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THE MEDICINES COMPANY ISSUES A NATIONWIDE RECALL FOR CERTAIN LOTS OF CLEVIPREX® THAT MAY CONTAIN PARTICULATE MATTER

FOR U.S. AUDIENCES ONLY

Parsippany, N.J., December 16, 2009—The Medicines Company (NASDAQ: MDCO) announced today that it is voluntarily recalling eleven (11) lots of Cleviprex® (clevidipine butyrate) injectable emulsion due to the potential presence of visible particulate matter which has been observed in some vials during a routine annual inspection. The affected Cleviprex lots are 61-978-DW, 61-979-DW, and 61-980-DW, Exp. 01/2010; 68-404-DJ, 68-405-DJ, and 68-406-DJ, Exp. 08/2010; 69-830-DJ, 63-385-DJ, 63-386-DJ, and 63-266-DJ, Exp 03/2011; and 64-453-DJ, Exp. 04/2011. No other lots are affected by this recall.

The Medicines Company has not received any product complaints or reports of adverse events related to this issue. The Company is cooperating with the U.S. Food and Drug Administration on this recall.

The particulate matter comprises sub-visible inert stainless steel particles of around 2.5 microns. When present in low numbers as observed, particles of this size are not known to constitute a health hazard. Experimental animal and human data indicate that they are scavenged by macrophages and other cells of the reticuloendothelial system without adverse effects. Although aggregates have not been observed, if the sub-visible particles were to aggregate, or if larger particles were present, then they could become visible and could theoretically reduce blood flow in capillaries, cause mechanical damage to some tissues, or initiate acute or chronic inflammatory reactions. Reduced blood supply to tissues may lead to ischemia or organ insufficiency in the brain, kidney, liver, heart or lungs.

Anyone with inventory from the affected lots of Cleviprex should arrange for its return through their pharmaceutical wholesaler/distributor. Unaffected product from lots 68-407-DJ, 68-408-DJ, 71-101-DJ and 71-106-DJ is being shipped to wholesalers and can be ordered by hospitals.

For medical inquiries, adverse event reporting or quality issues related to Cleviprex, please contact The Medicines Company Medical Information at 1-888-977-6326 Monday to Friday 8:00am-5:30pm EST or cleviprexrecall@themedco.com.

Any adverse reactions associated with the use of Cleviprex may also be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

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