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Merck, Novo, BMS to reassure FDA of drug safety

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Singapore: The US FDA is considering setting up a study, either through the agency or with the help of drug makers, to look deeper into whether medicines for type 2 diabetes, including Merck's Januvia and Bristol Myers-Squibb's Byetta, cause pancreatic cell growth that could turn cancerous.

During March 2013, there had been talks of unpublished findings that the FDA said may show pre-cancerous cellular changes in diabetics taking drugs called incretin mimetics. The FDA is reviewing the data and scientists from the agency and the companies are gathering today at the National Institutes of Health (NIH) to sort it out. Representatives from companies like Merck & Co, Novo Nordisk and Bristol Myers-Squibb (BMS) would be present at the meeting.

Some FDA scientists believe that the report that arose in March didn't show a direct link to significant cancer risk. It is also believed that additional data mining of the FDA's adverse event database is unlikely to shed more light and what is needed is adequately powered, long-term epidemiological data.

Dr Robert Ratner, chief scientific and medical officer, American Diabetes Association, said that, "We need some calm heads and to look at the data and try and make some reasonable judgments out of this. We are all anxious to be sure the therapies we have available are safe, but we also want to make sure we have therapies available."

Dr Alan Moses, global chief medical officer, Novo Nordisk, said that, "Some data have been overzealously interpreted. That's a real challenge for patients out there who are taking this medicine and we have no conclusive evidence that there's a problem and they're being scared to death. I am very reassured in the data that we have. I am hoping the listeners in the room will be likewise reassured."