

## Press Release

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### **Fresenius Kabi and Boehringer Ingelheim RCV successfully coupled HES to a therapeutic protein in an industrial scale applying Fresenius Kabi's HESylation® Technology**

Through the coupling of Fresenius Kabi's hydroxyethyl starch ("HES") to a therapeutic protein, the capability to produce robust HESylated pharmaceuticals on an industrial scale level was successfully demonstrated. Fresenius Kabi provided Boehringer Ingelheim RCV GmbH & CoKG with its HESylation® Technology to manufacture HES conjugated to a therapeutic protein.

The HESylated pharmaceutical deriving from both, the laboratory and the industrial scale were well comparable with regard to quality and process yield. The amount of the HESylated pharmaceutical equalled 30,000 once weekly doses of an already approved long acting second generation product.

Upon this first successful collaboration, Fresenius Kabi Deutschland GmbH and Boehringer Ingelheim RCV GmbH & Co KG will actively evaluate further opportunities to extend the collaboration and to apply HESylation® Technology, respectively.

#### **HESylation® Technology**

HESylation® Technology allows a targeted modification of drugs and their characteristics by site-specific coupling to HES molecules. HES-coupling enables the

modification of key pharmacological parameters such as absorption, metabolization, half-life, water solubility and safety.

Fresenius Kabi's Business Unit HESylation® Technology is a focused team of experienced professionals. With access to customized HES species and dedicated fully equipped R&D and GMP facilities the support for biopharmaceutical product developments are fulfilled at highest standards.

HESylation® Technology is based on the extensive expertise in the field of hydroxyethyl starch ("HES") that Fresenius Kabi has gathered as the world's largest producer of pharmaceutical grade HES. HES is derived from waxy maize starch and can be metabolized by the body's enzymes. HES solutions have been safely administered for over 30 years to treat deficient blood volume and to improve the rheological properties of blood.

Fresenius Kabi expects to enter into further collaborations with leading pharmaceutical and biotechnology companies to contribute to improved pharmaceutical products through its HESylation® Technology platform.

HESylation® Technology is covered by a broad portfolio of intellectual property rights. For further details please visit <http://www.HESylation.com>.

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## **Fresenius Kabi**

Fresenius Kabi is focused on products for the therapy and care of critically and chronically ill patients in and outside the hospital. Fresenius Kabi's core product range includes intravenously administered drugs, infusion solutions and parenteral as well as enteral nutrition and the medical devices for the application.

Fresenius Kabi has more than 22,000 employees worldwide and a global network of around 55 sales organizations and more than 55 production sites. In 2009, Fresenius Kabi achieved sales of € 3,086 million and an operating profit (EBIT) of € 607 million. Fresenius Kabi AG is a 100% subsidiary of the health care group Fresenius SE. For more information about Fresenius Kabi, please visit the company's web site at [www.fresenius-kabi.com](http://www.fresenius-kabi.com)

This release contains forward-looking statements that are subject to various risks and uncertainties. Future results could differ materially from those described in these forward-looking statements due to certain factors, e.g. changes in business, economic and competitive conditions, regulatory reforms, results of clinical trials, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. Fresenius does not undertake any responsibility to update the forward-looking statements in this release.

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## **About Boehringer Ingelheim**

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 142 affiliates in 50 countries and more than 41,500 employees. Since it was founded in 1885, the family-owned company has been committed for 125 years to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.

Boehringer Ingelheim Regional Center Vienna (BI RCV), the Austrian affiliate of Boehringer Ingelheim, is responsible for the human pharmaceuticals and animal health business in more than 30 Central and Eastern European countries. Moreover, the whole clinical research of the region is managed from Vienna, where also the oncology research center of Boehringer Ingelheim is located. Furthermore, BI RCV is the center of competence for microbial expression technologies and the development and GMP production of biopharmaceuticals for Boehringer Ingelheim and its third party customers.

Today, Boehringer Ingelheim is one of the world's leading companies for contract development and manufacture of biopharmaceuticals. All types of services from mammalian cell line or microbial strain development to final drug production can be delivered within a one-stop-shop concept. Boehringer Ingelheim delivers services for pre-clinical development up to global market supply with a strong commitment to its customers at its manufacturing facilities for mammalian cell culture and microbial fermentation. Boehringer Ingelheim has brought 17 molecules to market and has many years of experience in multiple molecule classes such as monoclonal antibodies, recombinant proteins, interferons, enzymes, fusion molecules and plasmid DNA. Furthermore, high-titer platform technologies for new antibody mimetic formats such as scaffold proteins and antibody fragments are available for the manufacture of customer products.

[www.biopharma-cmo.com](http://www.biopharma-cmo.com)

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