Fresenius
The Health Care Group

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Contact:
Birgit Grund
Fresenius AG
Investor Relations
Tel. ++49 - 6172 - 608 2485
Fax ++49 - 6172 - 608 2488
e-mail: ir-fre@fresenius.de
Internet: http://www.fresenius-ag.com

Fresenius Investor News

Immune Suppressive ATG-Fresenius S Receives Fast Track Status in the U.S. – First Patient Recruited in Clinical Trial

Fresenius Biotech and the U.S. Company Enzon Pharmaceuticals, Inc. today announced the recruitment of the first North American patient for a phase II study for approval of ATG-Fresenius S. The polyclonal antibody suppresses the immune reaction against transplanted organs to reduce the risk of rejection. It is already marketed in over 60 countries. The entry of the first patient into the clinical study is an important milestone to introduce this successful product in the North American market. The cooperation partner Enzon is responsible for the clinical development and approval in the U.S., Fresenius Biotech will manufacture and deliver ATG-Fresenius S.

Enzon and Fresenius Biotech also announced today that the U.S. Food and Drug Administration (FDA) granted Fast Track Status in the approval process for the use of ATG-Fresenius S in lung transplantation. The Fast Track process provides a particularly close working relationship with the FDA in order to accelerate the development and approval of pharmaceuticals that are appropriate to treat critically ill patients where adequate therapeutic modalities are not available.

A phase III study using ATG-Fresenius S in renal transplant patients is currently being prepared.

Fresenius Biotech signed a cooperation contract with Enzon Pharmaceuticals in 2003 for the U.S. approval of ATG-Fresenius S. This product is expected to be introduced to the U.S. market in 2007.

Enzon Pharmaceuticals is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics to treat life-threatening diseases. Further information can be found on the Company's website www.enzon.com

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