

## Solvay Pharmaceuticals Briefing Document Errata

### **Section 4.3, Paragraph 2:**

#### **The following text was inserted:**

“A murine histiocytic tumor was found in the spleen of one female mouse inoculated with  $10^1$  Solvay MDCK cells. It was confirmed by PCR not to be of canine origin and is considered a background finding that can be expected in this type of test animal and age. A lung adenoma was observed in one mouse inoculated with  $10^7$  reference ATCC MDCK cells and in one mouse inoculated with  $10^7$  Solvay MDCK cells. Both lung adenomas were confirmed by PCR to be of canine origin.”

### **Section 4.3, Paragraph 4:**

#### **The following text was replaced:**

“Murine retrovirus-associated lymphomas were observed at necropsy in two of 48 nude mice six months after inoculation with high levels of MDCK DNA; these lymphomas are not considered to be related to MDCK DNA exposure, as they are not abnormal for this animal at this age.”

**with**

“A lymphosarcoma was diagnosed in the thoracic cavity of one mouse and a tumor that closely resembles a histiocytic sarcoma was found in the liver of a second mouse. These findings are not abnormal for this animal at this age and they were attributed to spontaneous tumor development.”

### **Table 4.1:**

#### **Title change:**

“Testing of Intact MDCK Cells for Tumorigenic Potential”

#### **The following text was added to the Results for H0201.7.002X:**

“A lung adenoma was observed in one mouse inoculated with  $10^7$  reference ATCC MDCK cells and in one mouse inoculated with  $10^7$  Solvay MDCK cells. Both were confirmed to be of canine origin by PCR. A murine histiocytic tumor was found in the spleen of one female mouse inoculated with  $10^1$  Solvay MDCK cells.”

### **Table 4.2:**

#### **Title change:**

“Testing of Homogenized MDCK Cells for Oncogenic Potential”

### **Table 4.3:**

#### **Title change:**

“Testing of MDCK DNA for Oncogenic Potential”

#### **The following text was replaced:**

“Two females had apparently non-test-article-related tumors in internal organs.”

**with**

“One lymphosarcoma (thoracic cavity) and one histiocytic sarcoma (liver) were found in the test group.”