

Press Release

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

Fresenius Biotech has received approval from the Austrian Federal Office for Safety in Health Care for the use of a polyclonal antibody in stem cell transplantations (SCT). The preparation – ATG-Fresenius S – can be used in the indication “conditioning prior to SCT for prevention of graft-versus-host disease (GVHD) after SCT”. The approval is based on proof of significantly fewer GVHD complications following administration of ATG-Fresenius S. Austria is now the fifth country to approve the preparation in this indication, after Germany, Argentina, Portugal and Thailand.

According to the approval, ATG-Fresenius S may be used to treat adult patients with malignant hematologic diseases who undergo SCT involving HLA-compatible, unrelated donors. In such cases, ATG-Fresenius S is administered in combination with standard GVHD prophylaxis. The approval is based on results of a prospective, randomized, multi-center study of HLA-compatible unrelated SCT with 201 patients. The study compared the efficacy and tolerability of ATG-Fresenius S in combination with standard GVHD prophylaxis versus standard GVHD prophylaxis alone. One-year data were published in October 2009 in “The Lancet Oncology” medical journal (Finke et al.)¹.

¹ Finke 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

New long-term data were published in April 2011 in the "Blood" medical journal (Socie et al.)². With regard to acute GVHD grade III-IV, study results showed a significantly reduced incidence of 11.7% vs. 25.5% ($p=0.0392$) in ATG-Fresenius S and non-ATG-Fresenius S groups, respectively. The extensive chronic GVHD rate was significantly lower in ATG-Fresenius S patients, compared with the control group (12.2% vs. 45%; $p<0.0001$). The probability of survival without systemic immunosuppression therapy was three times higher in the ATG-Fresenius S group. Relapse of underlying malignant disease, mortality and overall survival were comparable between both groups.

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

² Socie et al., Chronic graft-versus-host disease: long-term results from a randomized trial on GvHD prophylaxis with or without anti-T-cell globulin ATG-fresenius, Blood, published April 5, 2011, 10.1182/Blood-2011-01-329821

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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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 March 31, 2011 the Fresenius Group had 140,111 employees worldwide. For more information visit the Company's website at www.fresenius.com.

Fresenius Biotech, a company of the Fresenius health care group, is focused on the development, marketing and commercialization of biopharmaceuticals in the fields of oncology and transplantation medicine. Fresenius Biotech is a German company headquartered in Munich. For more information, please visit www.fresenius-biotech.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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