

Investor News

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Birgit Grund
Senior Vice President
Investor Relations

Fresenius SE & Co. KGaA
Else-Kröner-Straße 1
61352 Bad Homburg
Germany
T +49 6172 608-2485
F +49 6172 608-2488
birgit.grund@fresenius.com
www.fresenius.com

Fresenius Biotech's ATG-Fresenius S approved for GVHD prophylaxis in stem cell transplantations in Germany

Fresenius Biotech is the first company in Germany to receive Paul-Ehrlich-Institut approval to use a polyclonal antibody in stem cell transplantations. As a result, the preparation – ATG-Fresenius S – can be used in the indication “prophylaxis of graft-versus-host disease (GVHD) for unrelated stem cell transplant donors in adults.” Germany is now the fourth country to approve the preparation in this indication, after Argentina, Portugal and Thailand.

“The preparation’s special mode of action and a steadily growing pool of unrelated donors make the application of ATG-Fresenius S in stem cell transplantations particularly attractive,” said Dr. Christian Schetter, CEO of Fresenius Biotech. “Furthermore, there has been a considerable recent increase in the incidence of hematologic diseases which can be treated with stem cell transplantations.”

In a randomized, multi-center prospective study with 201 patients, the efficacy and tolerability of ATG-Fresenius S in GVHD prophylaxis was assessed in unrelated donor stem cell transplantations. This study compared ATG-Fresenius S in combination with standard GVHD prophylaxis versus standard GVHD prophylaxis alone. Study results show that the acute and chronic GVHD rate could be reduced significantly following administration of ATG-Fresenius S. The results of this study were first presented in 2008 at the annual meeting of the American Society of

Hematology and published in September 2009 in the Lancet Oncology¹ medical journal.

About ATG-Fresenius S

ATG-Fresenius S is a polyclonal antibody that is used for GVHD prophylaxis shortly before stem cell transplantation is performed. The preparation's mode of action, which mainly targets activated T-cells, includes complement-mediated cytotoxicity and apoptotic induction of T-cells and antigen-presenting cells.

ATG-Fresenius S prevents the adhesion of T-cells to the endothelium, minimizes T-cell infiltration and blocks numerous signal transmission paths within the immune system. Furthermore, ATG-Fresenius S has a propagating effect on regulatory cells. A direct anti-tumor effect is described in various hematologic tumors.

The polyclonal antibody ATG-Fresenius S was developed in Germany over 30 years ago for the treatment and prophylaxis of acute rejection reactions in the transplantation of solid organs. ATG-Fresenius S has been approved for use in these indications worldwide in more than 45 countries.

About GVHD (graft-versus-host disease)

GVHD is a frequent complication of stem cell transplantation, which is associated with a high degree of morbidity and mortality. GVHD is an immunological reaction of the donor lymphocytes to the patient's foreign antigens. The following GVHD risk factors are known: the patient's age, the degree of kinship between the donor and the recipient, the type of preparation used for stem cell transplantation as well as the source of the graft. Several components contribute to GVHD's development, among others, tissue damage during preparations for stem cell transplantation, cytokine production and lymphocyte activation. Various immune cells (T-cells, antigen-presenting cells and natural killer cells) are involved in the GVHD mechanism. GVHD frequently causes severe organ and tissue damage, which can become chronic to some extent. GVHD can affect any organ or tissue; the skin, stomach, intestines, liver and the immune system are most frequently attacked. One of the strategies for GVHD reduction is T-cell depletion. ATG-Fresenius S depletes T-cells and consequently represents an important therapeutic advance in GVHD prevention.

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¹ Finke J et al., Standard graft-versus-host disease prophylaxis with or without anti-T-cell globulin in haematopoietic cell transplantation from matched unrelated donors: a randomised, open-label, multicentre phase 3 trial, Lancet Oncology 2009;10:855-864

Fresenius is a health care group with international operations, providing products and services for dialysis, hospital and outpatient medical care. In 2010, Group sales were approximately €16.0 billion. On Dec. 31, 2010, the Fresenius Group had 137,552 employees worldwide.

For more information, visit the company's website at www.fresenius.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.

Fresenius SE & Co. KGaA
Registered Office: Bad Homburg, Germany
Commercial Register Bad Homburg, HRB 11852
Supervisory Board: Dr. Gerd Krick (designated Chairman)

General Partner: Fresenius Management SE
Registered Office: Bad Homburg, Germany
Commercial Register Bad Homburg, HRB 11673
Management Board: Dr. Ulf M. Schneider (Chairman), Rainer Baule, Dr. Francesco De Meo,
Dr. Jürgen Götz, Dr. Ben Lipps, Stephan Sturm, Dr. Ernst Wastler
Chairman of the Supervisory Board: Dr. Gerd Krick