FRESENIUS KABI

Press Release

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Fresenius Kabi India reaches resolution to conclude 2013 Kalyani investigation

Fresenius Kabi Oncology Ltd. (FKOL), India, has reached an agreement with the U.S. Department of Justice (DOJ) that would conclude an investigation of events that took place in 2013.

In 2013, FKOL notified the FDA immediately upon discovering that certain employees at the company's plant in Kalyani, India, had failed to provide relevant records during an FDA inspection. These individuals acted in violation of Fresenius Kabi's compliance requirements, code of conduct and values. As a consequence, their employment was terminated immediately. Fresenius informed the public about these events in July 2013.

Patient safety was and has continued to be safeguarded at all times. Product supplied from this plant was within specifications. All necessary remediation actions were successfully implemented many years ago, and the plant has been fully operational ever since.

Under the agreement, which still must be reviewed and accepted by the United States District Court for the District of Nevada, FKOL will make a payment of USD 50 million. Given past accruals for this matter, the resolution will be net income neutral. The agreement includes a compliance addendum under which FKOL will build on its existing quality compliance management system to monitor compliance and provide the DOJ with regular reports on its effectiveness.

Mats Henriksson, CEO of Fresenius Kabi, said: "While we are pleased to have reached this resolution, we regret that such events happened years ago in one of our plants. In line with our commitment to highest ethical and quality standards, we immediately and consequently took all necessary measures to remedy the situation in full cooperation with the authorities. As a reliable partner of health care systems around the world, we continuously strive for the highest standards in pharmaceutical manufacturing."

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Fresenius Kabi is a global health care company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. The company's products and services are used to help care for critically and chronically ill patients. Fresenius Kabi's product portfolio comprises a comprehensive range of I.V. generic drugs, infusion therapies and clinical nutrition products as well as the devices for administering these products. In the field of biosimilars, Fresenius Kabi focuses on autoimmune diseases and oncology. In 2019, the first biosimilar product by Fresenius Kabi was launched. Within transfusion medicine and cell therapies, Fresenius Kabi offers products for collection of blood components and extracorporeal therapies.

Fresenius Kabi employs around 40,000 people worldwide. In 2019, the company reported sales of more than €6.9 billion. Fresenius Kabi AG is a wholly owned subsidiary of the Fresenius SE & Co. KGaA healthcare group.
For more information visit the company's website at www.fresenius-kabi.com

Management Board: Mats Henriksson (Chairman), Marc Crouton, John Ducker, Dr. Oskar Haszonits, Dr. Christian Hauer, Dr. Michael Schönhofen, Gerrit Steen
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