



## **Affymax Completes Treatment and Last Patient Follow-up in Phase 3 Program for Investigational Drug, Hematide(TM), to Treat Anemia in Chronic Renal Failure**

### ***Topline Results Expected in Q2 2010***

PALO ALTO, Calif., Jan 25, 2010 (BUSINESS WIRE) -- Affymax, Inc. (Nasdaq:AFFY) today announced completion of treatment and follow-up of patients with anemia due to chronic renal failure enrolled in the four-trial, Phase 3 clinical program for the investigational drug Hematide. The company expects to report topline results from all four Phase 3 trials in the second quarter of 2010. The Phase 3 clinical program enrolled approximately 2,600 chronic renal failure patients at approximately 400 clinical trial sites.

"Completion of this comprehensive Hematide program marks a major milestone and we anticipate an intensive period of data compilation and analysis," said Arlene Morris, president and chief executive officer of Affymax, Inc. "We look forward to sharing top-line data in the coming months that, if positive, will support our plan to file a NDA for Hematide in chronic renal failure later this year."

The Hematide Phase 3 program consisted of four open-label, randomized active-controlled clinical trials in the U.S. and Europe, including two trials in dialysis patients and two others in patients not on dialysis. The PEARL 1 and PEARL 2 trials conducted in non-dialysis patients were designed to evaluate the safety and efficacy of Hematide compared with darbepoetin alfa for treating anemia and maintaining hemoglobin levels over time based on the trial protocol.

In dialysis patients, the EMERALD 1 and EMERALD 2 trials evaluated the safety and efficacy of Hematide in its ability to maintain hemoglobin levels in the target range when patients were switched from epoetin alfa or epoetin beta to Hematide.

Analysis of efficacy for each of the four studies is based on assessments of non-inferiority to the comparator drugs. The primary efficacy endpoint is the mean change in hemoglobin from baseline. The hemoglobin target range is 11-12 g/dL for non-dialysis patients and 10-12 g/dL for those on dialysis.

In all studies, Hematide was dosed once every four weeks while comparator drugs were dosed more frequently according to their product labels. Treatment in each trial was continued until the last patient had been treated for at least 52 weeks. The primary safety assessment will be determined by the analysis of non-inferiority to comparator drugs using a composite cardiovascular endpoint from a safety database pooled from the four Phase 3 trials. The duration of the Phase 3 program was contingent on collecting a sufficient number of cardiovascular safety events for statistical analysis.

### **About Hematide**

Hematide is a novel synthetic, PEGylated peptidic compound that binds to and activates the erythropoietin receptor and thus acts as an erythropoiesis stimulating agent (ESA).

Affymax and Takeda are collaborating on the development of Hematide and plan to co-commercialize the product once approved in the United States. Phase 3 clinical trials investigated the potential for Hematide to treat anemia associated with chronic renal failure. The product, upon approval, will be commercialized in the European Union by Takeda.

### **About Anemia in Chronic Renal Failure (CRF)**

Anemia in CRF affects many individuals with Chronic Kidney Disease (CKD). According to the National Kidney Foundation, 26 million Americans - 1 in 9 U.S. adults - have CKD. Anemia develops in the early stages of CKD and worsens as patients progress towards total kidney failure and need a dialysis machine to eliminate waste and water from their blood. In severe or prolonged cases of anemia, the lack of oxygen in the blood can cause serious and sometimes fatal damage to the heart and other organs. Benefits of anemia correction in patients with CKD may include decreased morbidity, hospitalization, and mortality.<sup>1</sup>

### **About Affymax, Inc.**

Affymax, Inc. is a biopharmaceutical company committed to developing novel drugs to improve the treatment of serious and

often life-threatening conditions. For additional information, please visit [www.affymax.com](http://www.affymax.com).

*This release contains forward-looking statements, including statements regarding the success of the collaboration, timing, design and results of the Company's clinical trials and drug development program and the timing and likelihood of the commercialization of Hematide. The Company's actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties, including risks relating to the continued safety and efficacy of Hematide in clinical development, the potential for once per month dosing and room temperature stability, the cardiovascular event rate in our Phase 3 program, the timing of patient accrual in ongoing and planned clinical studies, regulatory requirements and approvals, research and development efforts, industry and competitive environment, intellectual property rights and disputes and other matters that are described in Affymax's quarterly report on Form 10-Q filed with the Securities and Exchange Commission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. The Company undertakes no obligation to update any forward-looking statement in this press release.*

<sup>1</sup>[http://www.anemia.org/pdf/mon Anemia and CKD.pdf](http://www.anemia.org/pdf/mon_Anemia_and_CKD.pdf)

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