndromes (MDS), including refractory anemia (RA), 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 (CMML).

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 azacitidine 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 azacitidine 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.

### **Important Safety Information**

Vidaza is contraindicated in patients with a known hypersensitivity to azacitidine or mannitol and in patients with advanced malignant hepatic tumors. In clinical studies, the most commonly occurring adverse reactions 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%). 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 azacitidine is potentially hepatotoxic in patients with severe pre-existing hepatic impairment, caution is needed in patients with liver disease. In addition, azacitidine 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 MDS**

The highest prevalence of MDS is in patients over 60 years of age. According to the American Cancer Society and the Aplastic Anemia and MDS International Foundation, there are approximately 10,000-30,000 new cases of MDS in the United States each year. Survival ranges from six months to many years for the different subtypes of MDS.

### **About Epigenetics**

DNA methylation and histone deacetylation are two of the more studied epigenetic regulators of gene expression. Epigenetics refers to changes in the regulation of gene expression. Epigenetic changes can silence gene expression and, unlike DNA mutations, may be reversed by targeting the enzymes involved. The silencing of key cell cycle control genes and tumor suppressor genes through these two mechanisms of epigenetic regulation have been demonstrated *in vitro* and *in vivo* in hematological malignancies and in solid tumors. Vidaza has been shown to reverse the effects of DNA hypermethylation with subsequent gene re-expression and likewise MGCD0103 has been shown, *in vivo*, to reverse the effects of inappropriate deacetylation resulting in gene expression reactivation. 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 Pharmion**

Pharmion is a leading global oncology 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<sup>®</sup>, a DNA demethylating agent. For additional information about Pharmion, please visit the company's website at [www.pharmion.com](http://www.pharmion.com).

**Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995:** *This release contains forward-looking statements, which express the current beliefs and expectations of management, including statements related to the potential efficacy of oral Azacitidine and Vidaza. Such statements are based on current expectations and beliefs only and are subject to risks and uncertainties, many of which are beyond our control, which could cause the actual results to differ significantly from the results expressed or implied 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. Important factors that could cause or contribute to such differences include, but are not limited to, the potential failure of product candidates, including oral Azacitidine, to demonstrate safety and efficacy in clinical and non-clinical testing; the possibility that topline results from the clinical trial discussed in this press release will not be confirmed upon full analysis of the results of the trial and that additional information relating to the safety, efficacy or tolerability of Vidaza may be discovered upon further analysis of data from that trial or analysis of data from other ongoing Vidaza clinical trials; the ability to*

*complete regulatory submissions and gain regulatory approvals in a timely manner; the ability to initiate and complete trials at the referenced times; the impact of competition from other products under development by Pharmion's competitors; the uncertainty of the regulatory environment and changes in the health policies of various countries; uncertainties regarding market acceptance of products newly launched, currently being sold or in development; and the failure of third-party manufacturers to produce the product volumes required on a timely basis. 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 June 30, 2007, its Annual Report on Form 10-K for the year ended December 31, 2006 and in our 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 publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.*

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