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Ranbaxy pleads guilty, will pay $500 mn to the US

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New Delhi: Ranbaxy Laboratories has reached a final settlement agreement regarding a previously disclosed investigation by the US Department of Justice (DOJ) of data integrity and manufacturing processes at certain Ranbaxy facilities in India.

On December 20, 2011, Ranbaxy announced that it had signed a consent decree with the US FDA, under which Ranbaxy committed to further strengthen procedures and policies to ensure data integrity and to comply with current good manufacturing practice cGMP. In anticipation of the settlement agreement with the DOJ announced today, Ranbaxy announced at that time its intention to make a financial provision of $500 million related to expected costs associated with resolving the DOJ investigation.

Under the terms of the final settlement agreement, Ranbaxy and its affiliates have agreed to settle alleged civil violations of the False Claims Act with the US, all 50 states and the District of Columbia. Separately, a US subsidiary, Ranbaxy US has agreed to plead guilty to a criminal information charging violations of the Food, Drug and Cosmetic Act and other criminal statutes. Ranbaxy's payments related to both the civil and criminal settlements total $500 million in aggregate. The financial provision Ranbaxy established in December 2011 will be sufficient to cover all material financial obligations under the agreement.

Mr Arun Sawhney, CEO and MD, Ranbaxy, stated that, "Today's announcement marks the resolution of this past issue. We are pleased to continue bringing safe, effective and quality medicines to market for the benefit of consumers in the US and other parts of the world. While we are disappointed by the conduct of the past that led to this investigation, we strongly believe that settling this matter now is in the best interest of all of Ranbaxy's stakeholders; the conclusion of the DOJ investigation does not materially impact our current financial situation or performance."

Mr Sawhney added, "Ranbaxy has successfully launched several generic products recently and is well-positioned for future growth in the US and around the world with a robust pipeline of important products as it continues to build a strong global portfolio of branded and generic prescription and OTC pharmaceuticals. Our conduct is guided by our philosophy of 'Quality and Patients First.'"