



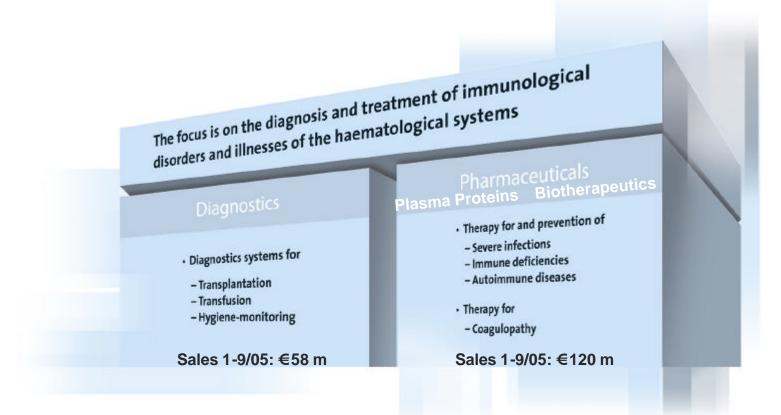


### **Agenda**

- Nine-Month Figures
- Global Specialist in Growing Markets
- Markets and Competitive Position
- Growth Strategy
- Unique R&D Pipeline in Biotherapeutics



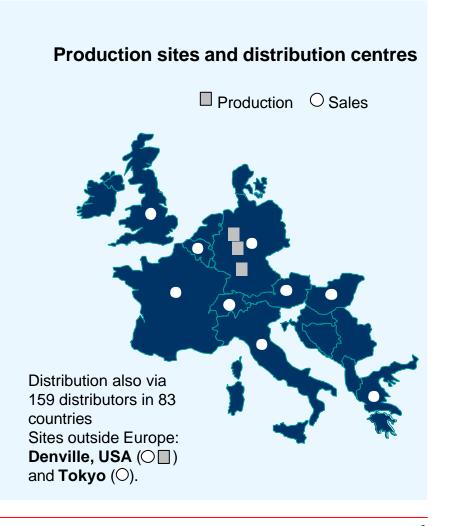
# A Global Specialist in Innovative Immunology and Haematology





## **Key Figures**

- Established international network –
   65 % of sales are generated outside
   Germany
- 1074 employees (FTP) worldwide
- 180 patents on products and procedures
- Experienced Staff in Clinical Research and Approval Procedures
- Promising R&D Pipeline in both
   Pharmaceuticals and Biotherapeutics





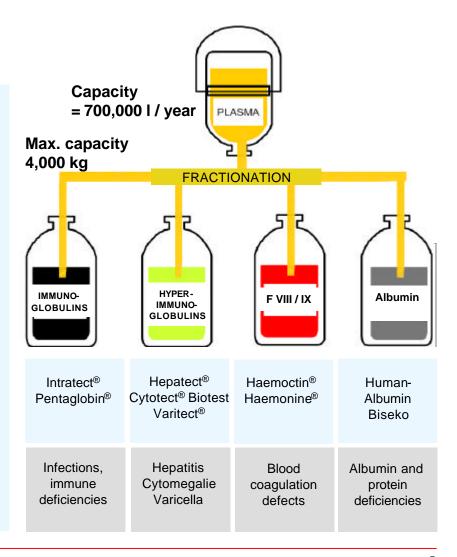
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#### **Biotest Plasma Derivatives**

- Market Share in relevant Markets: 9 %
- Major Competitors: Baxter, CSL/ZLB Behring, Talecris, Bayer Biologicals
- Intratect<sup>®</sup> market share in Germany already amounts to 14 %
- World market leader with Cytotect<sup>®</sup> Biotest and Varitect<sup>®</sup>
- Strong position with Hepatect<sup>®</sup> in Europe
- Albumin: Commodity



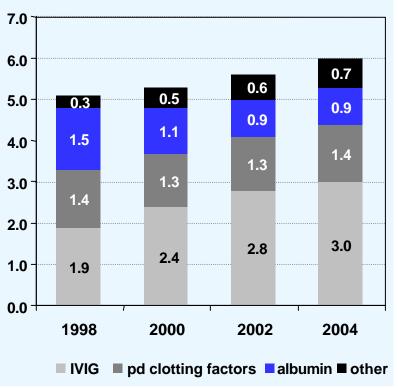


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#### **Plasma Derivatives Market**

- CAGR Immunoglobulins (98-04)= 7.9 %
- Growing demand for plasma-derived clotting factors in emerging markets
- Closure of plasma collection centres and fractionation facilities limits supply
- Price increase in US expected to continue on global scale
- Potential of the largest single market in the US has yet to be opened up by Biotest

## Global market for plasma protein (US-Dollar bn)



source: MRB. own calculations

PK 14.11.2005 Prof. Dr. Gregor Schulz



## **Biotest Diagnostic Reagents and Systems Solutions**

Indication	Main Products	Market Share

#### **Transfusion**

Definition of blood groups

Search of Antibodies

**TANGO®** (blood group system)

Erytype

Solidscreen

#### ·e

No 4 worldwide with a market share of 4 %

Third biggest Player in Europe

Main Competitors: Johnson&Johnson, DiaMed, Immucor

#### **Transplantation**

Typing of tissues (matching of donor's and recipient's tissue) **HLA-serology** 

**HLA-DNA** 

**Systems** (Quick Step, Elpha) No 3 worldwide with a market share of 12 %

Main Competitors: One Lambda, Dynal, Innogenetics

#### **Hygiene Monitoring**

Detection of germs and particles

OKI-Surface-Germ-**Indicators** 

RCS device

RSC foil

No 3 worldwide with a market share of 11 %

Main Competitors: VWR, Becton Dickinson



#### **Diagnostics Market**

• CAGR (02-04) = 5.6 %

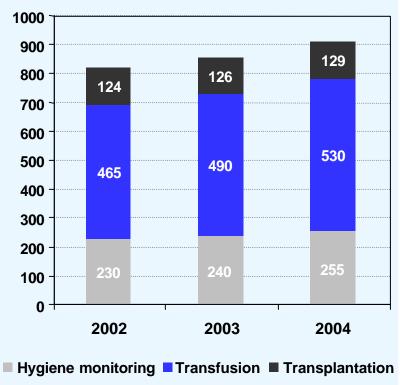
#### **Transfusion and Transplantation**

- IVD directive: new opportunities
- Attractive markets in EC, USA, Japan

#### **Hygiene Monitoring**

 Growing need in pharmaceutical industry due to regulatory demands

## Global market for transfusion and transplantation diagnostics and hygiene monitoring (€m)





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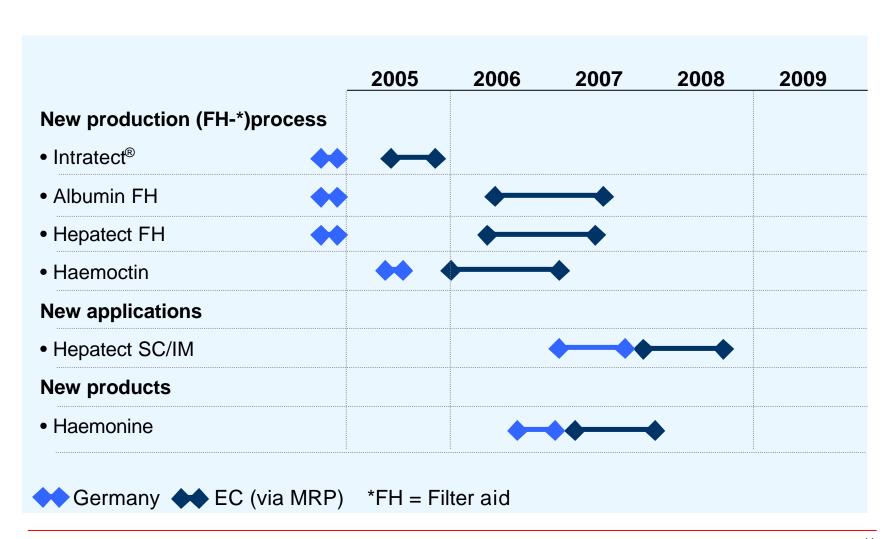
## **Growth Strategy in Pharmaceuticals**

- Building on the capacity of the modern plasma production plant (Total CAPEX 2005 e: €75,5 m)
- Increasing EC market share
- Entering US market (long term goal)
- Reducing dependence on volatile tender markets
- Developing new indications and applications for plasma derivatives
- Researching new products: von-Willebrand factor, IGM-enriched immunoglobulin preparation





## **Registration of Plasma Derivatives in Europe**





## Intratect® Ongoing Successful Sales Record

- Intratect sales in Germany pushed up revenues of polyvalent immunoglobulins by 30 %
- MR\*-Process successfully concluded in October 2005
- Approval in 9 European countries including UK and Italy with high demands
- € 200 m revenues forecast within
   5 years in Europe



<sup>\*</sup> MR = European Mutual Recognition Procedure



## **Clinical Development of Plasma Derivatives**

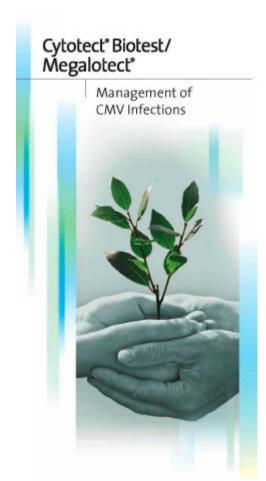
Product	Indication	Evaluation of Clinical Data
Intratect <sup>â</sup> *	primary immunodeficiency disease (PID)	2006
Intratect <sup>â</sup>	chronic pain syndromes	2007
Pentaglobin <sup>â</sup> *	beginning peritoneal infections (peritonitis)	2006
Cytotect <sup>â</sup> Biotest	CMV prophylaxis / therapy during pregnancy	2005
Pentaglobin	abdominal sepsis (bacterial Infection)	2007
Pentaglobin	sepsis in young children (bacterial Infection)	2007

<sup>\*</sup> Supportive data for already established indications



## **Successful Treatment with Cytotect® Biotest During Pregnancy**

- Large-scale clinical trial concluded significant reduction of severe malfunctions of unborn children
- Study was published in the prestigious "New England Journal of Medicine"
- Conventional drugs cannot be used (side effects)
- Study opens up a new application with big market potential:
  - 21,000 infections during pregnancy
     e.g. in Europe.
     Estimated market potential € 33 m.
  - 10 % of infected unborn children exhibit severe malfunctions.





#### **Growth Strategy in Diagnostics**

- Marketing of TANGO<sup>®</sup> in US and EC
- Distribution of manual reagents via own network
- Enforced development of HLA-Chips
- Building own production site for Heipha in the US





## Kick off for TANGO® Marketing in the U.S.

- FDA approval for TANGO reagents
   (BLA) end of July 2005
- Shipment of first 10 instruments to Olympus in September 2005
- 21 systems will be sold to Olympus in 2005
- Totally 300 systems are forecasted in the U.S. within 5 years
- Target: 20 % market share of the worlds leading transfusion market amounting up to \$ 200 m





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#### **Biotest Biotherapeutics**

- Three monoclonal antibody (MAB) projects
- Unique mode of action
- High medical need
- Fast growing markets
- Blockbuster potential
- Proof of concept and safety have been demonstrated in early clinical trials for MABs BT-061 and BT-063

#### **Biotest MABs and major indications**

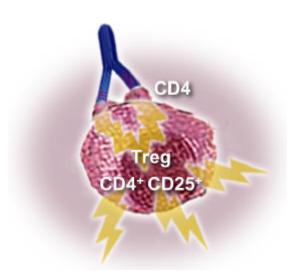
BT-061	Rheumatoid Arthritis Psoriasis
BT-062	Multiple Myeloma
BT-063	Systemic Lupus Erythematodes and other Autoimmune Diseases



## **BT-061 Target Indications: Rheumatoid Arthritis and Psoriasis**

- Unique mode of action:
   NOT immunosuppressive but immunomodulating
   High efficacy low toxicity
- Todays biological products (anti-TNF antibodies) dominating treatment of RA (sales worldwide: US-\$ 4,8 bn 2004)
- However 30 % of patients are non-responders to this therapy and additional 20 % show only weak response
- Due to different mode of action those patients will be an important target group of clinical development of BT-061

**BT-061** 





#### **Contract Manufacturing of BT-061 at Lonza**

- A leading contract manufacturer of monoclonal antibodies
- Start of pilot batch production in 3<sup>rd</sup> quarter 2005
- GMP batch production finalized in 2<sup>nd</sup> quarter 2006
- Preclinical evaluation of BT-061 ongoing
- Continuation of clinical phase I/II trials 2<sup>nd</sup> quarter 2006

#### **Production, Lonza Group**







#### **Development of BT-062 According Plan**

- Prof. Dr. K. Anderson\*:
   "I think the benefits of this targeted immunotoxin are very high, due to its selectivity, potency, and novel mechanism of action compared to any other conventional treatment or novel biologic under development."
- Clinical development discussed with Anderson in 9/05
- Humanisation of antibody was finalized in Q1/05
- Optimisation of production procedure ongoing with AERES
- \* Director of Jerome Lipper Multiple Myeloma Center at Dana-Farber Cancer Institute, one of the world's premium cancer centers

## Dana-Farber Cancer Institute, Boston, USA

