Biotest

From Nature for Life

Biotest AG

Kepler Cheuvreux Unicredit

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Disclaimer

- This document contains forward-looking statements on overall economic development as well as on the business, earnings, financial and asset situation of Biotest AG and its subsidiaries. These statements are based on current plans, estimates, forecasts and expectations of the company and thus are subject to risks and elements of uncertainty that could result in deviation of actual developments from expected developments.
- The forward-looking statements are only valid at the time of publication. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.
- All comparative figures relate to the corresponding last year´s period, unless stated otherwise.

Biotest Group H2 2015 – January 2016

- Biotest signed cooperation contract with Kedrion for US marketing & sales of Bivigam® , effective today
- Impairment of US business in Q3 2015
- IgM Concentrate shows encouraging results in life-threatening pneumonia
- FDA submission of RSV-hyperimmunoglobulin (licensed from ADMA Biologics, Inc.)
- Pentaglobin® – encouraging results in treatment of donor specific antibodies after lung transplantation
- Zutectra®: marketing approval for early use in EU
- " BNL Next Level" is on track with respect to timeline and budget
  - Roofing ceremony at new manufacturing site in Dreieich

Strategic Targets of Biotest

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- **Focus on Plasma business**

- **Focus on expansion project "Biotest Next Level"**
  - Broadening of product portfolio
  - Doubling of production capacity

- **Adjustment of R&D programme**
  - - Focus on IgG Next Gen, IgM Concentrate, Fibrinogen
    - Monoclonal antibodies: minimize expenses, continue activities up to next milestone to enable partnering

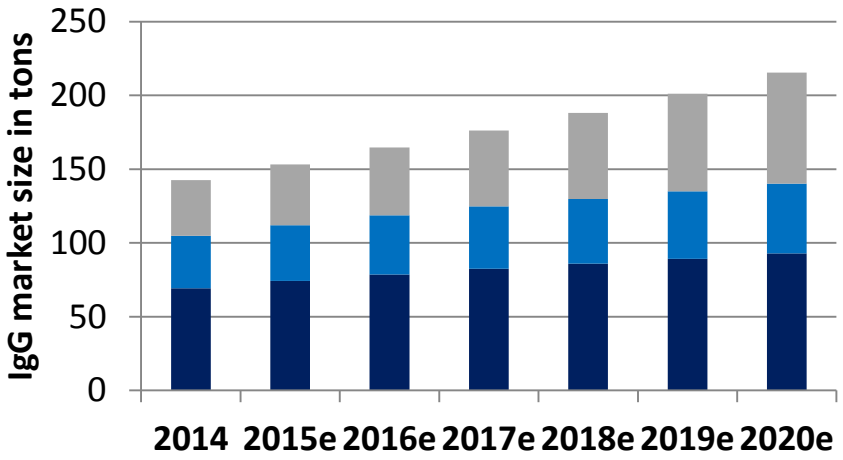
- Continue of "partnering-strategy" in selected areas

- **Increase of profitability**

Focus on Plasma business

Focus on plasma protein business

- Worldwide demand for plasma proteins still growing



Exp. annual growth CAGR 2014 – 2020e

RoW	12%
Europe	5%
North America	5%
World	7%

- Continue to grow business in Europe and RoW

- **Strengthen profitability of US business**

Sources: Biotest market research based on MRB (2013), PPTA (2015)

Factors supporting growth of IgG and plasma products

Market expansion

- Improvements in wealth and therapy reimbursement
- Improving access to care

Physicians' Awareness

- Awareness of treatment options and indications still low
- Many patients are still undiagnosed

Demographic development

- Growth of population
- Weight gain

Indications / Usage areas

- Use of IgG in a broader set of indications
- Regular treatment of patients with chronic conditions

Strengthen US profitability

Biotest Pharmaceuticals Corporation (BPC) and Kedrion Biopharma Inc., New Jersey signed a cooperation contract on marketing & sales of Bivigam®

- Kedrion will take over exclusively the marketing & selling of Bivigam® in the US
  - The manufacturing capacity utilization will be significantly increased
  - **Increase of profitability, in 2016 by USD 4-5 Mio.**

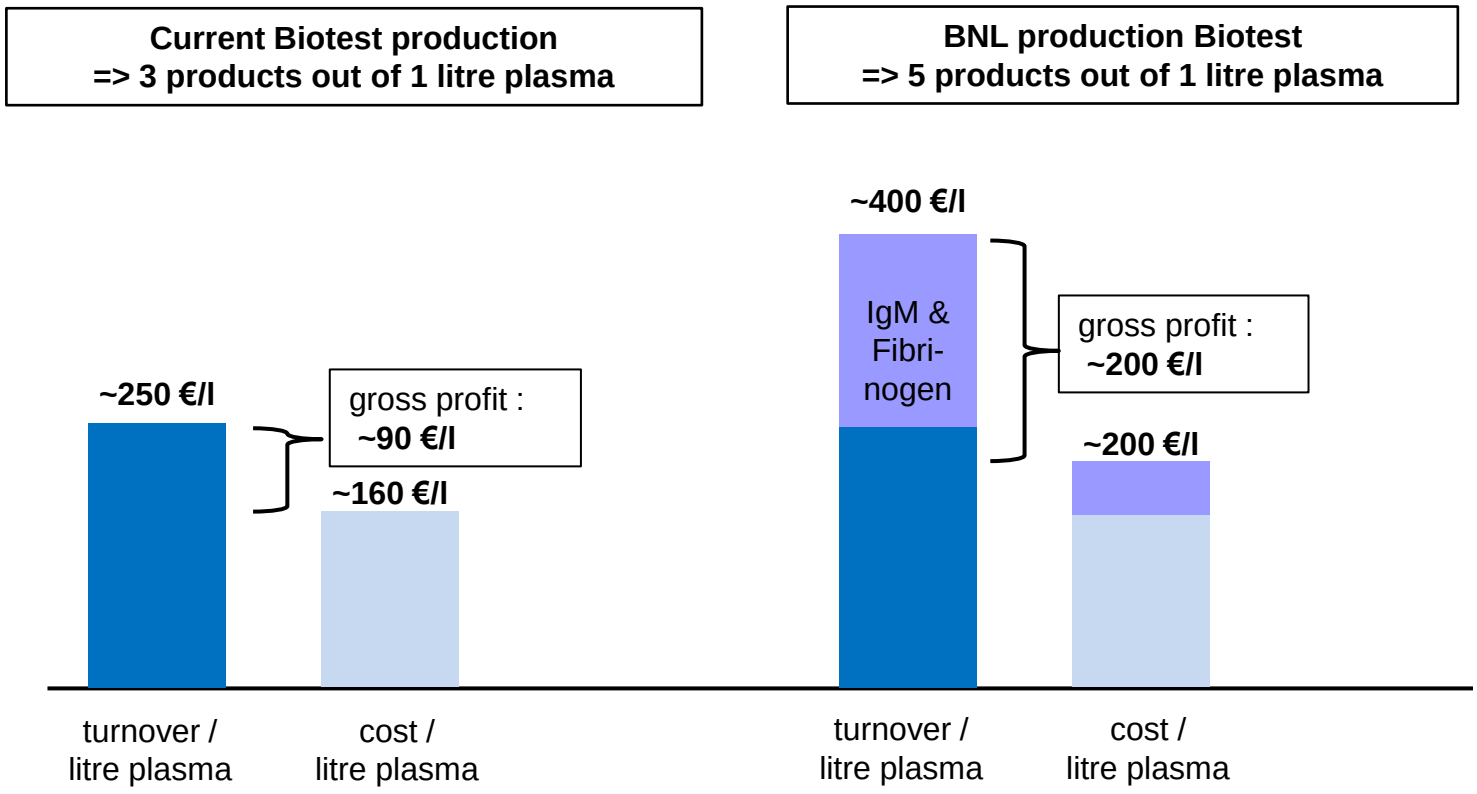
Focus on expansion project "Biotest Next Level"

"Biotest Next Level":
On track in terms of timeline and budget (April 2015)

"Biotest Next Level":
On track in terms of timeline and budget (January 2016)

Biotest Next Level - Broadening of product portfolio

- Expand product portfolio from 3 products to 5 products out of one litre plasma and double production capacity 5.5 t ➡ 13 t



Adjustment of R&D programme

Adjustment of R&D programme

- **Prioritise plasma protein R&D programme**
  - IgM Concentrate
  - IgG Next Generation
  - Fibrinogen

- **Adjustment of the monoclonal antibodies R&D programme**

  - Significant reduction in R&D spending for monoclonal Antibodies, continue activities up to next milestone to enable partnering

IgM Concentrate
Phase II CIGMA Study in Patients with sCAP

Objectives

- Evaluation of the efficacy and safety of IgM Concentrate in patients with severe community acquired pneumonia (sCAP)

Primary Endpoint

- Increase of ventilator free days (VFD)s

Secondary Endpoints

- **28-day all cause mortality**
- 28-day pneumonia cause mortality
- Time to discharge from ICU (intensive care unit)

VFD = Ventilator free days
BT 086 = IgM Concentrate

IgM Concentrate
Phase II CIGMA Study in Patients with sCAP

Objectives

- Evaluation of the efficacy and safety of IgM Concentrate in patients with severe community acquired pneumonia (sCAP)

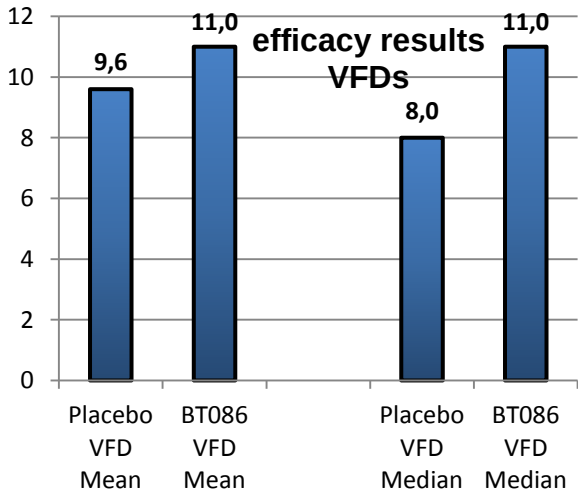
Primary Endpoint

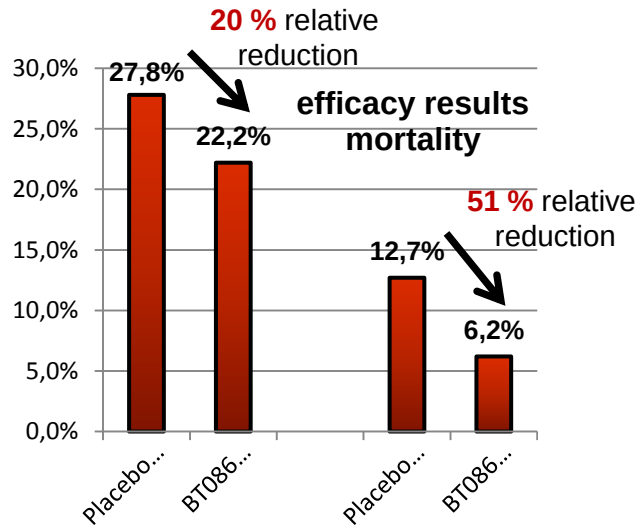
- Increase of ventilator free days (VFD)s

➡ shorter duration of artificial ventilation need

Secondary Endpoints

- 28 day all cause/ pneumonia cause mortality





VFD = Ventilator free days ; BT 086 = IgM Concentrate

IgM Concentrate

Attractive market potential

- **Severe Community Acquired Pneumonia**
  - Value driver based on CIGMA study results
  - Market size in sCAP approx. 350,000 patients worldwide*
  - Sales potential approx. €500 m p.a.

Potential upside indication (early to market indication)

- **Common Variable Immunodeficiency Disease (CVID)**
  - e.g. IgM deficiency

* Source: Biotest market research

Pentaglobin® – encouraging results in lung transplantation

Pentaglobin ®

- In lung transplantation donor specific antibodies (DSAs) are risk factors for mortality, and acute and chronic graft rejection

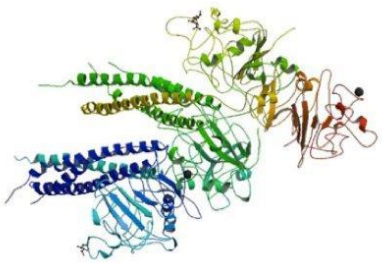
- Patients treated with Pentaglobin (a IgM/ IgA enriched immunoglobulin) with early DSAs development after lung transplantation had a significantly **higher survival rate** than patients treated with therapeutic Plasma exchange (standard therapy)

- Published data by the Hannover Medical School*
  - **> 70% reduction of relative mortality rate after one year**

> **Mortality risk caused by DSA after lung transplantation was significantly reduced with Pentaglobin (First generation IgM/ IgA enriched immunoglobulin)**

*: Ius.F et al. Transplantation, 2015 Dec 28

Promising development projects



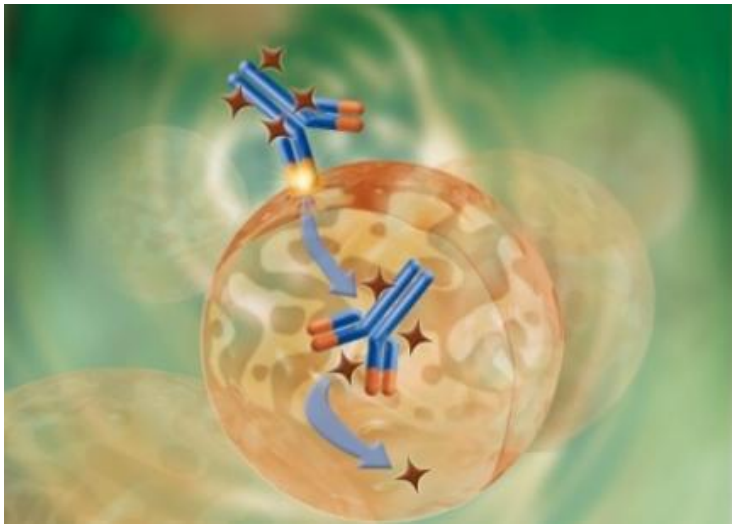
IgG Next Generation

- Development of successor of Intratect® and Bivigam® helps patients with immune system dysfunctions
- Global commercialisation planned

Fibrinogen

- Fibrinogen is for the treatment of acute haemorrhages due to congenital or acquired fibrinogen deficiencies

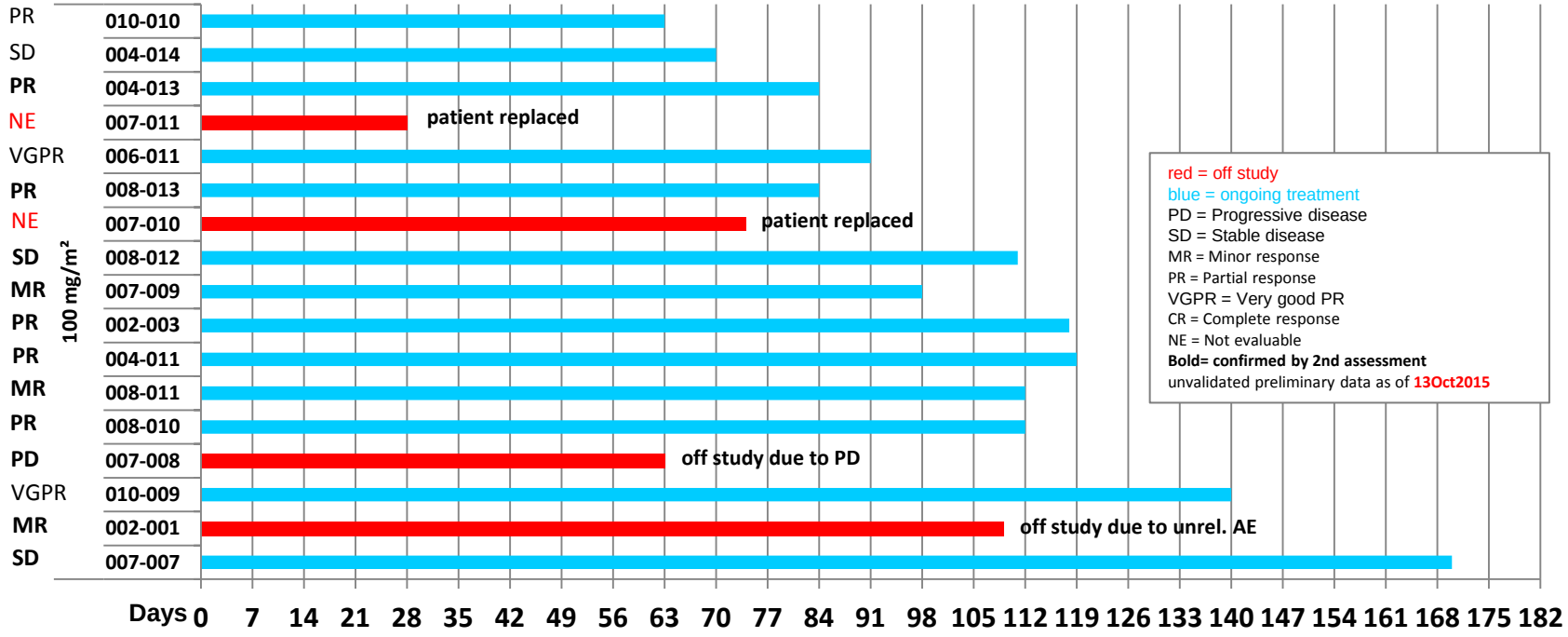
BT-062: Indatuximab Ravtansine - Overview



- Antibody Drug Conjugate (ADC), an innovative therapy approach for the treatment of multiple myeloma
- Combination of antibody and cytotoxic agent targets cancer cells
- Combination of efficacy and tolerability
- Multiple myeloma: all patients recruited, treatment ongoing; final study data expected in 2016
- Solid tumours: breast and bladder cancer; Phase I completed, recruitment in Phase II part ongoing

BT-062 Phase I/IIa Study No. 983 in Multiple Myeloma

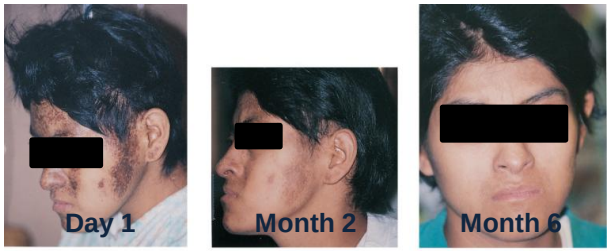
Results of BT-062 with Pomalidomide / Dexamethasone



- A total of 17 patients were enrolled
- 13 patients are on treatment without progressive disease

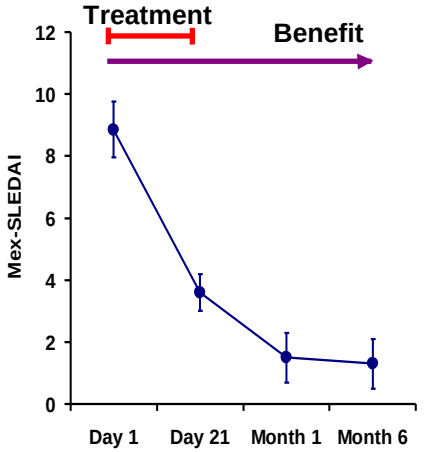
BT-063 in Systemic Lupus Erythematosus (SLE)

1. Efficacy Signals from a pilot study



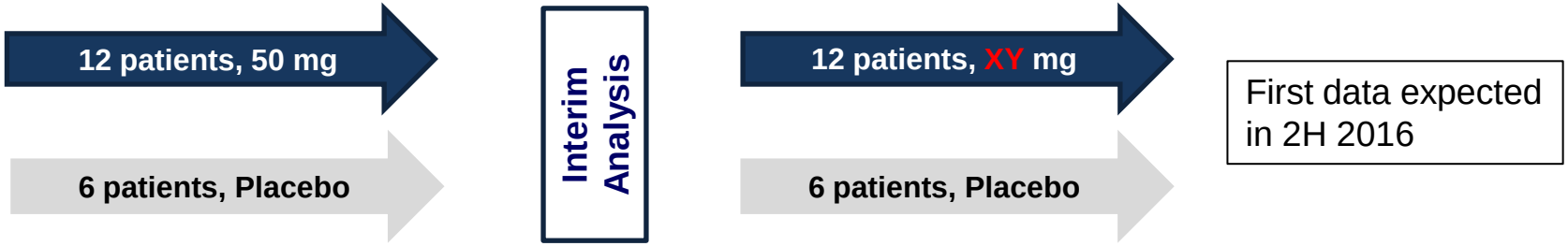
Evolution of discoid lupus following administration of the anti–interleukin-10 monoclonal antibody in 1 patient

- 6 steroid-dependent SLE patients
- **Treatment:** 20 mg/day for 21 consecutive days
- **Benefit:** 6 months follow-up period



2. BT-063 Clinical Proof of Concept Study Phase IIa Study No. 990

Patients with moderate to severe SLE on stable medication with joint and cutaneous manifestations
Duration: 3 months treatment + 4 months follow up



* Modified from Llorente et al., Arthritis & Rheumatism (2000)

Outlook & Summary

Profitable business with attractive R&D pipeline

Forecast 2015

- Low single digit sales growth 2015 vs. 2014
- Positive Q4 2015 EBIT of €5-10 m

Preliminary outlook

- Low single digit sales growth expected next year
- Profitability 2016 will be influenced by :
  - Additional requirements in quality and safety ~ €3-5 m
  - Biotest Next Level costs ~ €10-15 m
  - R&D monoclonal antibodies ~ €12 m
  - Unabsorbed costs for idle capacity ~ €8-10 m

  Despite these factors profitability 2016 in a range of ~ €30 m

Profitable business with attractive R&D pipeline

Contact
Financial Calendar 2016

Financial Calendar 2016

23 Mar 2016	FY Report 2015
10 May 2016	3M Report 2016
11 Aug 2016	6M Report 2016
10 Nov 2016	9M Report 2016

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