



SWEDISH ORPHAN INTERNATIONAL

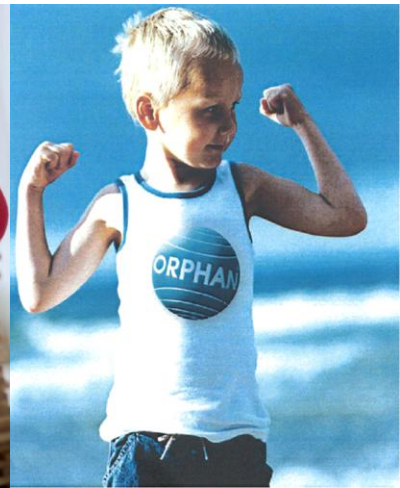
biovitrum.

Investor presentation



















Background information:
Key products and development pipeline

November, 2009

Background information: Key products and development pipeline



Product overview

	Product	Therapy	Disease indication	Commercial rights	Share of total sales (2009e)
Key products	 	Hematology	Hemophilia A	Nordic	
		Inflammatory	Rheumatoid arthritis	Global	
	ORFADIN®	Metabolic	Hereditary Tyrosinemia Type1 (HT-1)	Global	
		Cancer	Oral mucositis in conjunction with chemotherapy and radiation	Global	
	 	Metabolic	Urea cycle disorders	Europe, Middle East, Russia	
		Cancer	2nd line Soft Tissue Sarcoma	Nordics and Baltics, C. and E. Europe	
	MULTIFERON®	Cancer/Other diseases	Advanced malignant melanoma and 2nd line to rIFNs	Global	
New launches		Hematology	Pernicious anemia	Europe	
		Cancer	2nd/3rd line platinum sensitive ovarian cancer	Nordics and Baltics, C. and E. Europe	

ReFacto AF[®] / Xyntha[®]

ReFacto AF
Morotocog alfa
(Recombinant Coagulation Factor VIII)
Albumin-Free Cell Culture Process

xyntha
Antihemophilic Factor (Recombinant),
Plasma/Albumin-Free

Indication	<ul style="list-style-type: none"> Hemophilia A
Description	<ul style="list-style-type: none"> Recombinant coagulation factor VIII concentrate used in patients with Hemophilia A
Deal structure	<ul style="list-style-type: none"> Three part agreement with Wyeth <ol style="list-style-type: none"> Sole manufacturer of active ingredient Royalties on Wyeth's global sales Co-promotion in Nordic region
Opportunities for growth	<ul style="list-style-type: none"> Global launch of ReFacto AF[®] / Xyntha[®] Biovitrum is currently launching ReFacto AF[®] in the Nordic region
Market	<ul style="list-style-type: none"> USD ~4.5 billion in 2010* 90,000 patients CAGR ~6%* Wyeth global market share 12% Biovitrum market share in the Nordic region >30%



Country	Market share in 2008
Sweden	26%
Denmark	37%
Norway	30%
Finland	50%

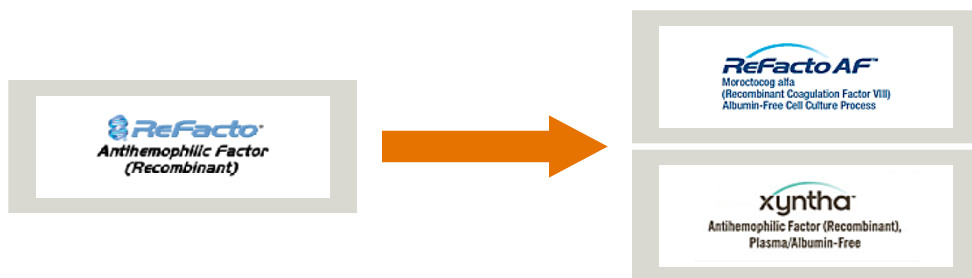
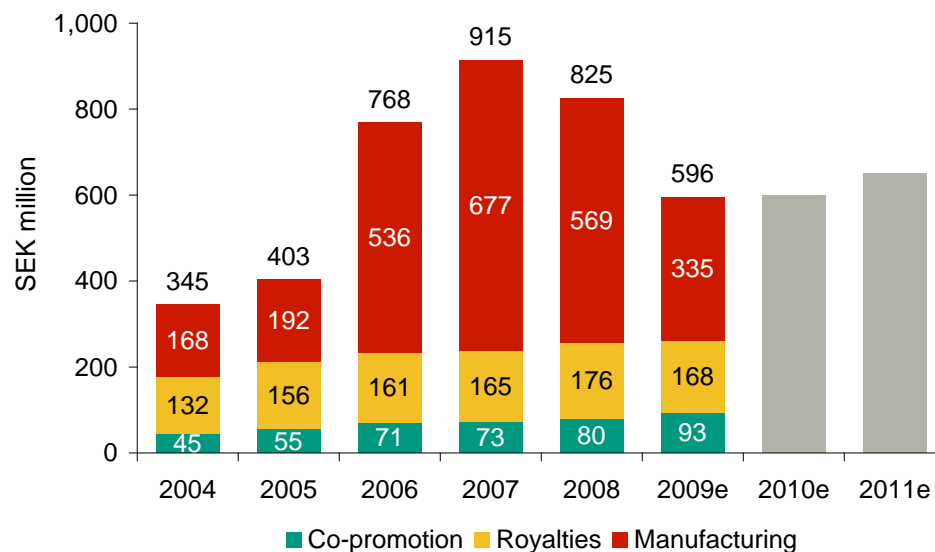
Source: Biovitrum

*) The Marketing Research Bureau

ReFacto AF[®] / Xyntha[®] supply key source of revenue

- Supply agreement extended until December 31, 2015
 - Biovitrum sole producer
 - Royalties from Wyeth's global sales
 - Nordic co-promotion rights
- Reduced revenues in 2009 and 2010
 - Switch to ReFacto AF[®] / Xyntha[®]
 - Improved, protein free process
 - Volumes expected to increase

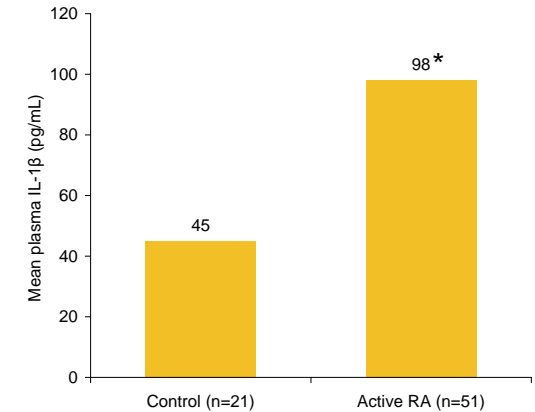
ReFacto AF[®] / Xyntha[®] revenue trend



Kineret®



Indication	<ul style="list-style-type: none"> Rheumatoid arthritis (RA)
Description	<ul style="list-style-type: none"> Recombinant IL-1 antagonist that reduces pain and swelling in RA Only approved IL-1 drug for the indication
Deal structure	<ul style="list-style-type: none"> Exclusive global license agreement with Amgen (future milestones only) Patent protection until 2014 (Europe) and 2020 (US)
Opportunities for growth	<ul style="list-style-type: none"> Growth opportunity in responder population identification and new rare disease (orphan) indications <ul style="list-style-type: none"> Anakinra protein modifications
Market	<ul style="list-style-type: none"> 1% prevalence in the entire population Approx. 750,000 patients world-wide on biologicals 10-15% would respond to Kineret = 75,000-100,000 Approx. 2,000 Kineret RA patients = 2-3% penetration



*P<0.0001 vs. control

Confirmatory efficacy study: Trial design

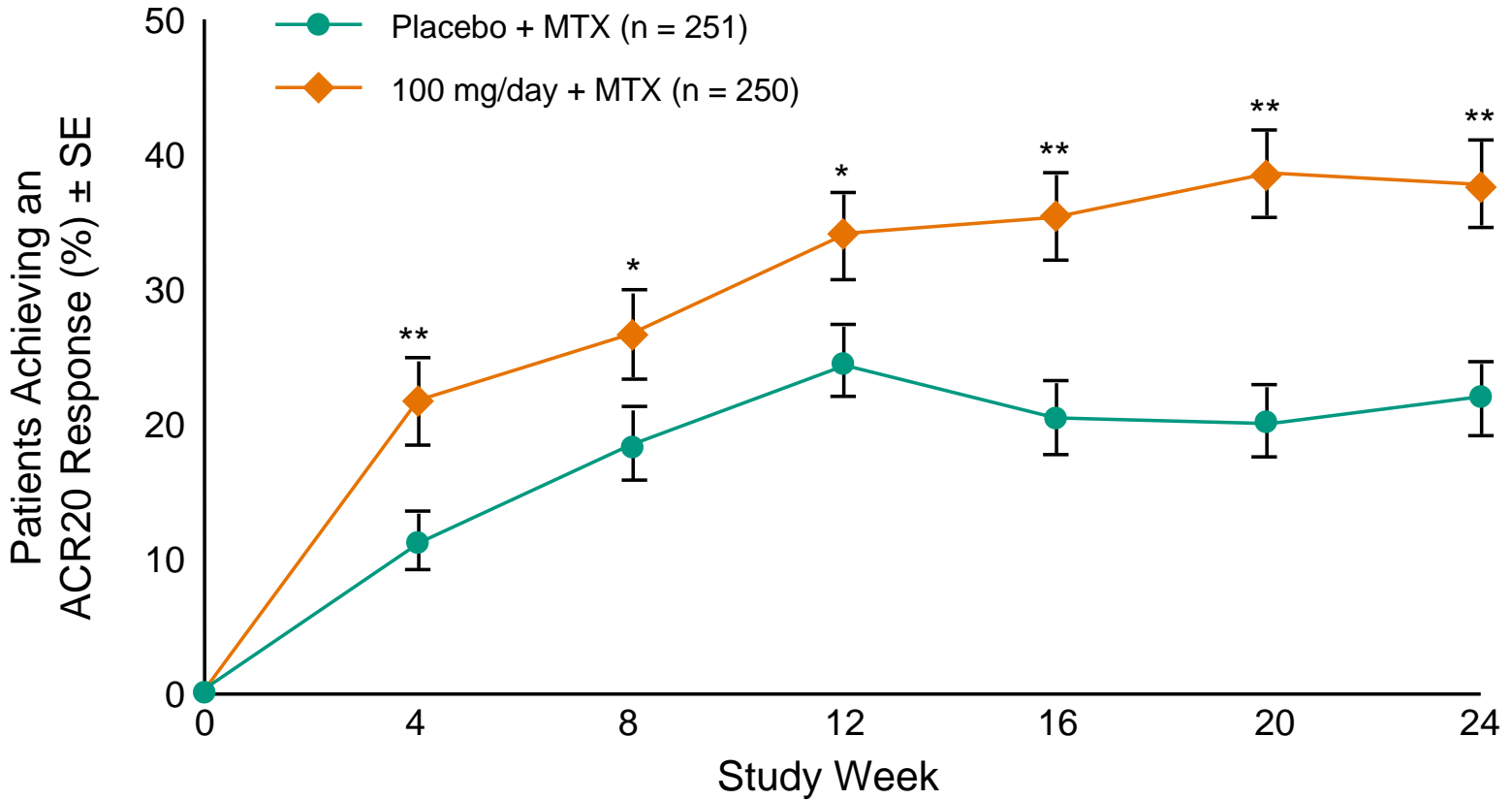
Design	Randomized, double-blind, placebo-controlled
Dosage	Placebo or Kineret® at 100 mg/day via subcutaneous injection
Patients	906 patients with active disease receiving MTX 15–25 mg/week
Duration	52 weeks
Location	USA, Canada, Australia
1° end-point	Modified Sharp score at 52 weeks (remains blinded)
Signs/symptoms	ACR20 criteria at 24 weeks (n = 501)

Note: ACR = American College of Rheumatology; MTX = methotrexate

Cohen S, et al. Ann Rheum Dis. 2002;61(Suppl 1); 173



ACR20 response with Kineret[®] according to Study Week: Early onset of action

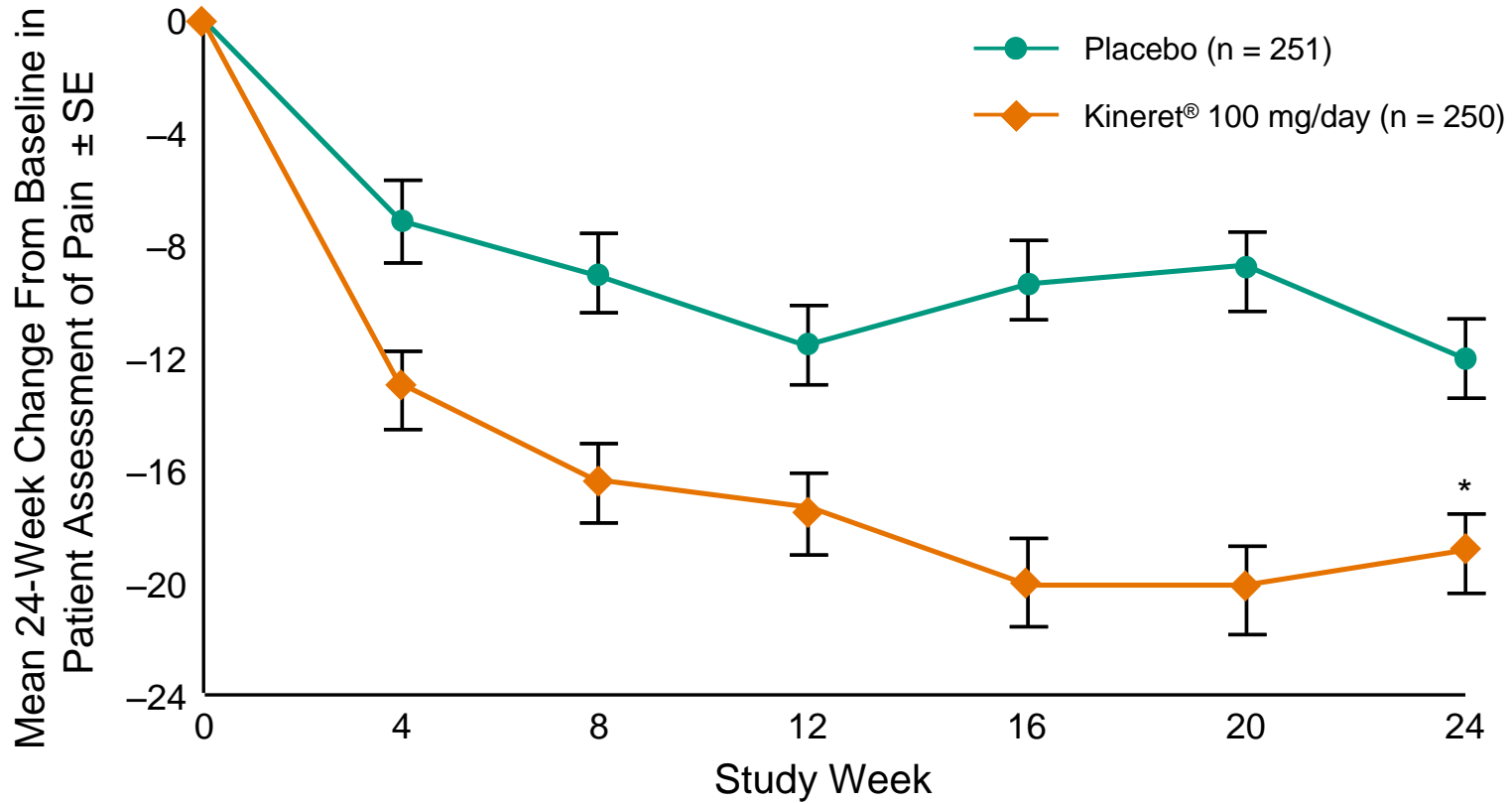


Intent-to-treat with non-responder imputation; MTX = methotrexate

*P < 0.05, **P < 0.01, vs placebo

Kineret[®] (anakinra) FDA Briefing Information, August 16, 2001. Available at: <http://www.fda.gov>

Kineret[®] has a rapid and sustained effect on patient-centred outcomes: Patient assessment of pain



P < 0.001 vs placebo
Data on file. Amgen Inc, Thousand Oaks, Calif



SWEDISH ORPHAN INTERNATIONAL

biovitrum.

Strategic plan for Kineret

- Manage supply until April 2011
- Preparatory market activities in 2010
 - EULAR, ISSAID and local Nordic meetings
 - Training and education material
 - Prepare for market expansion: partner identification and contracts, registration, KOL contacts
 - Publications of ongoing studies
 - Medical marketing/relationship building
 - Clinical studies to assess data mining hypothesis (as applicable)
 - Clinical studies to confirm predictive testing (as applicable)
 - Registration of autoinflammatory indications: SoJIA, CAPS, AOSD, FMF
- 2011-12: Re-launch to accelerate growth
 - Hire S&M staff
 - Communicate new message to customers
- 2013-14: Consolidate growth
 - Expansion into new markets

Orfadin®



Indication	<ul style="list-style-type: none"> • Hereditary Tyrosinemia Type 1 (HT-1)
Description	<ul style="list-style-type: none"> • Life long treatment of the metabolic disease HT-1 • Only treatment available for HT-1, no competition on market or in pipeline • Highly profitable and strongly growing product
Deal structure	<ul style="list-style-type: none"> • Exclusive global licensing agreement on all orphan drug indications • Orphan drug EU (Feb 2015), USA (Jan 2009), Australia in progress (5 yr) • IP EU (2017), USA (2013)
Opportunities for growth	<ul style="list-style-type: none"> • Geographic expansion (Russia, India, China) • Increased diagnosis of HT-1 with newly available, improved diagnostic • Increased survival, increased patient weight → more product used per patient • New, higher dosing guidelines → more product used per patient • Scope for price increases • Potential in additional indications • Life cycle management
Market	<ul style="list-style-type: none"> • Incidence 1/100,000 live births • ~90% mortality risk in childhood or adolescence

Before Orfadin



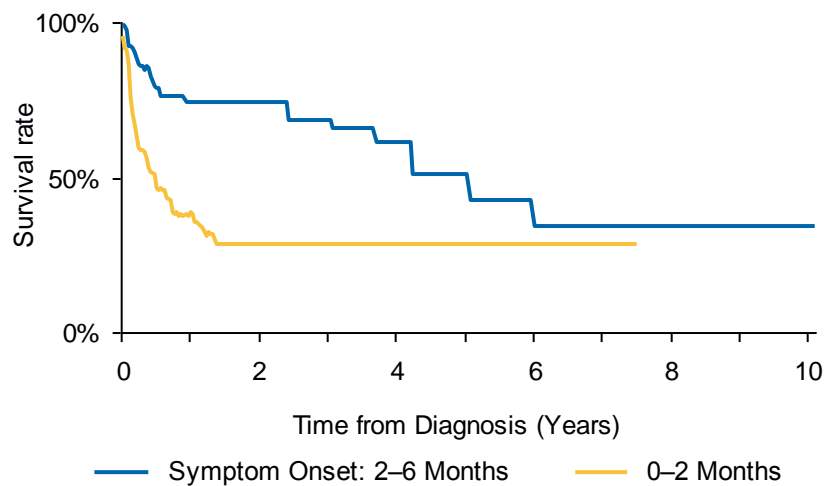
After Orfadin



Orfadin[®]

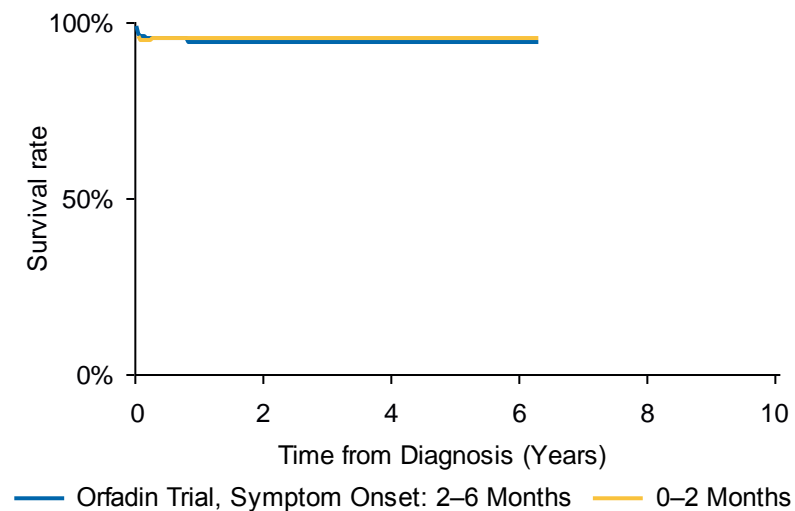
Life-saving treatment

Before Orfadin[®]



Source: Van Spronsen et al. *Hepatology* 1994; 20: 1187-1191

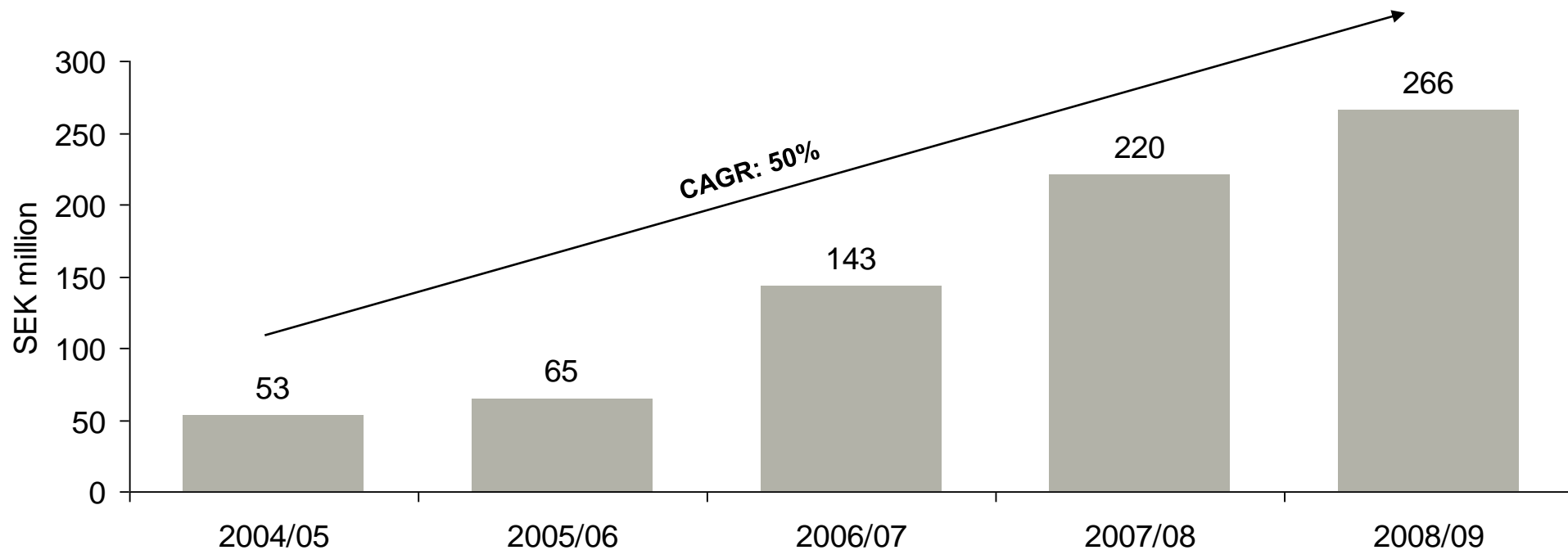
After Orfadin[®]



Source: EPAR (EMA)

Orfadin®

Revenue development¹



Orfadin has shown impressive growth since approval as an orphan drug

Notes
Swedish Orphan FY from May to April
Sales growth in 2006/07 due to take-over of product from European distributor
European sales from both third party distributor and Swedish Orphan and also includes Middle East and Turkey
Sales in Americas represent Swedish Orphan royalties



Kepivance®



Indication	<ul style="list-style-type: none"> • Prevent oral mucositis in conjunction with chemotherapy and radiation in connection with bone marrow transplantation in blood cancer 	
Description	<ul style="list-style-type: none"> • Recombinant Keratinocyte Growth Factor (KGF) <ul style="list-style-type: none"> – Used prior to and after bone marrow transplantation • Alternative treatments <ul style="list-style-type: none"> – Cryotherapy – Antibiotics and antifungals – Mouthwashes – Narcotics, total parenteral nutrition (TPN) and antibiotics 	
Deal structure	<ul style="list-style-type: none"> • Global rights acquired from Amgen in 2008 (future milestones) • Patent protection until 2019 (Europe) and 2023 (US) 	
Opportunities for growth	<ul style="list-style-type: none"> • Label expansion <ul style="list-style-type: none"> – Prevention of oral mucositis after chemotherapy and radiation in children (1-16 years) – Solid tumors: Amgen running clinical trials that Biovitrum may assume – Other indications under consideration (together with external expertise) • Several investigator sponsored studies (ISS) ongoing 	
Market	<ul style="list-style-type: none"> • 140,000 hematological cancers in total <ul style="list-style-type: none"> – 50,000-60,000 patients receiving bone marrow transplantation globally <ul style="list-style-type: none"> • 24,000 in Europe, 36,000 in North America • Severe oral mucositis 18,000 • 1,600 patients currently treated 	

Grading scale of oral mucositis

I. Painless ulcers, erythema, or mild soreness



II. Painful erythema, edema, or ulcers but can eat solids



III. Painful erythema, edema, or ulcers, requires liquid diet



IV. Requires enteral or parenteral support



Pivotal Phase III study (20000162)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

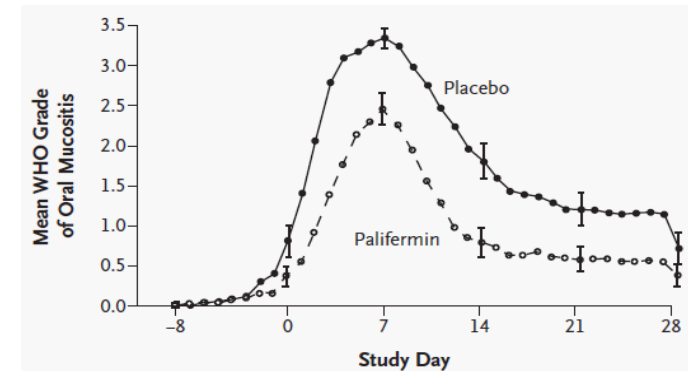
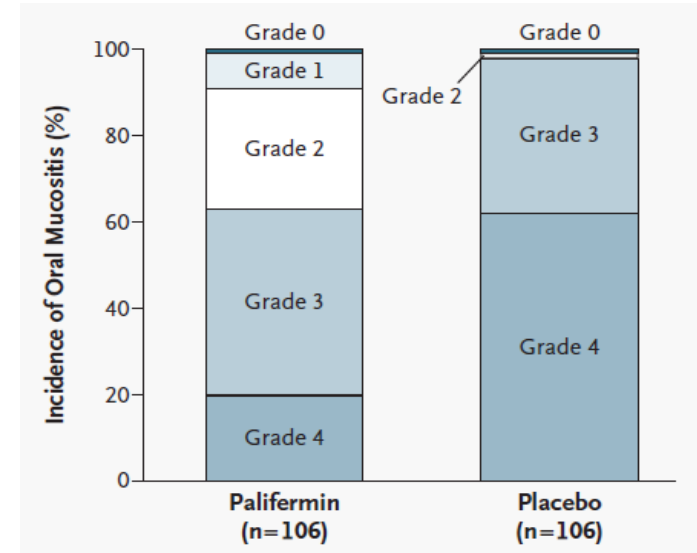
Palifermin for Oral Mucositis after Intensive Therapy for Hematologic Cancers

Ricardo Spielberger, M.D., Patrick Stiff, M.D., William Bensinger, M.D., Teresa Gentile, M.D., Ph.D., Daniel Weisdorf, M.D., Tarun Kewalramani, M.D., Thomas Shea, M.D., Saul Yanovich, M.D., Keith Hansen, M.D., Stephen Noga, M.D., Ph.D., John McCarty, M.D., C. Frederick LeMaistre, M.D., Eric C. Sung, D.D.S., Bruce R. Blazar, M.D., Dieter Elhardt, Ph.D., Mon-Gy Chen, M.S., and Christos Emmanouilides, M.D.

N Engl J Med 2004;351:2590-8.

Copyright © 2004 Massachusetts Medical Society.

- Randomized double-blind clinical trial in 212 patients
- Autologous HSCT with myeloablative total body irradiation (TBI) and high-dose chemotherapy
- The incidence, severity and duration of OM was reduced in the palifermin treated patients compared with placebo



Ammonaps/Ammonul

Indication	<ul style="list-style-type: none"> • Ammonaps – Urea cycle disorders • Ammonul – Acute treatment of urea cycle disorders
Description	<ul style="list-style-type: none"> • Urea cycle disorders are caused by complete or partial deficiency of a liver enzyme, which leads to the accumulation of ammonia in the patient's urea cycle. Ammonia is highly toxic to the brain and vital organs and can cause severe brain damage and eventual death <ul style="list-style-type: none"> – Ammonaps is a long-term oral treatment that improves the patient's chance of survival through bypassing the lacking enzyme – Ammonul is an injection provided in the acute setting for rapid onset
Partner	<ul style="list-style-type: none"> • Ammonaps was contracted from the US-based company Ucyclid in 1997 <ul style="list-style-type: none"> – SOI is the MA holder in Europe since 2006 – Ammonaps marketed by SOI within Europe and is provided on a Named Patient basis in countries outside of Europe including Turkey, Middle East, North Africa • Ammonul was contracted from Ucyclid in 2004 <ul style="list-style-type: none"> – Ammonul is currently provided to patients on Named Patient basis
Strategy	<ul style="list-style-type: none"> • New agreement with Ucyclid in 2009 to file for approval of Ammonul in the EU <ul style="list-style-type: none"> – Analysis and planning for filing is in progress – Currently expect approval in 2011
Market	<ul style="list-style-type: none"> • No known direct competition to Ammonaps, although the product is subject to competition from a non-pharmaceutical product manufactured by a UK chemical company



Rights



+ Saudi Arabia, Oman, UAE, Kuwait, Qatar, Bahrain, Libya, Israel, Jordan, Lebanon

Yondelis

Indication	<ul style="list-style-type: none"> • 2nd/3rd line treatment of soft tissue sarcoma and platinum sensitive ovarian cancer
Description	<ul style="list-style-type: none"> • EU approved orphan drug • Can significantly extend life expectancy by decreasing tumor growth • Attractive pricing
Deal structure	<ul style="list-style-type: none"> • Distribution agreement with PharmaMar (2007) • Promotion and marketing rights in 15 countries (Nordics and Eastern EU)
Opportunities for growth	<ul style="list-style-type: none"> • Opportunity for an accelerated uptake • Changes in treatment paradigms, i.e. move to 1st line treatment in soft tissue sarcoma • Potential to develop for additional oncological indications
Market	<ul style="list-style-type: none"> • Total world wide sales for Yondelis of EUR 1bn projected by PharmaMar • Prevalence of soft tissue sarcoma calculated at 2 per 10,000 EU population • Incidence of ovarian cancer approx. 16/100,000 females in EU population



Rights



multiferon®

Indication	<ul style="list-style-type: none">• Malignant melanoma• 2nd line for patients who are intolerant to or do not respond to treatment with rIFN-α
Description	<ul style="list-style-type: none">• Multiferon contains six human subtypes of rIFN-α (interferon)• Multiferon is approved, being launched in Nordic countries and Eastern Europe• Approval in western EU countries expected by 2012/13
Deal structure	<ul style="list-style-type: none">• Proprietary product acquired by Swedish Orphan in 2007<ul style="list-style-type: none">– Process patents, use patents in EU and USA
Opportunities for growth	<ul style="list-style-type: none">• Majority of projected sales from treatment of HCV• Even small improvements vs rIFN-α would translate into significant sales• Additional indications possible<ul style="list-style-type: none">– Multiple sclerosis, hematological diseases
M.M. Market	<ul style="list-style-type: none">• High-risk melanoma market USD ~130 million, CAGR 4%• ~15,000 patients world wide with High-risk melanoma (stage IIb, stage III)
HCV Market	<ul style="list-style-type: none">• ~170 million people infected with HCV globally• rIFN-a is standard of care• Current market USD ~3.1 billion and growing strongly



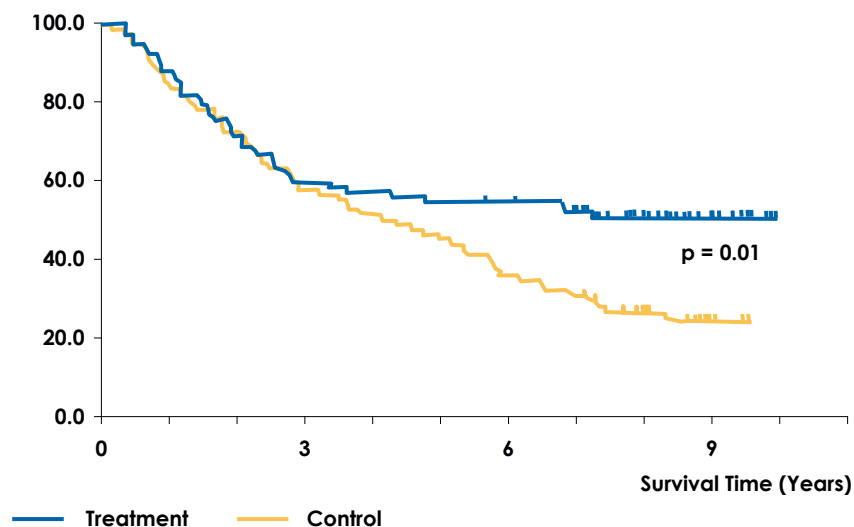
multiferon[®]

Malignant Melanoma

Melanoma

Overall survival in high-risk melanoma (Stage IIb-III)

ITT-population (n=162)



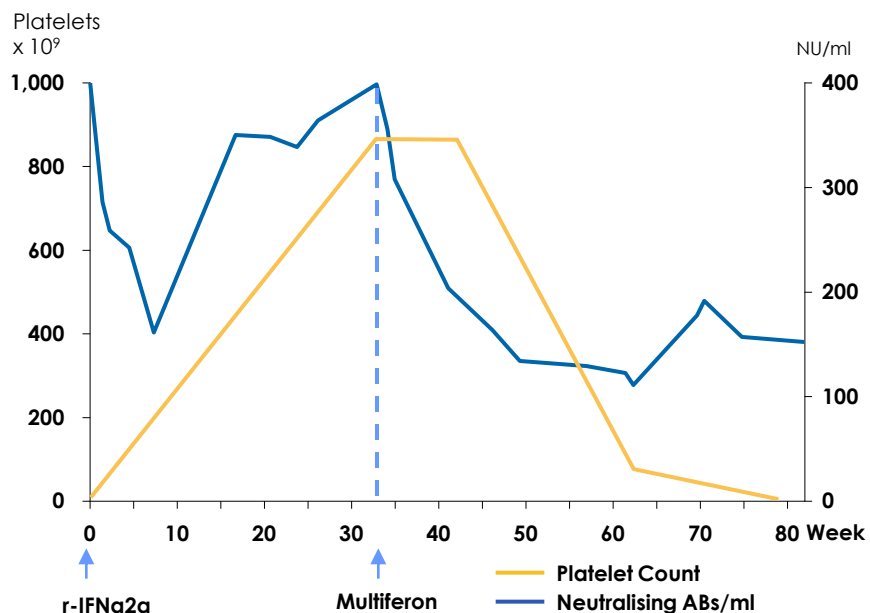
- MM represents ~5% of all cases of skin cancer but causes 75% of all skin cancer deaths
- Reduces risk of melanoma associated death by almost 50%
- The only adjuvant treatment for MM therapy that has produced clinically significant survival benefits

Source: Stadler R. *Acta Oncologica*, 2006;45:389-399

multiferon®

2nd line to recombinant interferon

2nd line to recombinant interferon



- Approved for patients who are intolerant to or do not respond to treatment with rIFN- α
- Lack of efficacy in ~40% of patients treated with rIFN- α sometimes due to antibody development

Source: Merup M et al. *European Journal of Cancer* 1994, vol 30A, No 11; 1729-1730





Nascobal

Indication	<ul style="list-style-type: none"> • Maintenance of normal hematologic status in pernicious anaemia (B12 deficiency) patients
Description	<ul style="list-style-type: none"> • Once weekly nasal application of essential vitamin B12, indicated for the maintenance of normal hematologic status in pernicious anaemia (B12 deficiency) patients <ul style="list-style-type: none"> – B12 deficiency is a common co-morbidity for many orphan disorders, such as Crohn's disease, Ulcerative Colitis and Multiple Sclerosis
Partner	<ul style="list-style-type: none"> • Contracted from US based QOL Medical in 2008 (acquired by Strativa in 2009) <ul style="list-style-type: none"> – Broad pan-European mandate for Nascobal, with marketing rights covering all of the EU and the remaining parts of geographical Europe, including Russia, Turkey and Ukraine – The rights are not limited to indication or brand – Strativa acquired the global rights for Nascobal for USD 54.5 million in 2009
Strategy	<ul style="list-style-type: none"> • Currently preparing for regulatory filing of the product in the EU and the rest of our territory, with filing expected during the next financial year • Opportunities surrounding potentially targeting a much larger patient population outside of orphan indications to be investigated
Market	<ul style="list-style-type: none"> • Will only be marketed to a sub-segment of the B12 market initially; patients with pernicious anaemia where oral treatment is unsuitable and injections is the only viable alternative • Nascobal could potentially be used by a much larger patient population outside the orphan scope and the right to sub-license the product for broader indications has been secured



Emerging late stage clinical development pipeline

Indication	Project	Partner	Phase I	Phase II	Phase III	Reg.
2nd line to rIFNs	Multiferon®					**
Hemophilia B	rFactor IX Fc	biogen idec				
Fat malabsorption in preterm infants	Kiobrina™					
Fat malabsorption in CF patients	Exinalda™					
Rh-immunization	Rozrolimupab			*		
Platelet disorder (ITP)	Rozrolimupab					
Oral mucositis - pediatric	Kepivance®					
Hemophilia A	rFactor VIII Fc	biogen idec				

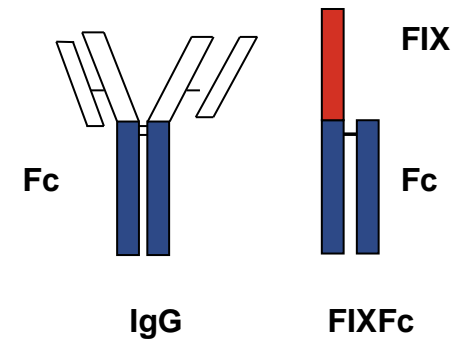
*) A dose adjusting red blood cell challenge healthy study preceding phase III

**) Approved in 15 European countries. Trials supportive to registration in remaining EU countries



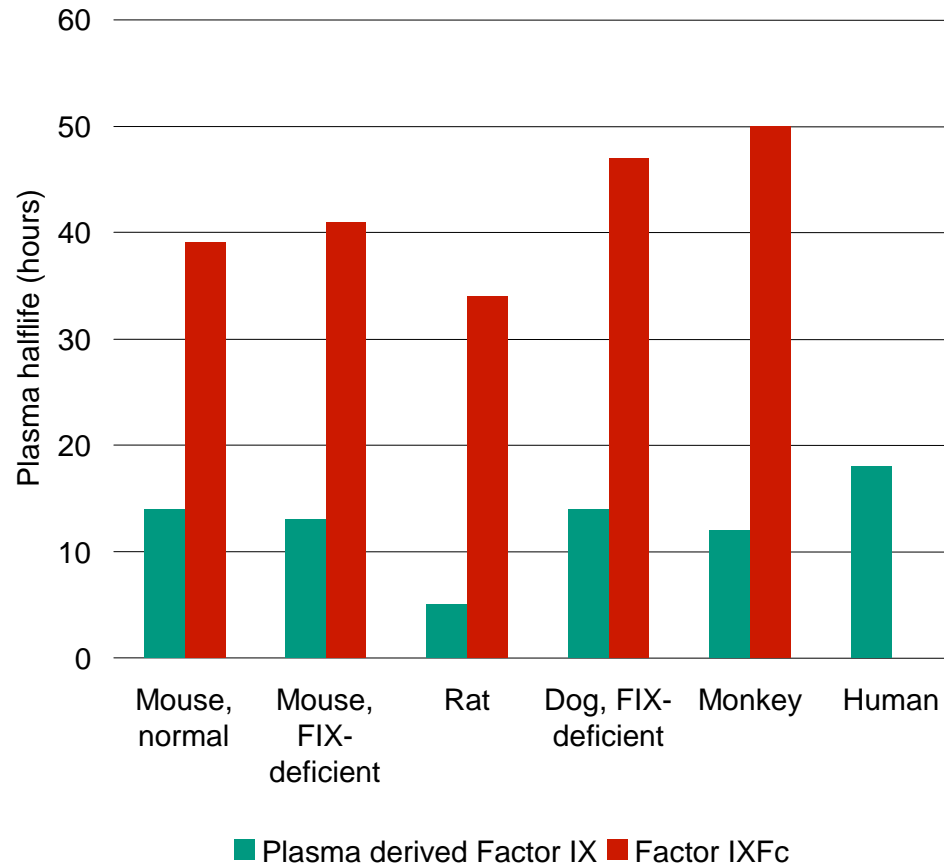
Factor IX Fc

Indication	<ul style="list-style-type: none"> • Hemophilia B
Description	<ul style="list-style-type: none"> • Medical need – less frequent infusions <ul style="list-style-type: none"> – Prophylactic treatment requires two or more infusions per week – any reduction in frequency perceived as a major advantage • Based on novel Fc-fusion construct • FIXFc most clinically advanced compound • 50/50 co-development/co-commercialization with Biogen Idec
Development status	<ul style="list-style-type: none"> • Clinical phase I/II to be reported H2 2009 <ul style="list-style-type: none"> – Documentation of safety, tolerability and pharmacokinetics – EMEA and FDA orphan drug designation • Rapid move to phase III if positive outcome (~70 patients) • Pre-clinical studies demonstrate >3 times extended half-life • BLA is planned for 2011/12 • Possible launch in 2012
Market	<ul style="list-style-type: none"> • USD ~1.2 billion in 2010* <ul style="list-style-type: none"> – 2015 forecast USD ~1.5 billion* • CAGR ~5.5%* • Prophylactic segment 50% of current market and growing rapidly • Estimated peak year sales potential USD >500 million

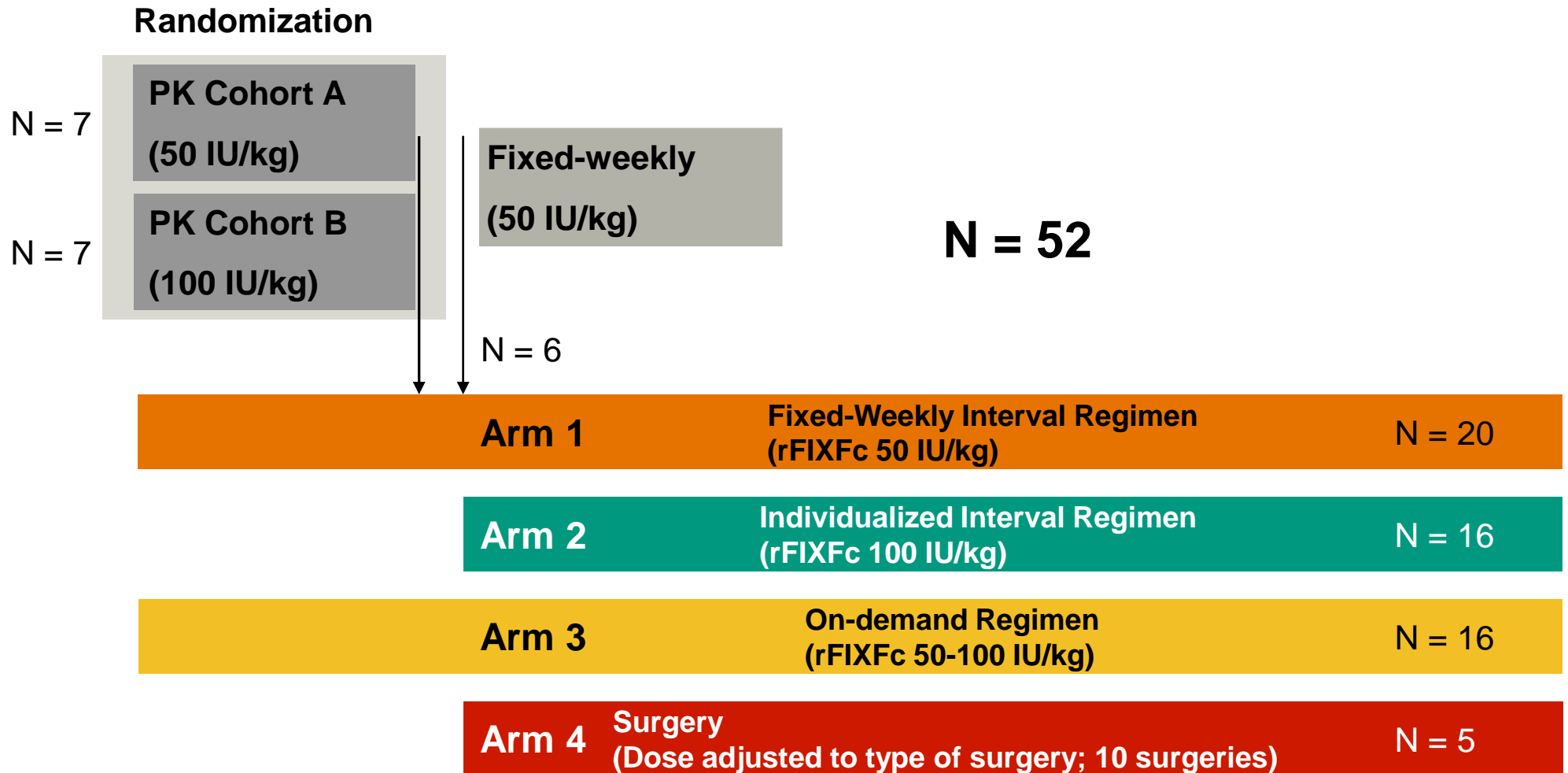


*) The Marketing Research Bureau

Comparison of plasma derived Factor IX and Factor IXFc in various species

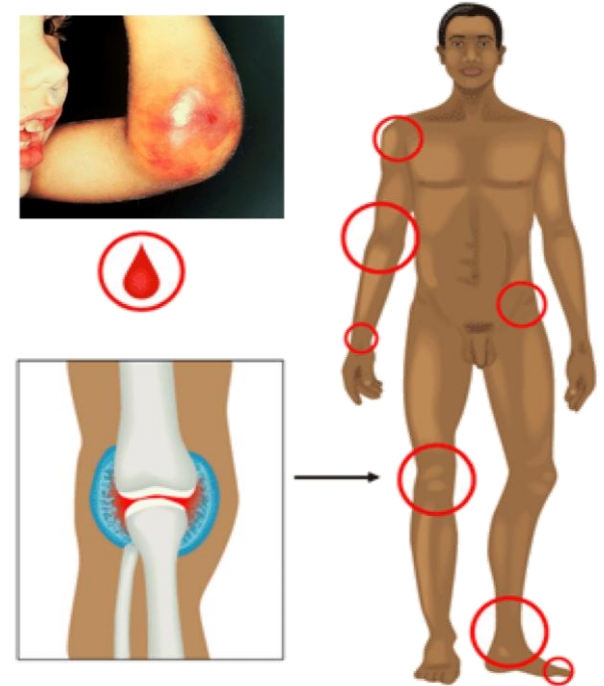


Pivotal study – Study design



Factor VIII Fc

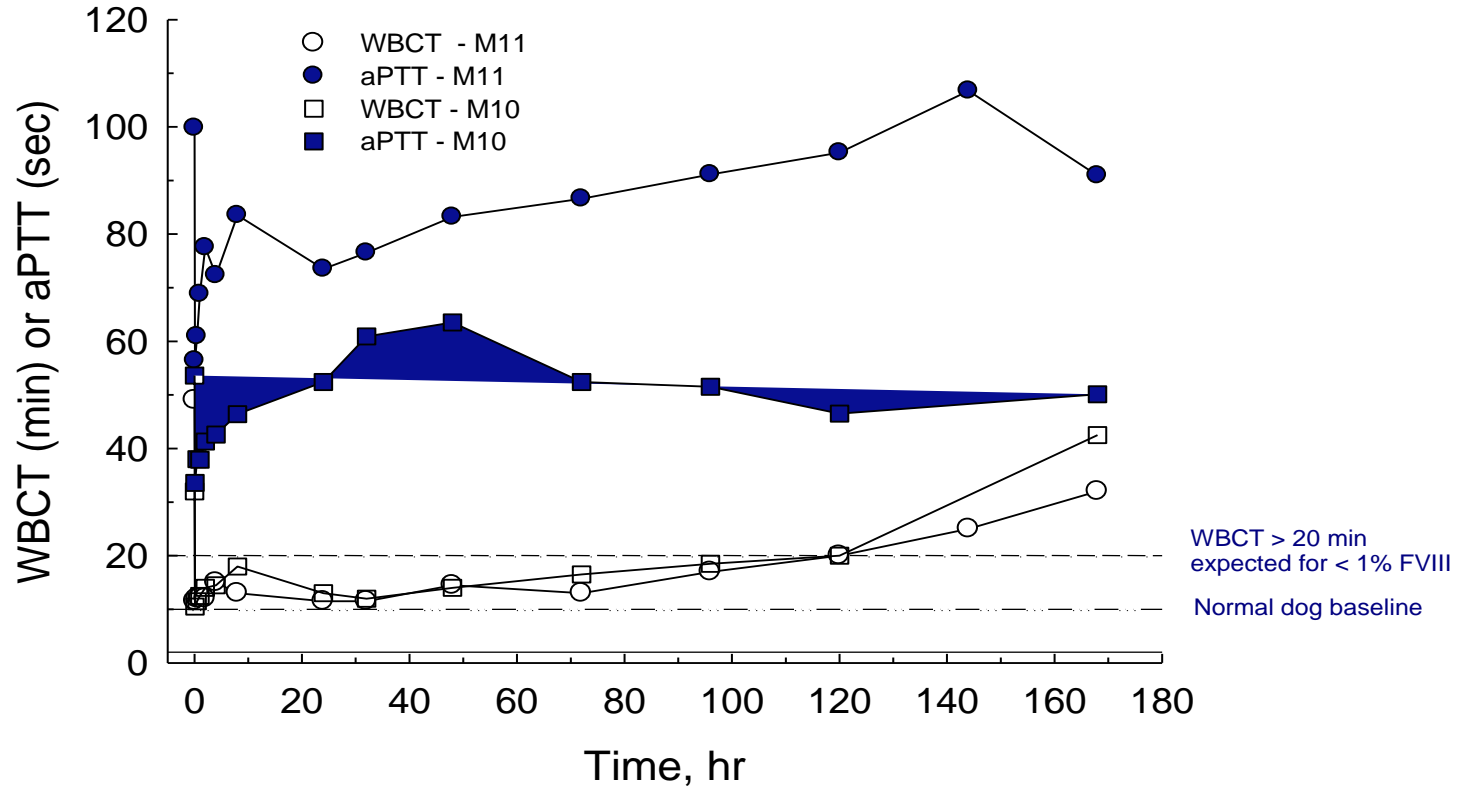
Indication	<ul style="list-style-type: none"> • Hemophilia A
Description	<ul style="list-style-type: none"> • Medical need – less frequent infusions <ul style="list-style-type: none"> – Prophylactic treatment requires two or more infusions per week – any reduction in frequency perceived as a major advantage • Based on novel Fc-fusion construct • 50/50 co-development/co-commercialization with Biogen Idec
Development status	<ul style="list-style-type: none"> • IND submitted to FDA for first clinical phase I/II study <ul style="list-style-type: none"> – ~15 patients – Safety, tolerability, pharmacokinetics • Submission for orphan drug designation under consideration • Phase III study may start in 2010 followed by BLA 2012/13
Market	<ul style="list-style-type: none"> • USD ~4.5 billion in 2010* • CAGR ~6%* • Estimated value in 2020 USD 7.7 billion* • Estimated peak year sales potential USD ~1.5 billion



*) The Marketing Research Bureau

Whole blood clotting time in FVIII-deficient dogs

Study 1 – Single IV dose of FVIII Fc



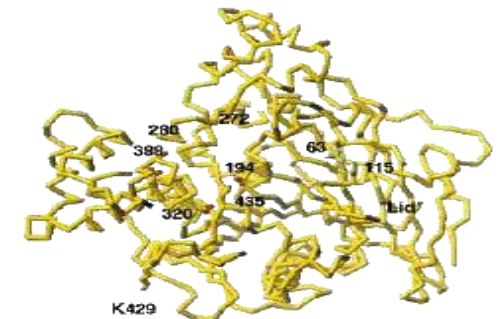
University of North Carolina with Tim Nichols

Kiobrina™

Indication	<ul style="list-style-type: none"> • Fat malabsorption in preterm infants
Description	<ul style="list-style-type: none"> • Recombinant human lipase to improve lipid absorption in premature infants <ul style="list-style-type: none"> – Lack of key enzyme for lipid uptake (Human bile salt-stimulated lipase (BSSL)) – Insufficient growth catch-up – Impaired cognitive function development risk • No product of this type is available in the market today
Development status	<ul style="list-style-type: none"> • Two phase II clinical trials in Italy and France <ul style="list-style-type: none"> – rhBSSL administered in milk formula <ul style="list-style-type: none"> • Patient recruitment completed and analysis is ongoing – rhBSSL administered in pasteurized breast milk <ul style="list-style-type: none"> • Results expected during 2009 • Phase III study to involve ~350 patients • Possible launch in 2013
Market	<ul style="list-style-type: none"> • ~ 90,000 babies <1,500 grams are born annually in Europe and USA • ~ 50% do not receive fresh mother's milk = 45,000 preterm market annually • Estimated peak year sales potential USD >400 million in Europe and USA • Analysis currently ongoing on emerging markets such as China and Latin America

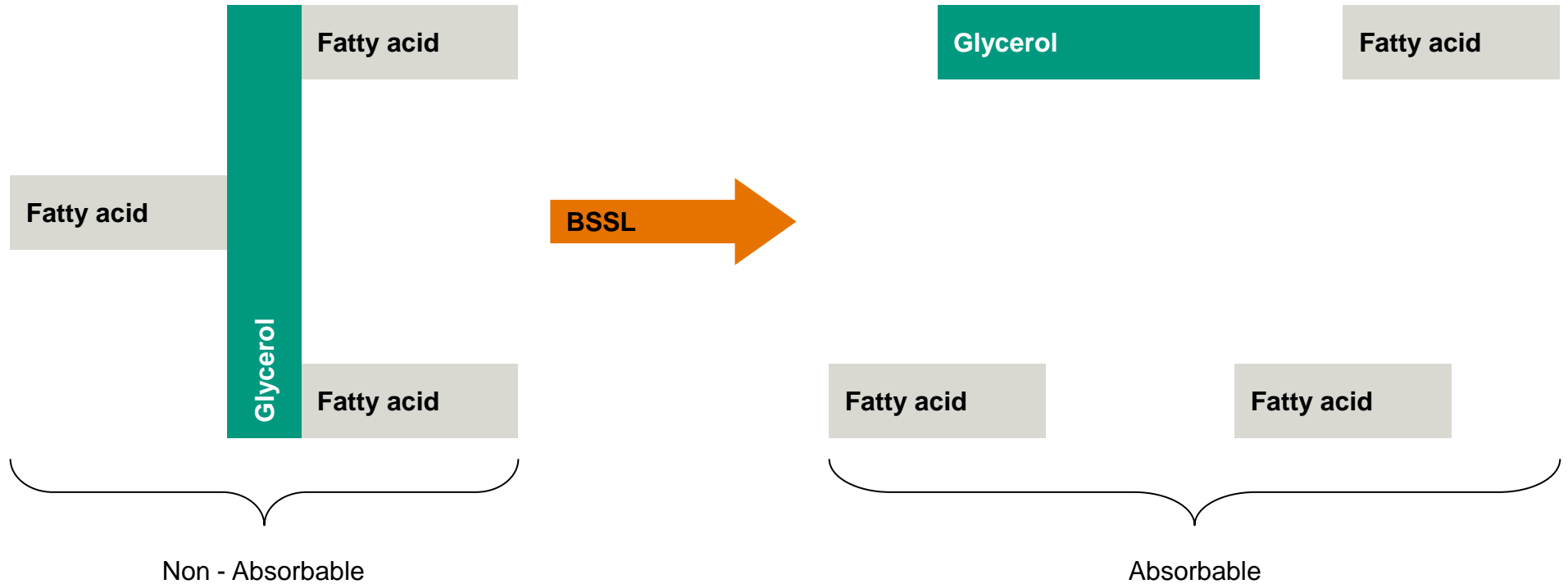


Human bile salt-stimulated lipase (BSSL)



Source: More et al, JMA, 2001

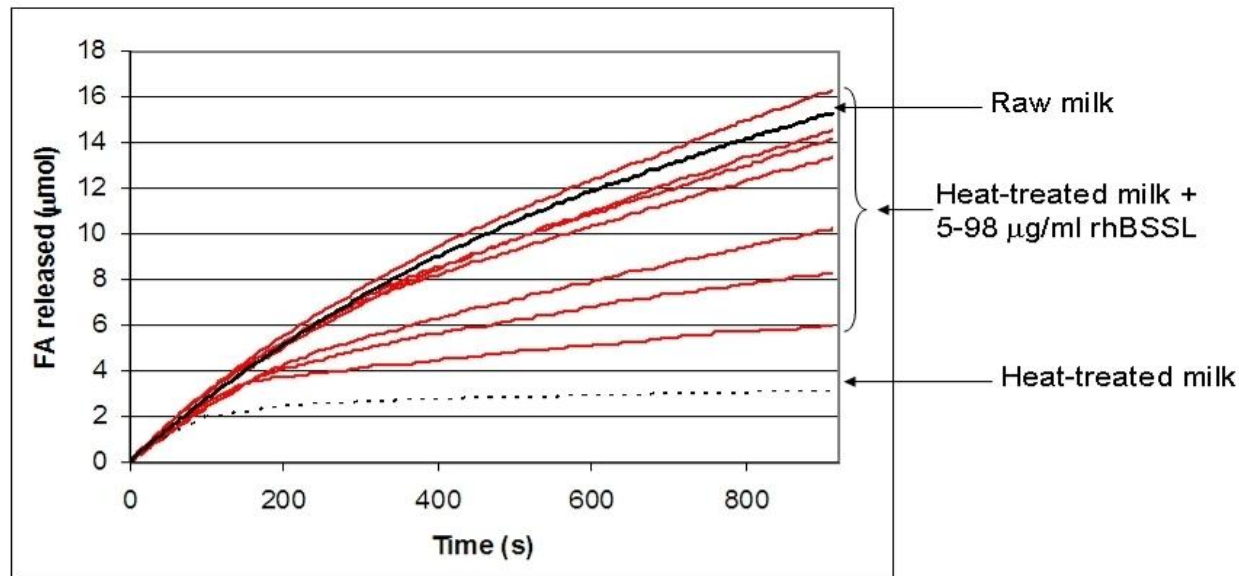
BSSL hydrolyzes triglycerides for the generation of free fatty acids



rhBSSL restores lipase activity heat-treated human milk

Breast milk

- Endogenous BSSL level in breast milk is about 1% of the total protein content or 0.1 mg/ml (Hernell and Bläckberg, 1997)
- Biovitrum studies have shown that 80 µg/ml rhBSSL is sufficient to restore lipase activity to endogenous level in pooled heat-treated human milk



First clinical studies in preterm infants (Phase II)

- rhBSSL therapy in infants fed with pasteurized breast milk
- rhBSSL therapy in infants fed with formula
- Study design
 - Double-blind, placebo-controlled, cross-over, 7 days treatment 0.15 g/L BSSL to formula or past milk
- Patients
 - Preterm infants born before week 32 of gestation
 - N=32 /study
- Primary efficacy
 - Coefficient of fat absorption from 72h stool collection last days of treatment with BSSL and placebo
- Secondary
 - Daily knee to heel length (mm), daily weight (g)

Phase III clinical studies in preterm infants

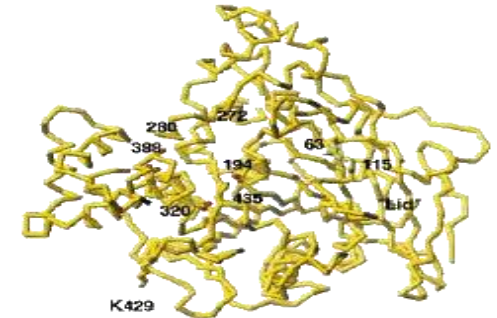
- Study design
 - Double-blind, placebo-controlled, randomized, four weeks treatment with 0.15 g/L BSSL to formula or pasteurized milk
- Patients
 - Preterm infants born before week 32 of gestation
- Primary efficacy
 - Growth velocity (g/kg/day) difference between treatment with BSSL and placebo



Exinalda™

Indication	<ul style="list-style-type: none">• Fat malabsorption in CF patients (pancreatic insufficiency)
Description	<ul style="list-style-type: none">• Recombinant human lipase used to improve lipid absorption in patients with pancreatic insufficiency such as in cystic fibrosis patients
Development status	<ul style="list-style-type: none">• A bioactivity study is currently being assessed• A second clinical study (proof of principle) has been completed<ul style="list-style-type: none">– The primary end point was not met (CFA)– Biovitrum is currently evaluating next steps
Market	<ul style="list-style-type: none">• Approximately USD 800 million• Current market consists of relatively old and inexpensive porcine derived products

Human bile salt-stimulated lipase (BSSL)



Source: *More et al, JMA, 2001*

Rozrolimupab in platelet disorder

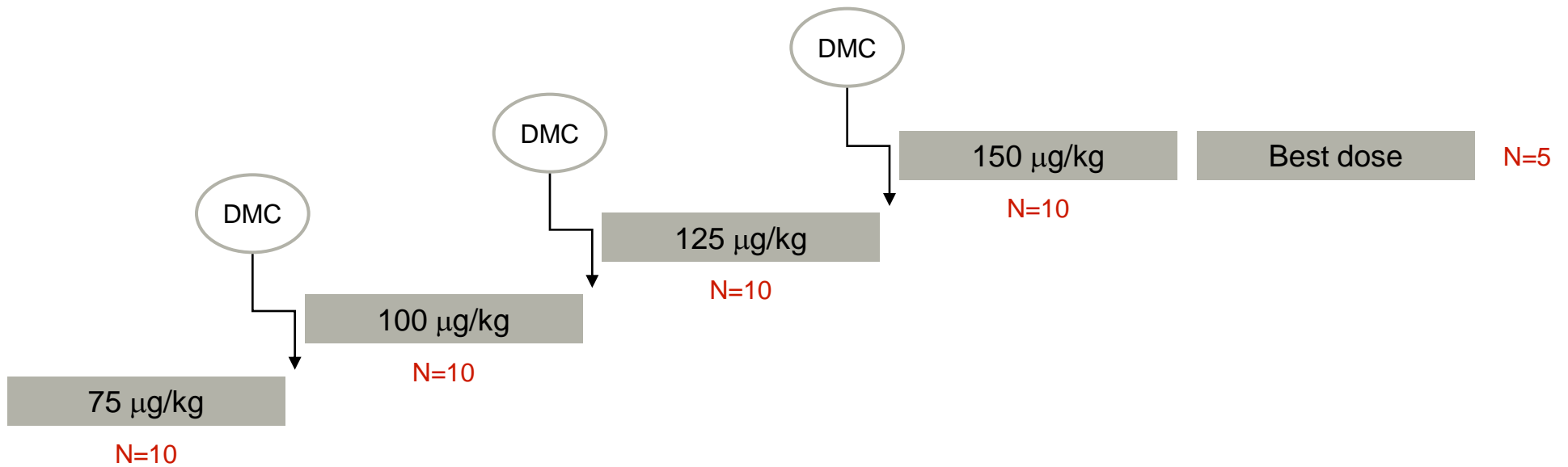
Indication	<ul style="list-style-type: none">• Immune Thrombocytopenic Purpura (ITP)
Description	<ul style="list-style-type: none">• Treatment of adult (and pediatric) patients with (chronic and acute) ITP to rapidly increase platelet counts to prevent bleeding• First recombinant polyclonal antibody project for this indication
Development status	<ul style="list-style-type: none">• Phase I study successfully completed• Phase II study ongoing at 23 clinics in Europe<ul style="list-style-type: none">– Study the safety and efficacy in ITP patients– Three dose cohorts 75, 100, and 125 µg (10 patients per group). Next planned dose 150 µg• Orphan drug status• Study expected to be completed in the first half of 2010
Market	<ul style="list-style-type: none">• USD 300 million• Incidence: 27 adults/million (platelet count < 50k); women and men (2:1)• Affects children (80% acute) and adults (80% chronic)• Plasma derived anti-D and IVIG is main treatment option today• Replacement of blood-derived immunoglobulin products (IVIG and anti-D) for fast onset treatment in Rh+ patients



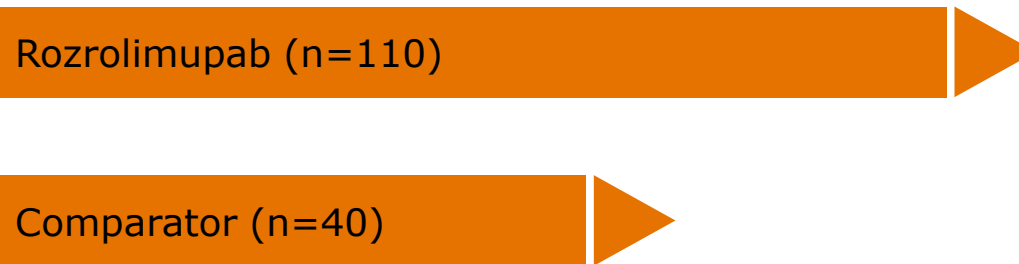
Rozrolimupab is well tolerated

- Non-clinical summary
 - Rozrolimupab is well tolerated and produced no evidence of systemic toxicity in a 4-week repeat-dose toxicity study after intravenous doses up to 7.5 mg/kg
- ITP phase II safety/dose range finding study initiated June 2008
 - 10 sites
 - Poland, Germany, Spain, Belgium
- Clinical status October 2009
 - Rozrolimupab has been documented safe and well-tolerated in 83 healthy RhD– and RhD+ individuals
 - No safety concerns have emerged in ITP patients exposed to rozrolimupab (dose range 75 - 125 µg/kg)

ITP phase II – the Design



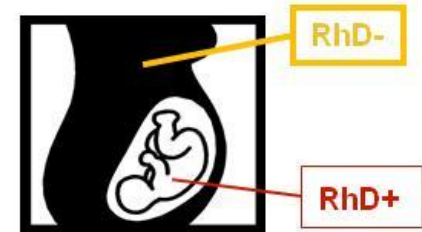
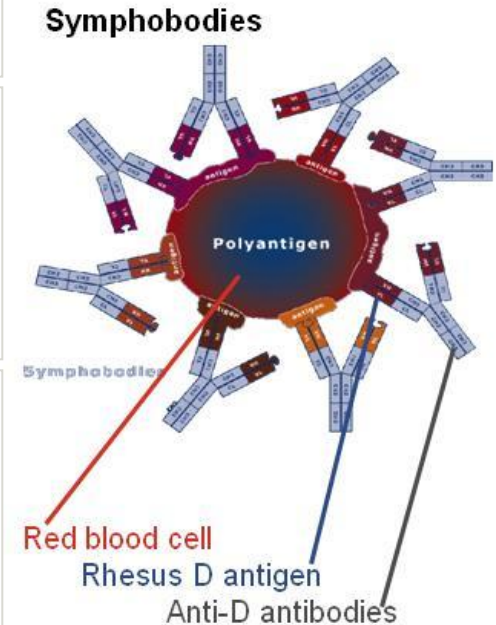
Phase III proposal



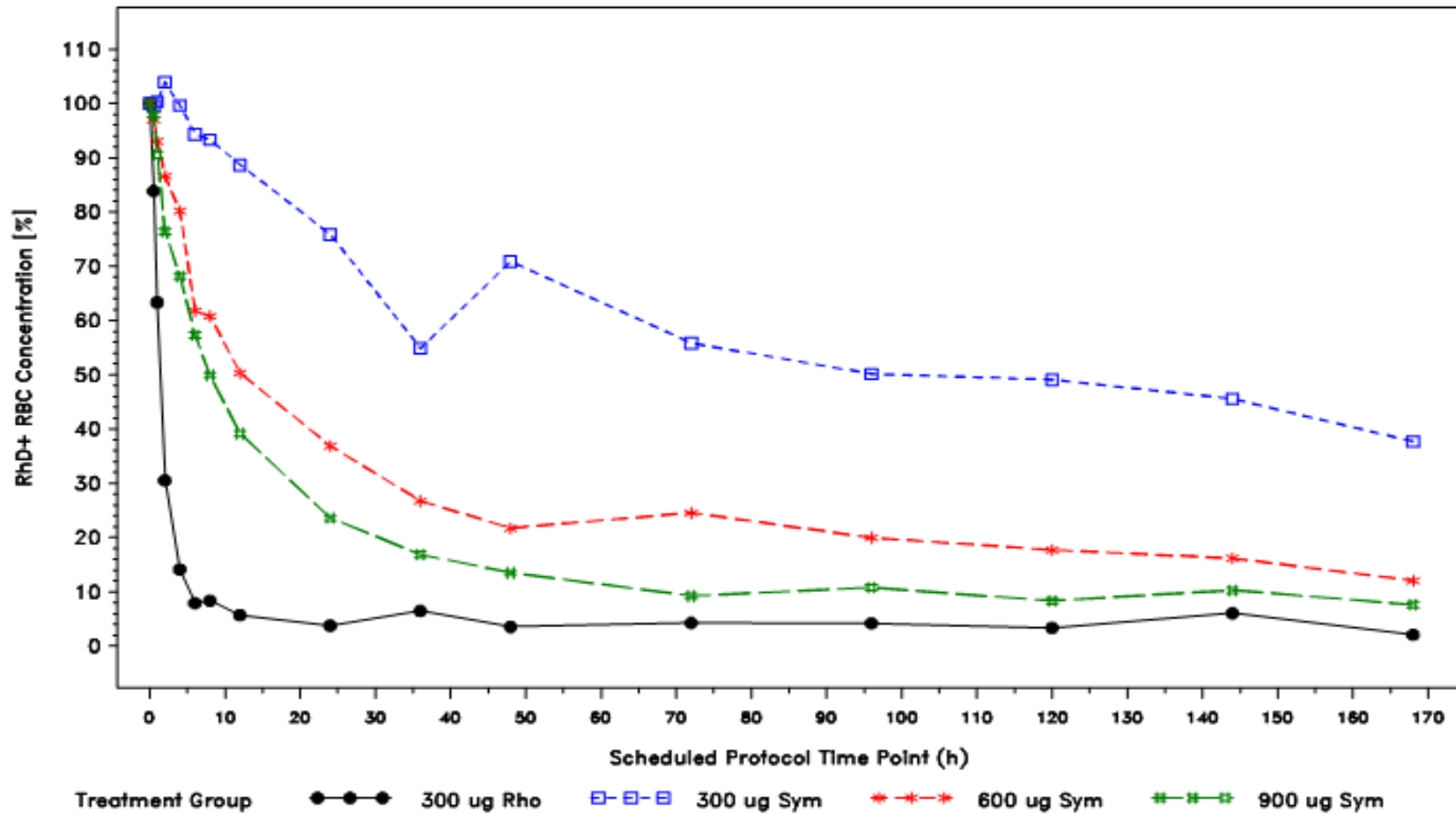
- Primary end-point proposed
 - Proportion of patients achieving an increase of PC to $\geq 30 \times 10^9/L$ and an increase by $> 20 \times 10^9/L$ relative to baseline at 8 days
 - Supported by clinical guidelines 2003, 2004, 2008
- Secondary end-point
 - Proportion of patients achieving an increase of PC to $\geq 50 \times 10^9/L$

Rozrolimupab in Rh-immunization (Anti-D prophylaxis)

Indication	<ul style="list-style-type: none"> • Rh-immunization
Description	<ul style="list-style-type: none"> • Prophylaxis of Rh-immunization of RhD-negative women during pregnancy • In RhD- individuals transfused with RhD+ RBCs or blood • First recombinant polyclonal antibody project • Aiming to replace plasma derived products (anti-D)
Development status	<ul style="list-style-type: none"> • Phase I study successfully completed • Clinical study showing that Rozrolimupab can eliminate RhD positive red blood cells from the circulation of RhD negative healthy volunteers completed • Next step depending on the outcome of the ITP study
Market	<ul style="list-style-type: none"> • USD 170 million • Annually 1.3 million RhD-negative women give birth in Europe and USA • Plasma derived anti-D treatment used today



Clearance results



Near-term pipeline news flow

- Two phase II projects close to “Decision for Full Development” (phase III) before year end, and one project in early 2010
 - FIXFc in hemophilia B
 - Kiobrina in pre-term infants
 - Rozrolimupab in ITP
- One project may enter clinical phase I/II before year end
 - FVIII Fc in hemophilia A
- One project with proof of principle data soon available
 - Exinalda in cystic fibrosis patients

Pre-clinical projects are focused on rare diseases

- Anakinra (IL-antagonist)
 - Improved version of Anakinra (IL-1Ra) enabling less frequent dosing and/or dosing amount
 - Gout, asbestosis/silicosis, idiopathic pulmonary fibrosis, hyper IgD syndrome, Cryopyrinopathies, SolJA, Behcet's disease, inflammatory myopathies
- Complement protein C5
 - Paroxysmal Nocturnal Hemoglobinuria (PNH), Systemic Lupus Erythematosus (SLE), ANCA vasculitis etc.
 - A project utilizing Affibody technologies
- CCL2 derived anti-fibrotic antagonists (MCP-1)
 - Systemic sclerosis
- Lysosomal storage diseases
 - Sulfamidase enzyme replacement therapy

