



Company Profile



In Brief

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. Our current research and development activities are primarily concentrated on the clinical development of immunotherapeutic products based on innovative antibody technologies. The company also holds a majority interest in the "European Institute for Research and Development of Transplantation Strategies" (EUFETS AG).

Fresenius Biotech was founded in 2003. The company is headquartered in Gräfelfing near Munich, Germany, and employs about 200 people.

Product Pipeline

	Phase of Development / Clinical Trial					Commer- cialization & Phase IV
	R&D	Preclinical	Phase I	Phase II	Phase III	
ATG	█	█	█	█	█	█
ATG in Stem Cell Transplantation	█	█	█	█	█	
ATG USA	█	█	█	█	█	
catumaxomab Malignant Ascites	█	█	█	█	█	
catumaxomab Ovarian Cancer	█	█	█	█		
catumaxomab Gastric Cancer	█	█	█	█		
ertumaxomab Breast Cancer	█	█	█	█		
FBTA05 Chronic Lymphocytic Leukemia	█	█	█			



Research & Development / Products

Oncology: Trifunctional Antibodies

Fresenius Biotech develops trifunctional antibodies for use in targeted cancer treatment in cooperation with the biotechnology firm TRION Pharma, Munich. In this partnership, Fresenius Biotech is responsible for clinical research and development as well as marketing & sales.

The postulated mode of action of these specific monoclonal antibodies is based on linking cancer cells directly to cells of the body's own immune system, thereby inducing the destruction of the tumor cells.

After completion of a Phase II/III study Fresenius Biotech applied to the EMEA (European Medicines Agency) for marketing authorization of the trifunctional antibody catumaxomab for the treatment of patients with malignant ascites due to epithelial tumors.

The anti-tumor effect of catumaxomab is also being investigated for ovarian and gastric cancer. The antibodies ertumaxomab and FBTA05 are currently being developed for the therapy of breast cancer and lymphatic leukemia, respectively.

Transplantation: Antibody-based Immunosuppression

ATG-Fresenius S (ATG) is a product comprised of polyclonal antibodies applied to suppress undesired immune reactions. ATG has been used successfully for prevention of acute transplant rejection in organ transplantation for over 25 years in more than 60 countries.

With the objective to expand the range of indications for ATG, a Phase III study is currently ongoing to assess its efficacy in the prevention of "graft-versus-host disease" following allogeneic stem cell transplantation. The aim of this treatment with ATG is to suppress the attack of recipient's tissues by donor T-cells.

Manufacturing of Products for Cell or Gene Therapy

The European Institute for Research and Development of Transplantation Strategies (EUFETS AG) is a competence center for gene and cell therapy where Fresenius holds a majority interest. EUFETS has a comprehensive know-how for the development and production of cell therapeutics, retroviral vectors and the genetic modification of primary cells or cell lines.

The GMP services (Good Manufacturing Practice) include a broad spectrum from process development and validation up to the production of material for clinical trials as well as for the market.

In addition, EUFETS can provide cell based in vitro safety and efficacy studies under GLP conditions (Good Laboratory Practice) as well as support of clinical studies.

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