

For Immediate Release

Contact:

Allen K. Roberson
Chief Financial Officer
CyDex Pharmaceuticals, Inc.
913.685.8850
aroberson@cydexpharma.com

CyDex Pharmaceuticals Receives Orphan-Drug Designation for Melphalan

LENEXA, Kansas – December 8, 2008 – [CyDex Pharmaceuticals, Inc.](http://www.cydexpharma.com) today announced that it has received orphan-drug designation from the U.S. Food and Drug Administration (FDA) for melphalan “as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation.”

Currently under development, CyDex’s new intravenous formulation of melphalan (propylene glycol-free) is enabled by CAPTISOL[®] – the company’s proprietary and patented sulfobutylether β-cyclodextrin. Melphalan is an FDA-approved chemotherapy for multiple myeloma marketed under the brand name Alkeran[®] by GlaxoSmithKline. Alkeran is packaged as two separate vials that must be combined prior to use and, due to its limited stability, administered shortly thereafter. *Captisol-Enabled[®]* melphalan is a one-vial formulation with extended room-temperature stability and does not contain harsh co-solvents.

“Receiving FDA orphan-drug designation for melphalan is an important step for CyDex as we develop our [retained product pipeline](#),” said Theron E. Odlaug, Ph.D., president and chief executive officer. “Creating a chemotherapy product with improved ease of administration has the potential to advance the treatment of cancer. It is also a key initiative in CyDex’s core strategy, which is to develop and market our own line of specialty pharmaceutical injectable products. We look forward to moving *Captisol-Enabled* melphalan through the clinical development and FDA review process.”

Orphan-drug designation is a special status for diseases or conditions affecting fewer than 200,000 patients in the United States. It provides CyDex seven years of U.S. market exclusivity for its intravenous melphalan product after FDA approval of a marketing application, as well as access to clinical research grants and potential development program assistance through such means as the special protocol assessment.

CyDex enlisted the expertise and services of Beckloff Associates, Inc. to help prepare and file the Orphan-Drug Application. “This designation is an exciting and important milestone for CyDex and will allow for the development of products necessary to treat unmet medical needs in small populations,” said Michael C. Beckloff, president, Beckloff Associates.

About CyDex Pharmaceuticals

[CyDex Pharmaceuticals, Inc.](http://www.cydexpharma.com) is a specialty pharmaceutical company developing products and licensing its CAPTISOL[®] technology. CyDex is developing its own pipeline of products using its enabling technology solutions, and partnering with leading pharmaceutical, specialty pharmaceutical and biotechnology companies. For additional information on business development opportunities, please contact Ralph Johnston at rjohnston@cydexpharma.com or 913.685.8850. CyDex is a privately held company located in suburban Kansas City. To learn more about the company, please visit www.cydexpharma.com.

###