STATEMENT BY DINESH THAKUR REGARDING US GOVERNMENT'S CASE AGAINST RANBAXY

FOR IMMEDIATE RELEASE - Washington, D.C. (May 13, 2013)

Today, the United States government brought to a conclusion an eight-year criminal and civil investigation of Ranbaxy Laboratories Limited, India's largest generic drug company, and Ranbaxy, Inc., Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories, Inc., Ranbaxy USA, Inc., and Ohm Laboratories, Inc. ("Ranbaxy"). Ranbaxy has agreed to pay $500 million to resolve allegations of falsifying drug data and systemic manufacturing violations. Ranbaxy USA Inc. has pleaded guilty to multiple criminal violations. Dinesh Thakur served as the whistleblower in this case and is the former Ranbaxy Director and Global Head, Research Information & Portfolio Management.

Statement by Dinesh Thakur:

"I am relieved that the government's investigation has concluded. I am thankful for the remarkable effort of United States Food and Drug Administration, Department of Justice, United States Attorney's Office for the District of Maryland, USAID, and State Medicaid Fraud Control Units. Their work has been tireless and dedicated.

"Eight years ago, as the Director of Project & Information Management at Ranbaxy, I discovered that the company falsified drug data and systemically violated current good manufacturing practices and good laboratory practices. Ranbaxy's management was notified of these widespread problems. When they failed to correct the problems, it left me with no choice but to alert healthcare authorities.

"I worked with U.S. regulatory authorities for two years to expose the fraud. In furtherance of this effort, I filed a lawsuit to hold Ranbaxy accountable. It took us eight years to help government authorities unravel a complicated trail of falsified records and dangerous manufacturing practices that threatened to compromise the quality and safety of Ranbaxy drugs. Along the way, the government barred the importation of Ranbaxy drugs, held the company accountable for its data fraud under FDA's Application Integrity Policy, and required it to implement corrective measures to prevent the problems from recurring.

"As a senior pharmaceutical executive, I understand the importance of regulatory oversight in ensuring drug quality and safety. There are unique challenges in a global drug market, which is highly dependent on international manufacturing and distribution. In fact, approximately 78 percent of prescription drugs dispensed in the United States are generic, and a growing percentage of drugs – both generic and name brand – is manufactured overseas. This case highlights the need for effective regulation that applies to drugs sold in the United States, regardless where they are manufactured.
I would like to thank FDA's Office of Criminal Investigation, United States Attorney's Office for the District of Maryland, Department of Justice, USAID, and Andrew M. Beato, Bob Muse, and Rory Kelly of Stein Mitchell Muse & Cipollone LLP. I hope that our actions and this case have helped to improve the quality and safety of drugs in the United States and abroad."

FOR MORE INFORMATION
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