R&D Briefing

December 3, 2014

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Agenda December 2014 R&D Briefing

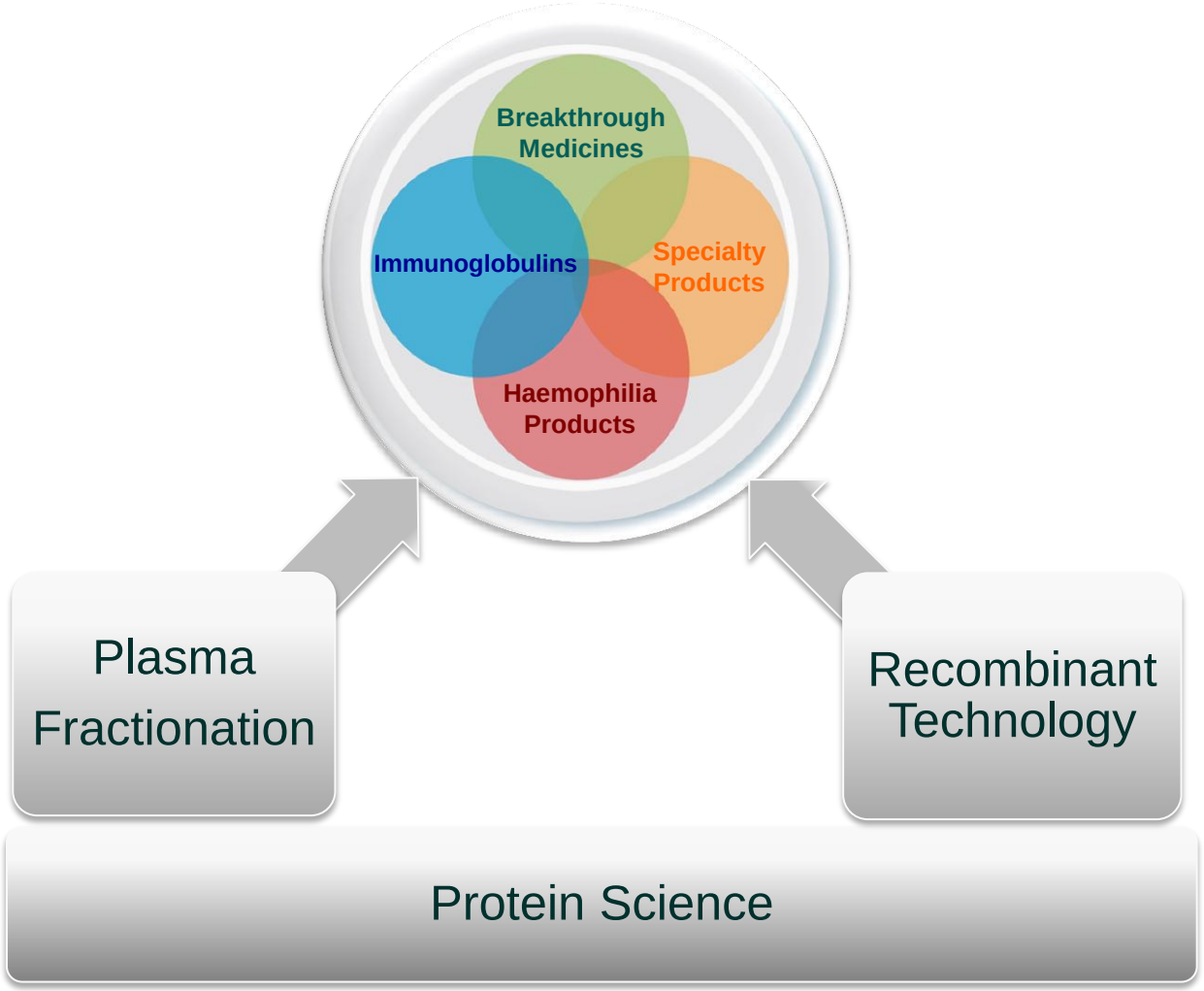
• Welcome	Mark Dehring
• Introduction & Highlights	Andrew Cuthbertson
• Protein Science Research	Andrew Nash
• Immunoglobulins & Specialty Products	
◦ Clinical Development	Charmaine Gittleson
◦ Commercial Opportunities	Bob Repella
• Q&A	

Break

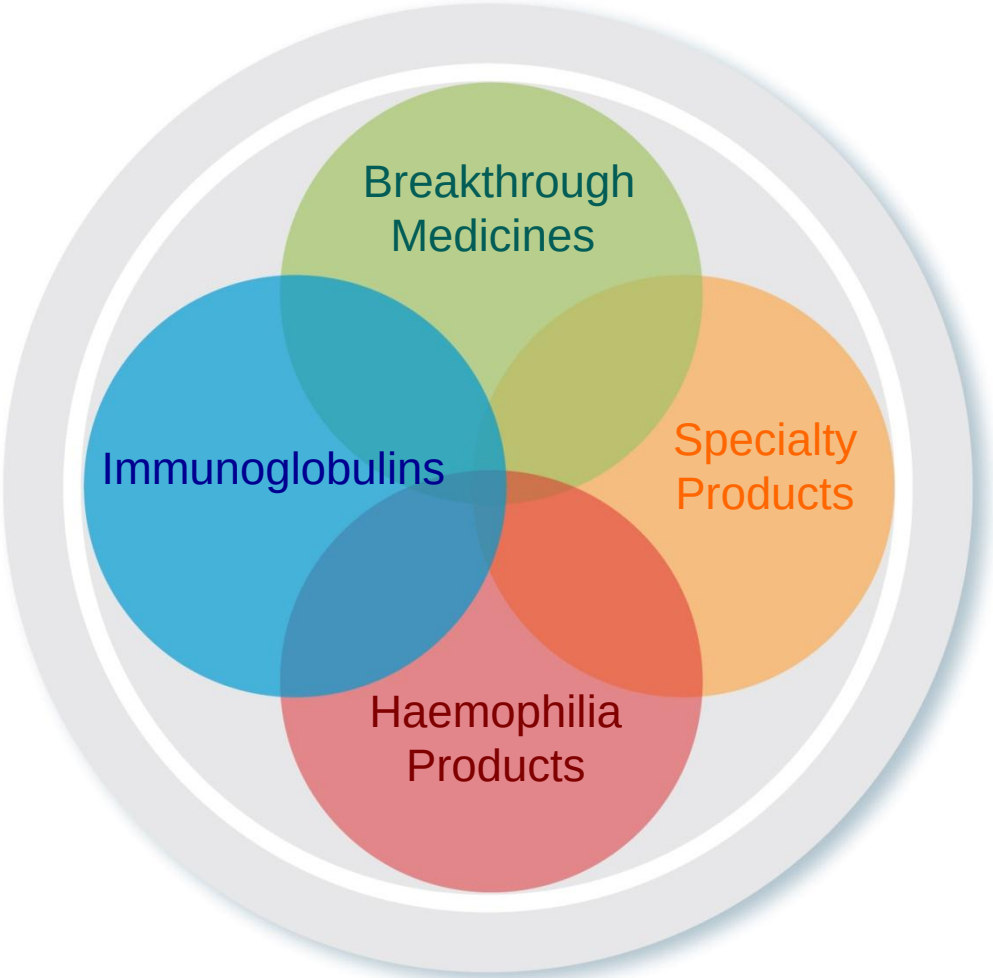
• Coagulation/Haemophilia	
◦ Clinical Development	Charmaine Gittleson
◦ Commercial Opportunities	Bob Repella
• Breakthrough Medicines & Licensing	Andrew Cuthbertson
• Summary	Andrew Cuthbertson
• Q&A	

Introduction and Highlights

CSL Protein Therapeutics Technical Platform



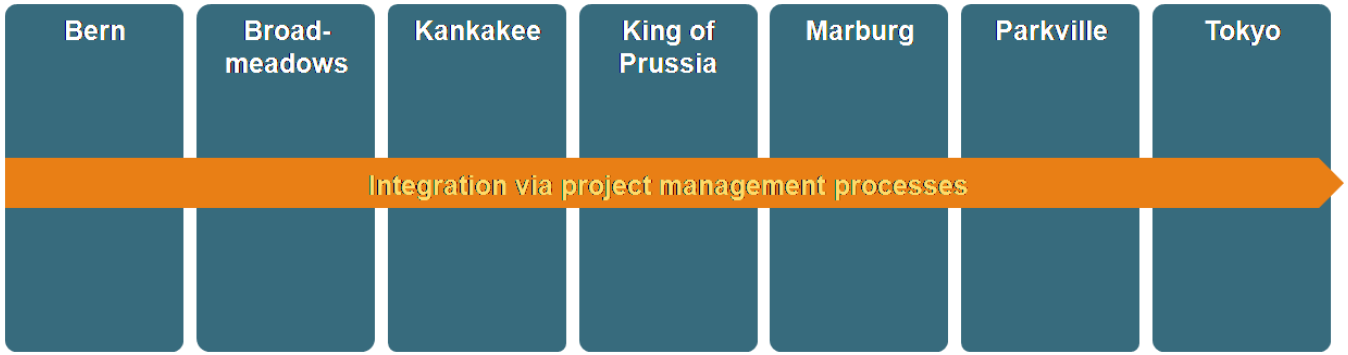
CSL R&D Strategy



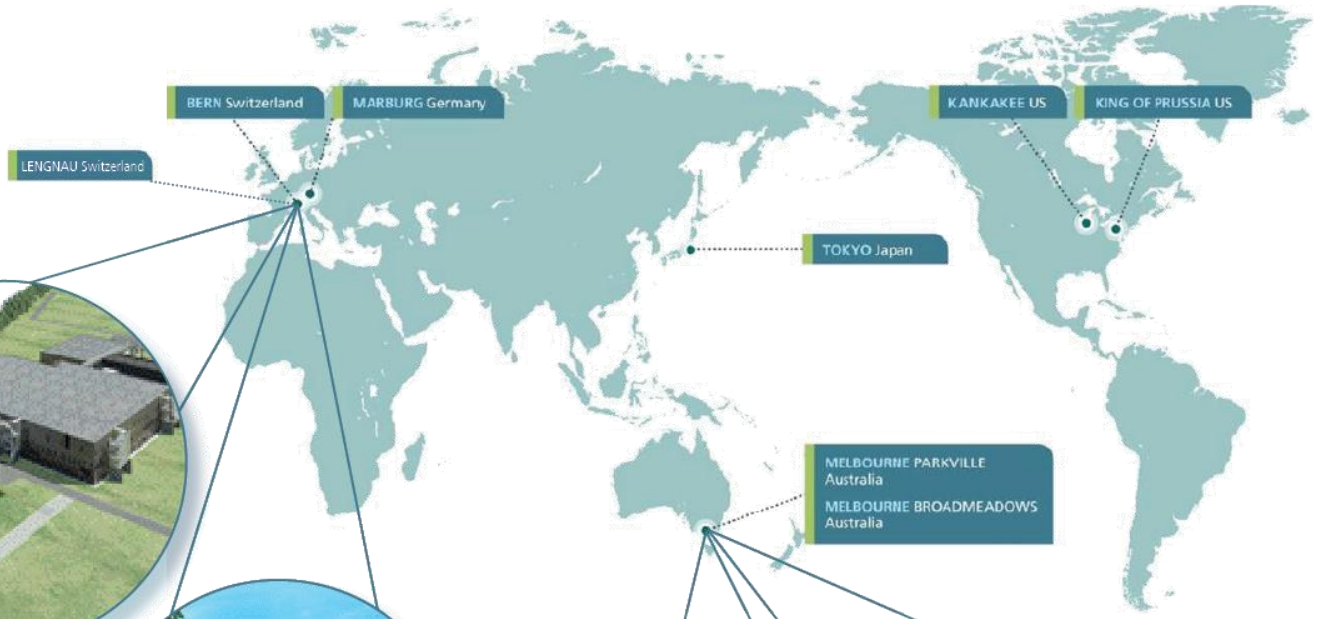
- Maintain commitment to extracting maximum value from existing assets and supporting and improving current products
- Develop new protein-based therapies for treating serious illnesses focusing on products that align with our technical and commercial capabilities

Leveraging Global Capabilities

- >1,100 scientists globally



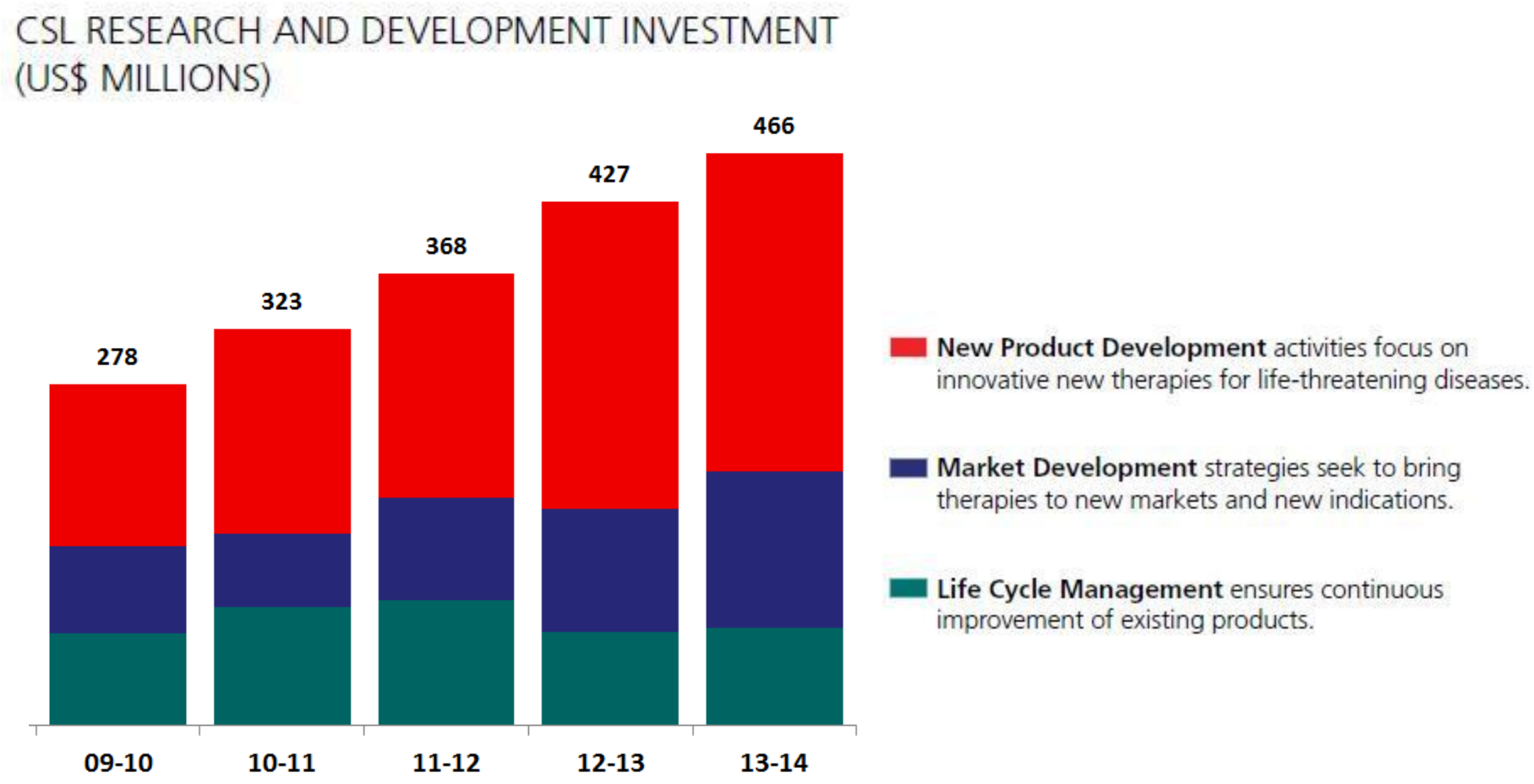
Building Global Recombinant Capabilities



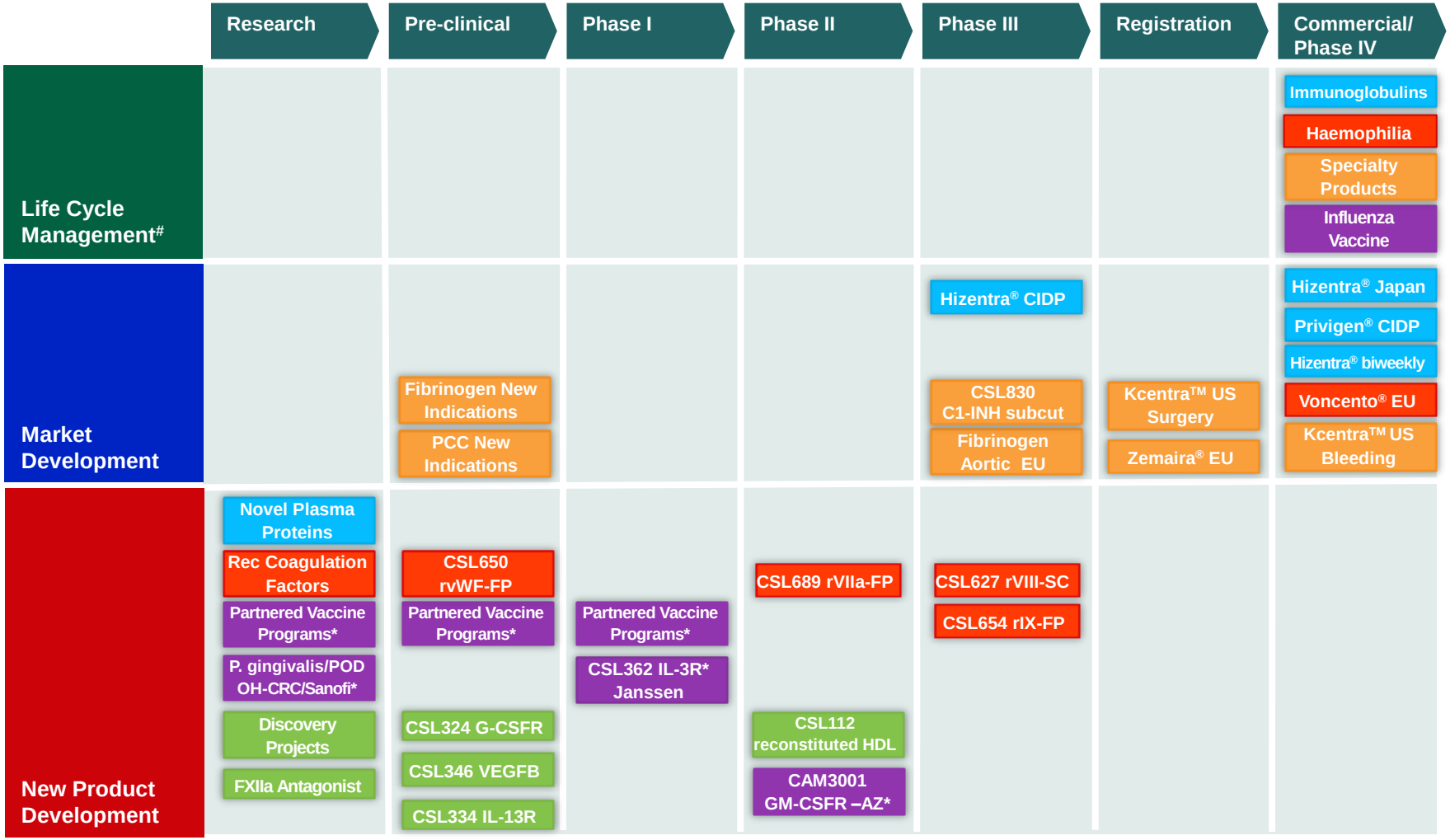
Lengnau rCOAG Manufacturing Facility

Broadmeadows Biotech Manufacturing Facility

R&D Investment



Global R&D Portfolio December 2013

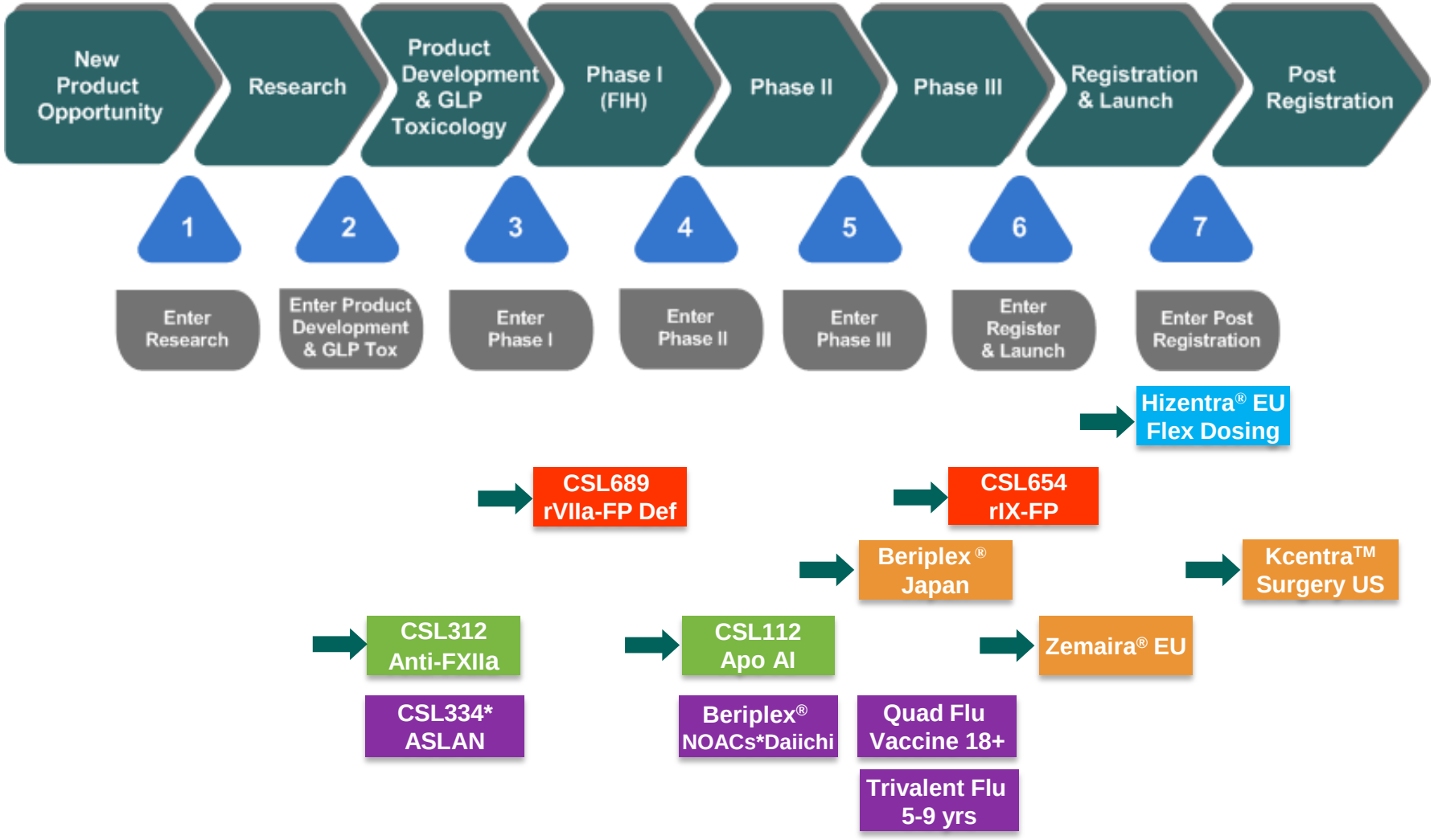


Core Capabilities: Immunoglobulins | Haemophilia | Specialty Products | Breakthrough Medicines | Vaccines & IP

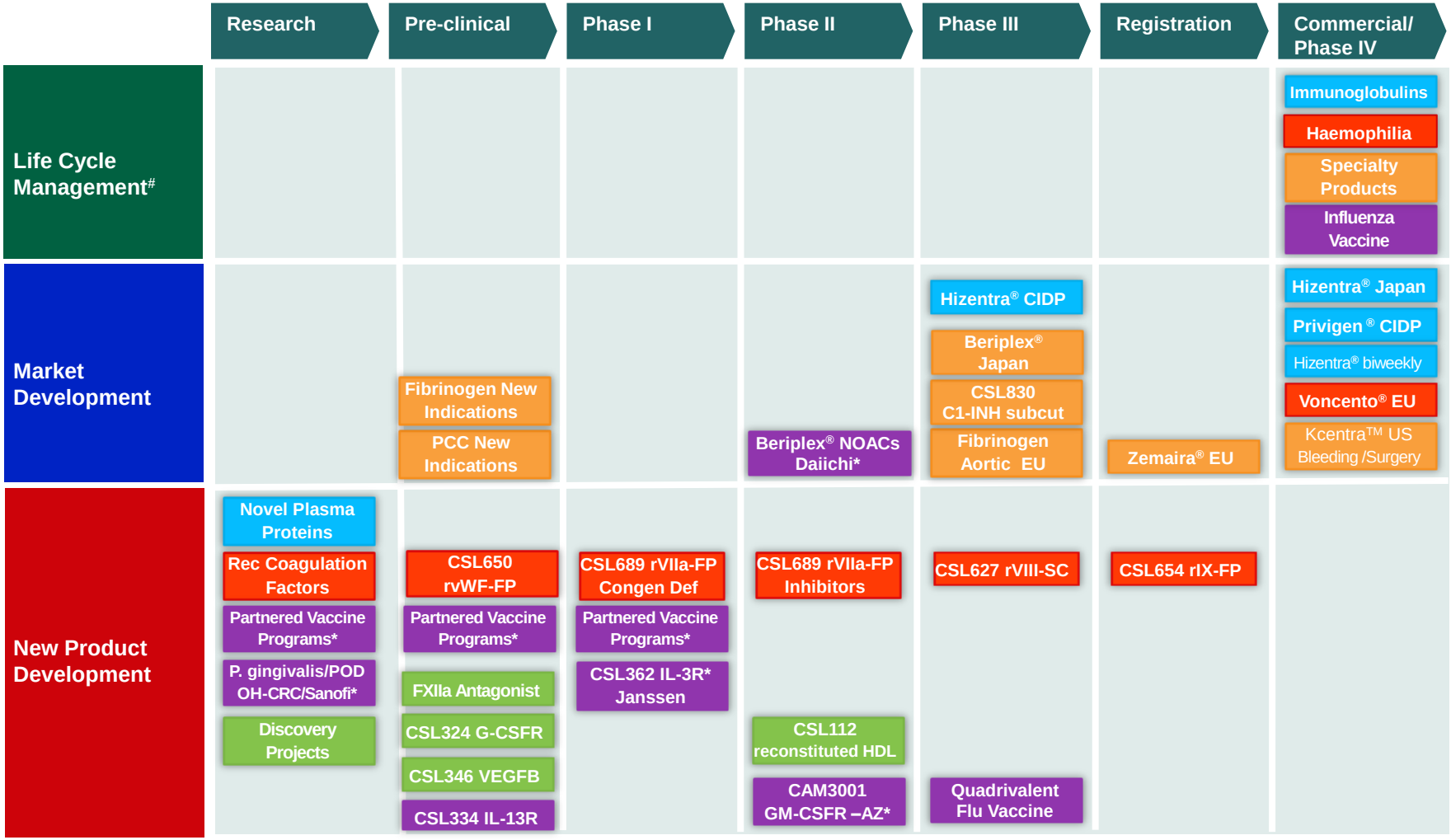
***Partnered Projects**

#LCM includes direct post marketing commitments as well as pathogen safety, capacity expansions, yield improvements, new packages and sizes for all registered products

Progress through Stage Gates in 2014



Global R&D Portfolio December 2014



Core Capabilities: Immunoglobulins | Haemophilia | Specialty Products | Breakthrough Medicines | Vaccines & IP

***Partnered Projects**

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Protein Science Research

CSL's Global Research Capability

- Hub & spoke model
- Single coordinated project portfolio
- Research excellence in therapeutic proteins
- Plasma and recombinant manufacturing platforms

Bio21 - Research Hub

- Located within world class university, medical research and hospital precinct in Parkville, Melbourne
- Technical expertise
  - protein engineering, molecular biology, cell biology, models of disease, genomics / bioinformatics
- Improved access to
  - high quality staff
  - cutting edge technologies
  - ideas / innovations / collaborations
  - patients and patient samples
- Model for Biotech / Pharma Research
  - decentralisation into high quality academic research hubs

CSL Research Project Portfolio

Some examples from the CSL Research Project Portfolio

Priority	Immunoglobulins	Haemophilia	Specialty Products	Breakthrough Medicines
High	Ig Formulations	FVIII half-life ext.	Beriplex NOACs Reversal	CSL312 HAE/Throm CSL362 SLE*
Medium				*P.ging* vaccine / mAb* CSL334 Asthma*
Lower	Ig Biomarkers		Haptoglobin / Hemopexin	

*** Partnered project**

Current products

- new indications, new formulations, MOA, Biomarkers

New product candidates

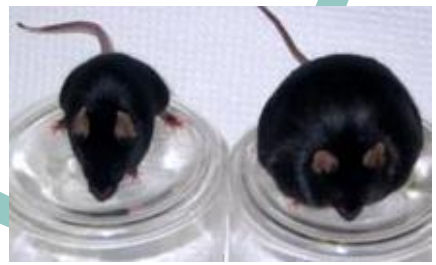
- novel protein-based therapeutics and vaccines, plasma and recombinant

Plasma and Recombinant Proteins

- **Capabilities from discovery to market**

Target

Protein Engineering Lab



Animal models of disease

Manufacturing CLD Lab

Phase I / II manufacturing

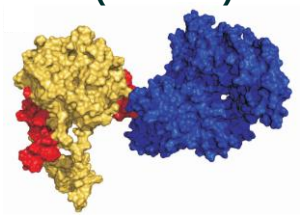
Phase III / launch manufacturing

Patient

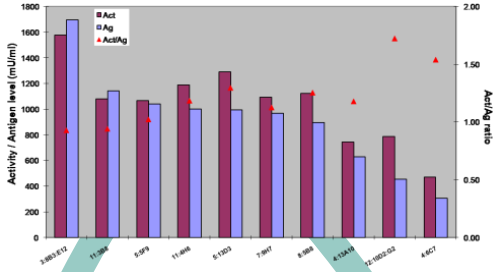
Market

CSL654 (rIX-FP) – Discovery to Development

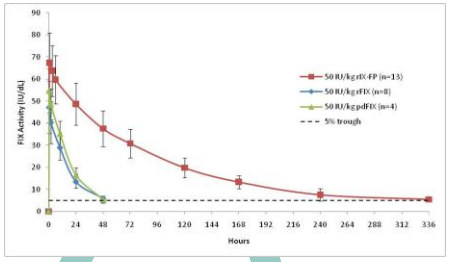
Factor IX fused to human albumin (CSL654)

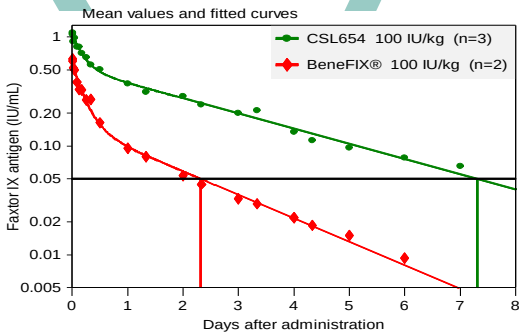


CSL654 manufacturing CHO clones



CSL654 $T_{1/2}$ extension in Haem B patients compared to Benefix



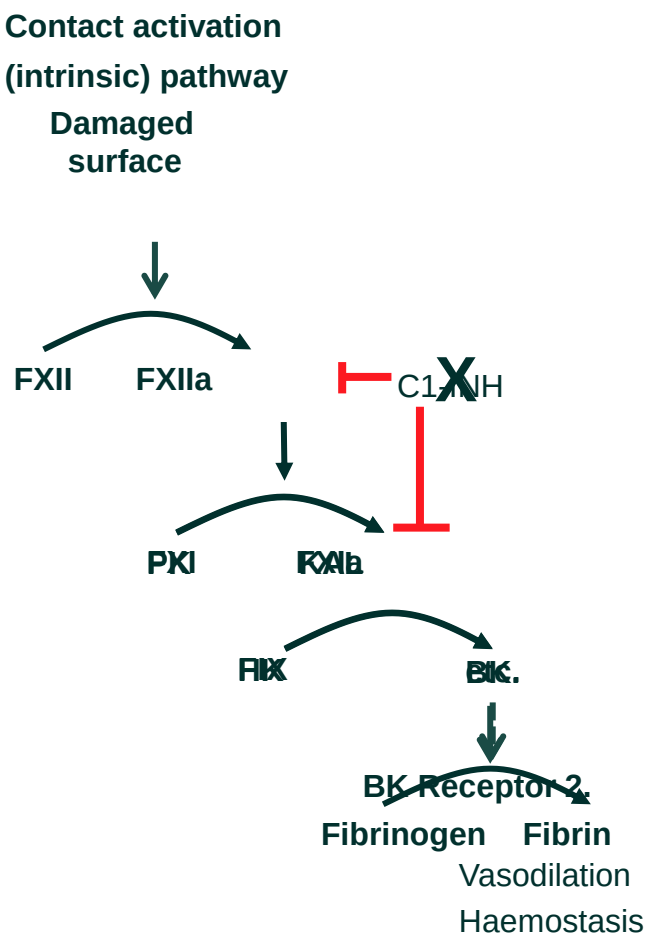


CSL654 $T_{1/2}$ extension in Haem B dogs compared to Benefix

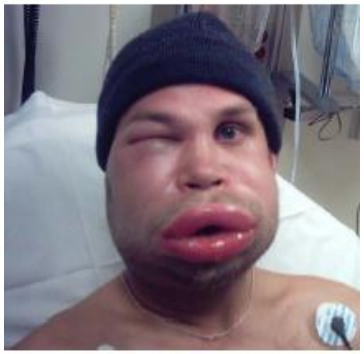
500L fed batch fermentation

Market

CSL312 (FXIIa antagonist mAb)



Hereditary Angioedema (HAE I, II, III)



HAE attack

Current therapeutic strategy

- On demand treatment with:
  - plasma derived C1-Inhibitor (Berinert)
  - small molecule kalikrein inhibitor
  - small molecule BR2 inhibitor
- Prophylaxis limited by convenience issues
  - subQ Berinert

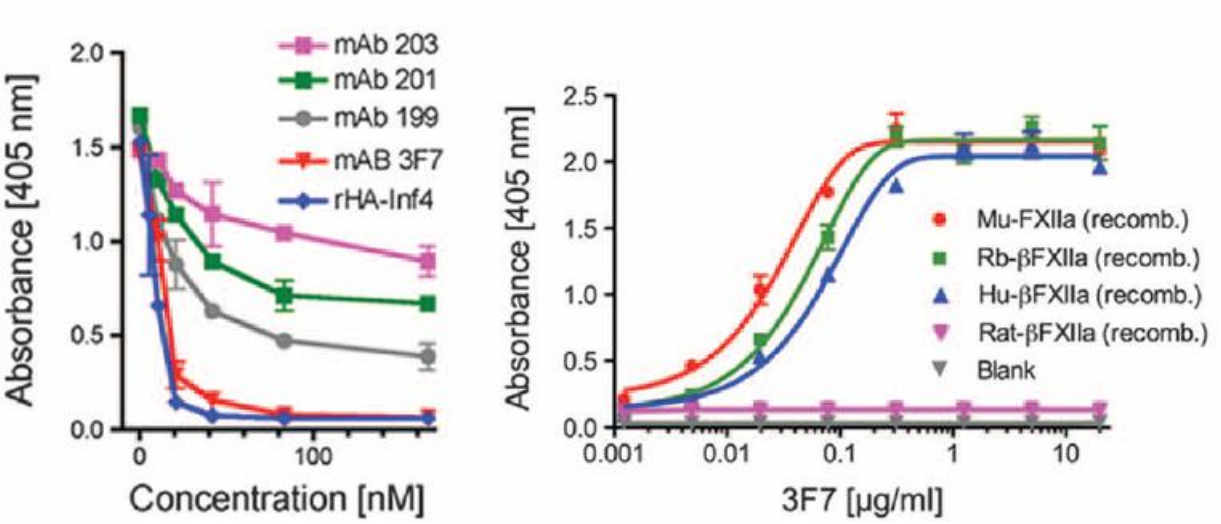
Opportunity

- Improve clinical outcomes and patient QoL by enabling prophylaxis

CSL312 (FXIIa antagonist mAb)

Generation & characterisation of a human FXIIa antagonist mAb

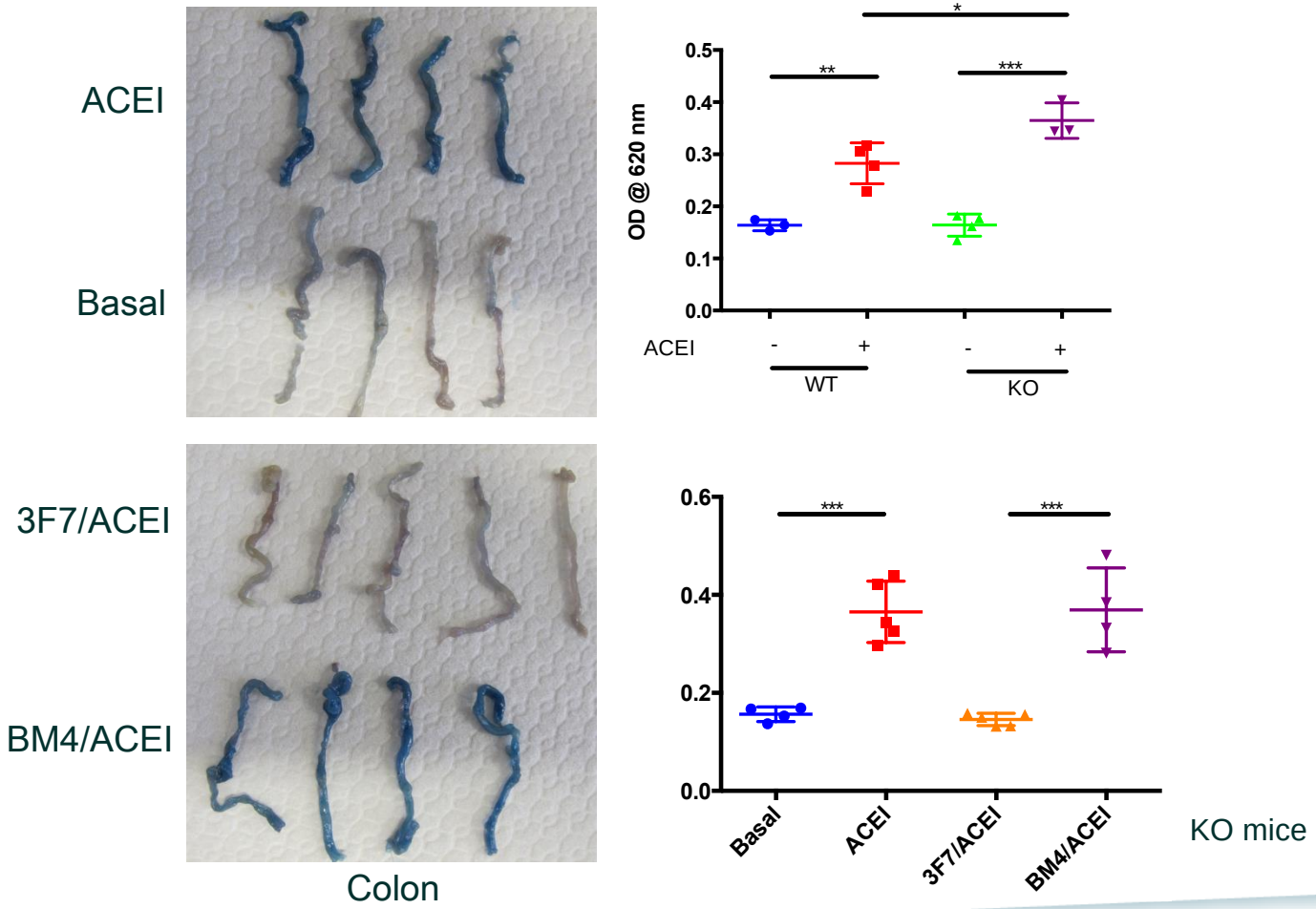
- screening of human Ab (Fab) phage display library



- mAb 3F7 shows complete inhibition of FXIIa
- affinity matured 3F7 (**= CSL312**) shows further specificity improvements

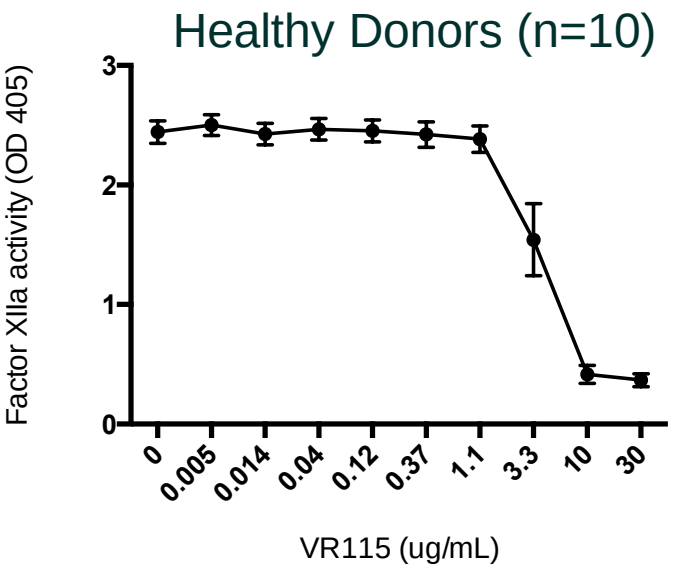
CSL312 – Hereditary Angioedema

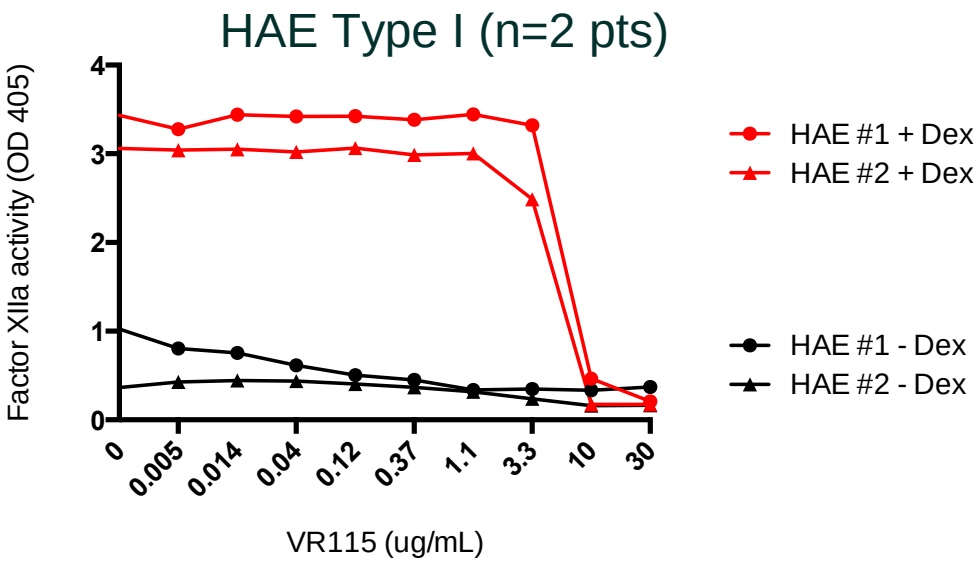
CSL312 inhibits vascular leakage in ACEI treated C1-INH null mice



CSL312 – Hereditary Angioedema

CSL312 inhibits Factor XIIa activity in human plasma





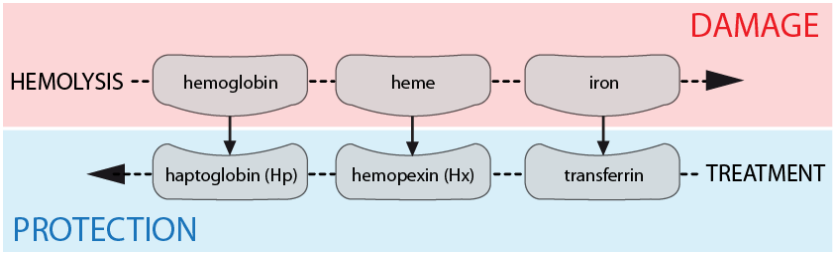
Current status

- CSL312 has progressed into product development and toxicology

Haptoglobin (Hp) / Hemopexin (Hx)

Red blood cell lysis and inflammation / tissue damage

- In pathological settings RBC lyse to release haemoglobin (Hb)
- Haemoglobin is further oxidised leading to the release of heme
- Free Hb and heme are toxic and contribute to disease pathology
  - NO scavenging
  - reactive oxygen species, oxidative stress
  - activation of inflammatory pathways (heme / TLR4)
- Acute phase proteins Hp and Hx sequester and dispose of free Hb and heme



- Hp and Hx are significantly depleted in acute and chronic disease

→ Opportunity for replacement therapy

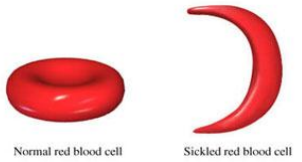
Haptoglobin (Hp) / Hemopexin (Hx)

Sickle Cell Disease

- Mutation in β-Hb gene, aggregation of β-Hb, sickle-shaped RBC
- Obstruct microvasculature, prone to lysis and release of Hb / heme

Diverse manifestations

- Acute chest syndrome, severe pain, pulmonary hypertension, stroke, splenic infarction, sepsis and renal failure



Aetiology

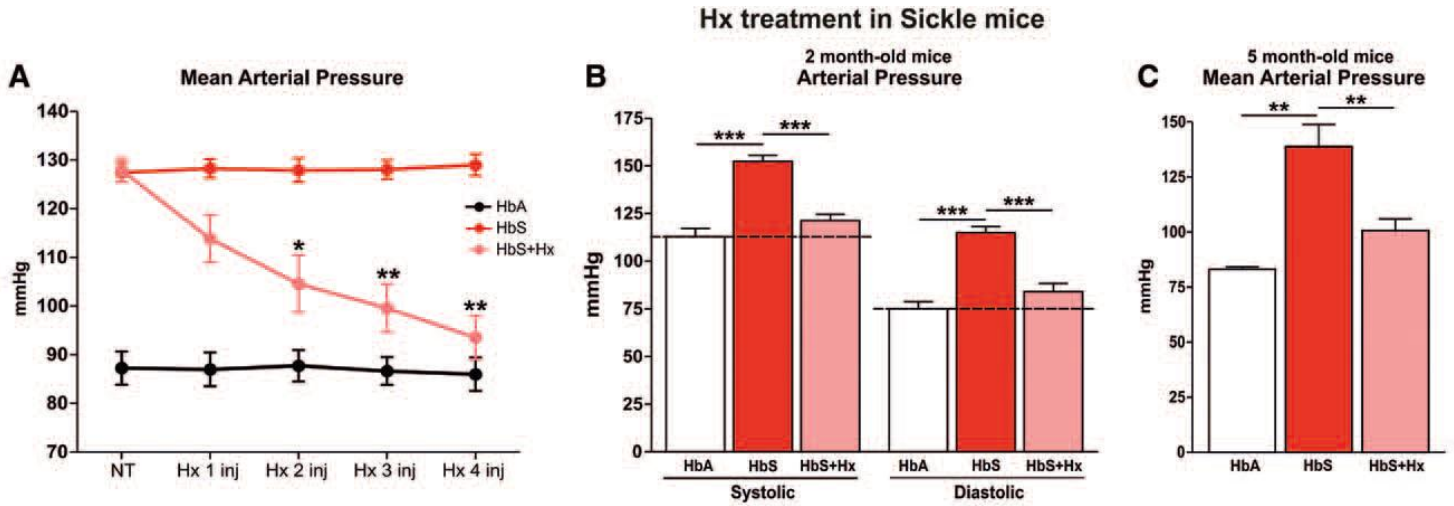
- Chronic low level and acute higher level exposure to Hb and heme
  - → Vasoconstriction, vascular damage / local inflammation
  - → Vaso-occlusive crisis
    - mechanical and heme induced obstruction of capillaries

- **Hp is absent and Hx significantly depleted in SCD patients**

Haptoglobin (Hp) / Hemopexin (Hx)

Hx therapy normalises blood pressure in SCD mice

- Transgenic mice that express human α-globlin and β-globin incorporating the sickle mutation (HbS), no expression of mouse Hb genes
- 0.7mg Hx, 2x per week for 4 weeks from 1 month of age



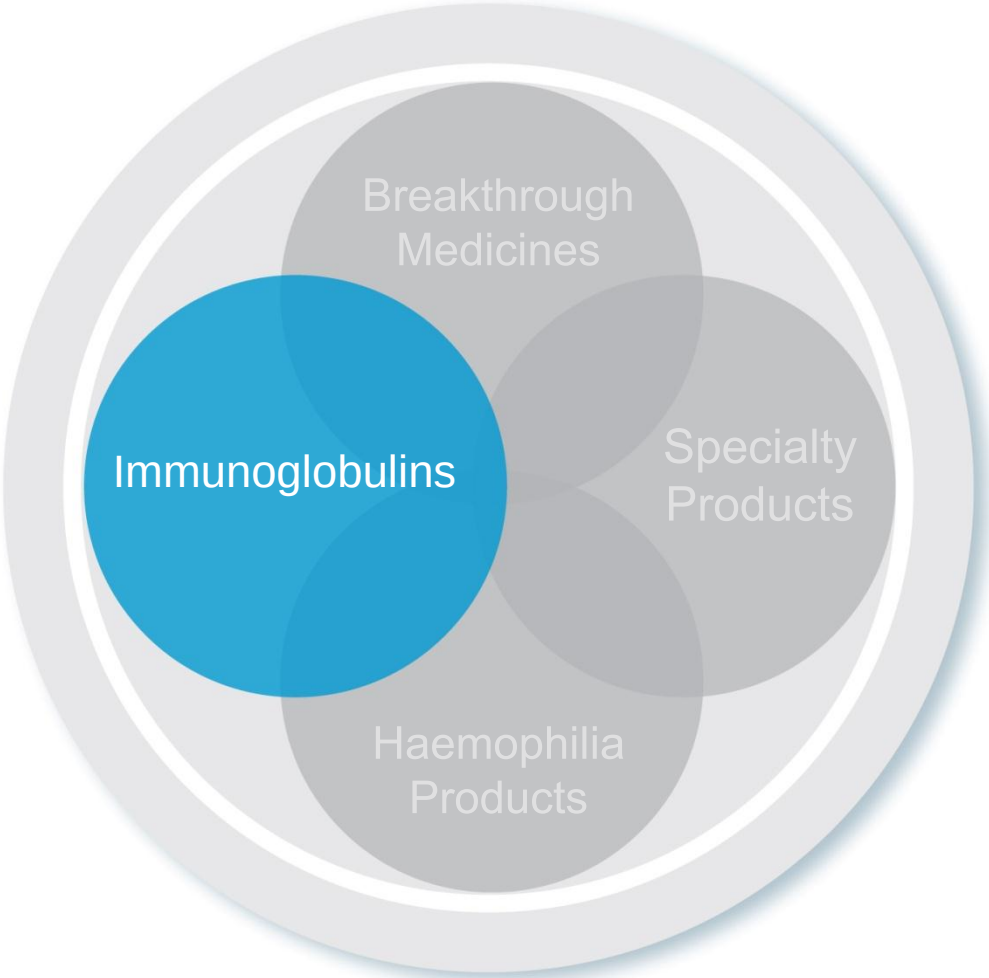
Vinchi *et al*., Circulation 2013

CSL Research on Hp / Hx

- Swiss government funding since 2011
- Collaborators: University of Zurich, University of Torino, FDA CBER
- Processes for purification of Hp and Hpx from plasma developed
- Initial pre-clinical proof-of-concept data generated *in vitro* and *in vivo*
- Planning to progress into product development during 2015

Immunoglobulins

Immunoglobulins



Maintaining leadership position through focus on:

- Patient convenience
- Yield
- Label
- Formulation science
- Specialty Igs

Key Focus

- Hizentra®
- Privigen®

privigen®
IVIG therapy made simple

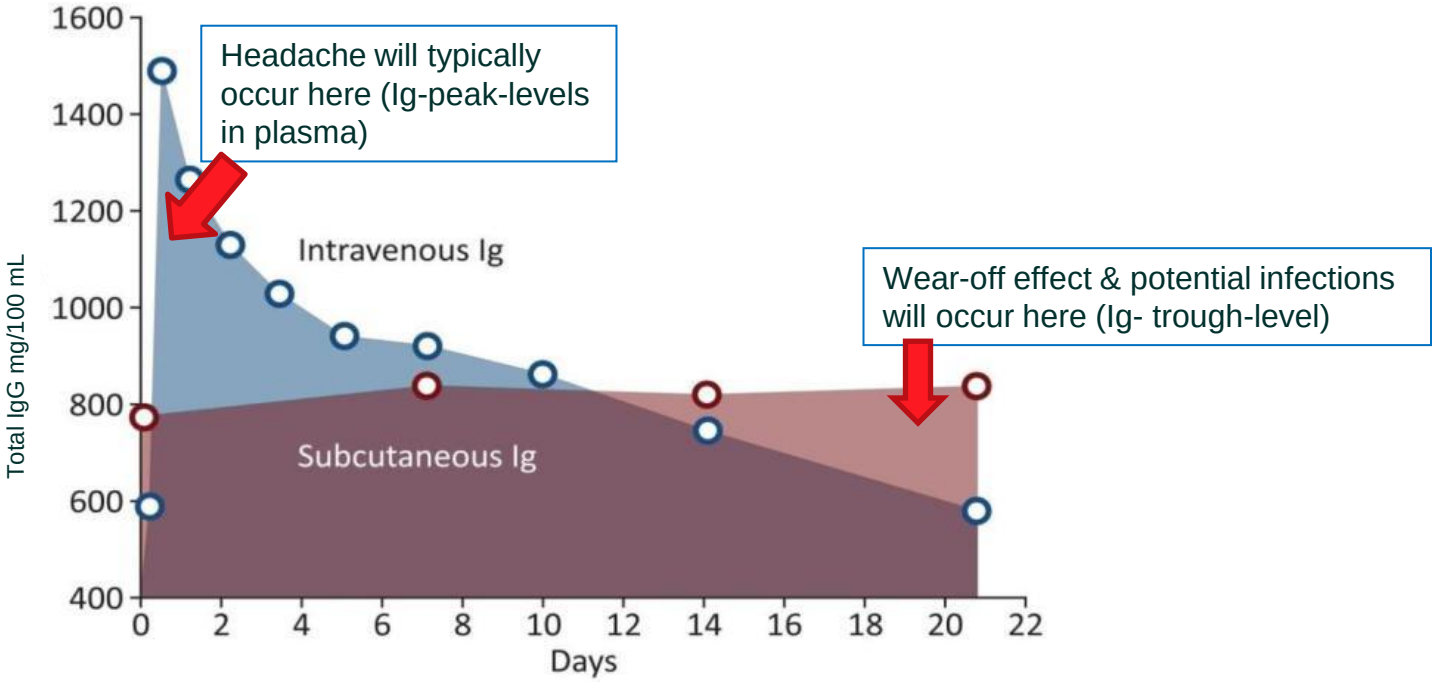
The first and only 10% liquid intravenous immunoglobulin (IVIg) therapy that is proline stabilised with room temperature storage up to 36 months

Hizentra®
Immune Globulin Subcutaneous (Human) 20% Liquid

The first 20% high concentration low volume SCIG for convenient self administration providing steady-state Ig levels and an established long-term safety record with chronic administration

CSL™

Benefits of Hizentra®: Steady-State Kinetics



Pharmacokinetic Profile of IVIG vs. SCIG

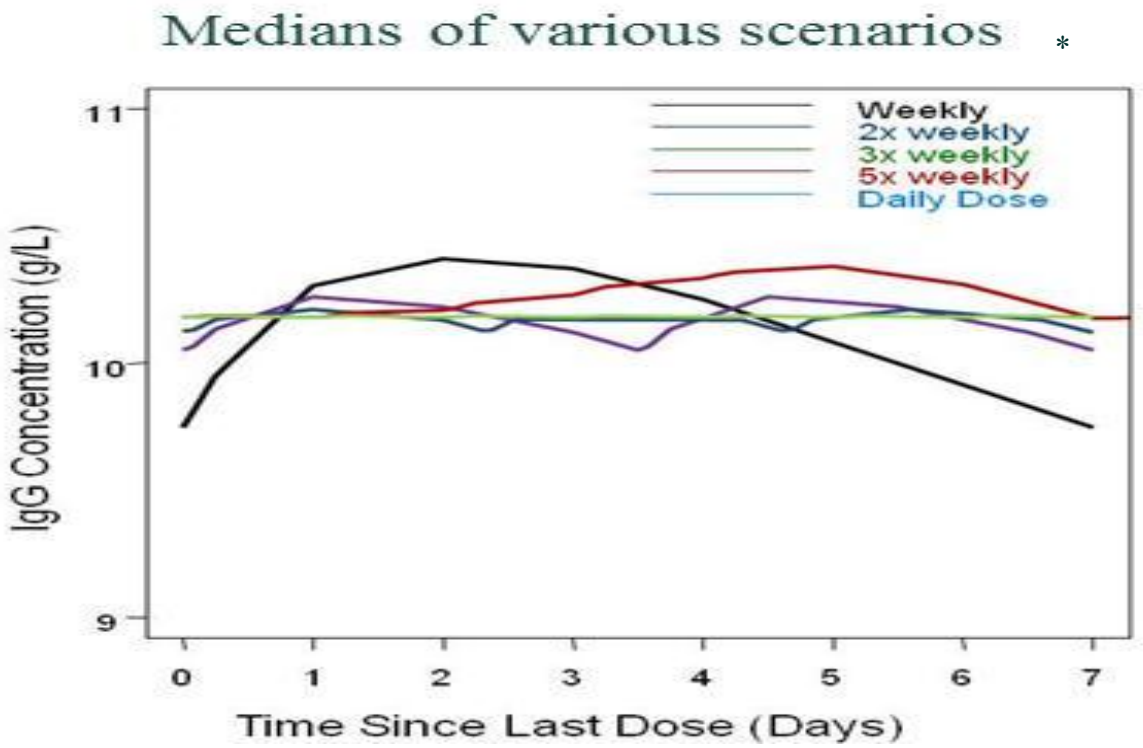
- SCIG weekly dosing results in steady IgG levels (no peaks, no troughs) [1]
- Patients report less wear off effect switching from IVIG to Hizentra® [2]

1.Data shown for a patient with X-linked agammaglobulinemia who received a single infusion of 5% IVIG (30 g followed by 16% SCIG (12 g) every 7 days.
2. Igarashi A. *Clin Ther*. 2014 Sep 15

Hizentra® Schedules Beyond Biweekly

Hizentra®
Immune Globulin Subcutaneous (Human) 20% Liquid

Individualised dosing strategies for patient protection

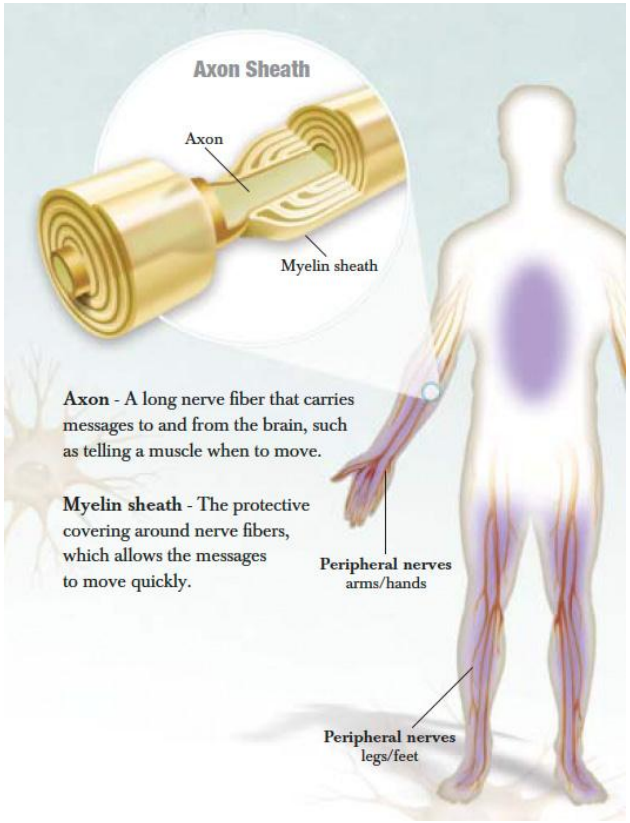


- More optionality, better management of dosing holiday
- Approved by EMA
- Under FDA review

Data on file CSL Behring

*Hizentra® pharmacometric modeling and simulation

Strengthening Presence in Neurology



Chronic Inflammatory Demyelinating Polyneuropathy

- Increased use of Privigen® across Europe and Canada in patients with CIDP
- Hizentra® CIDP orphan designation in the US
- Ongoing progress in Hizentra® Path study

privigen®
IVIG therapy made simple

Hizentra®
Immune Globulin Subcutaneous (Human) 20% Liquid

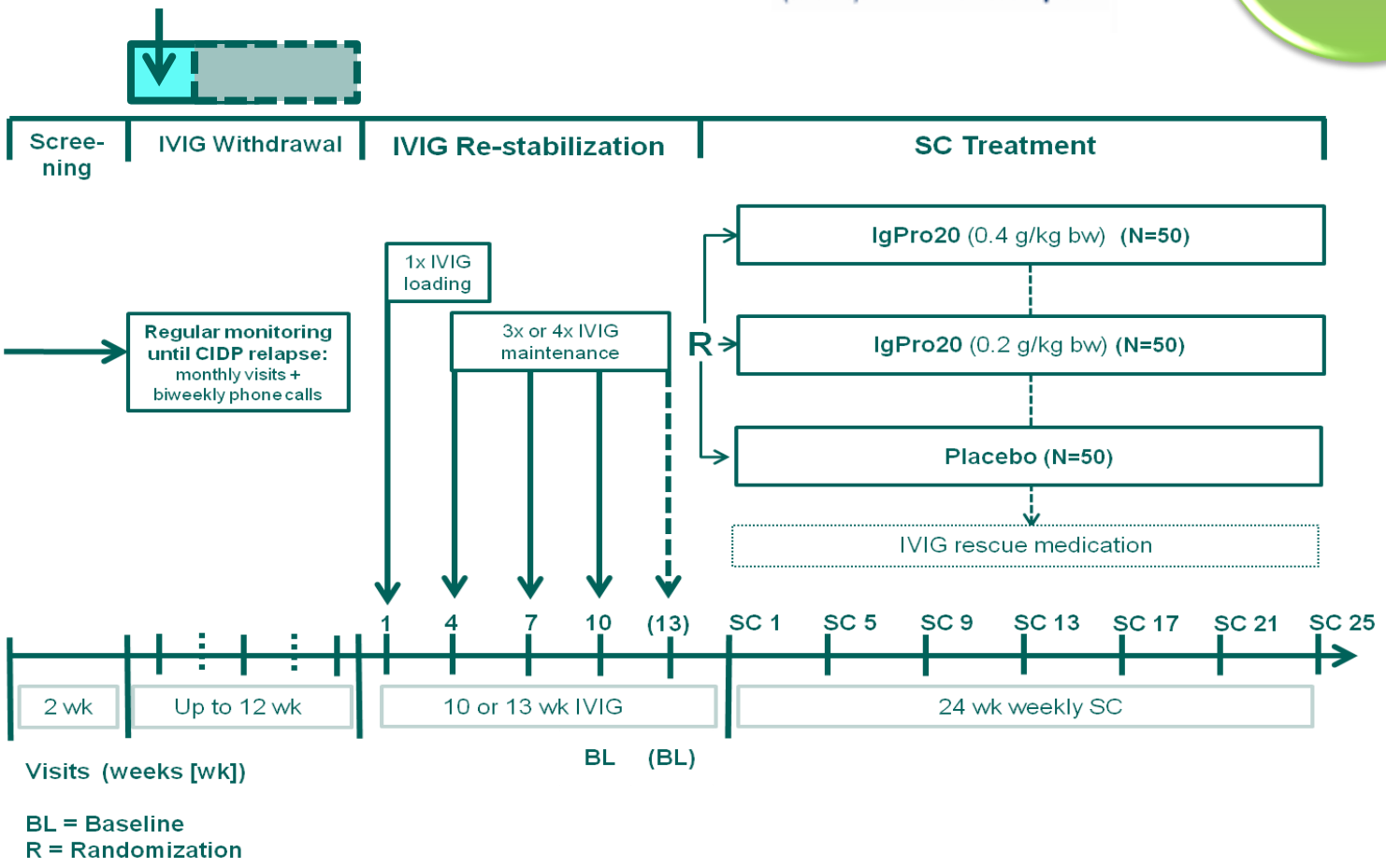
CSL™

Path Phase III Study Design

Hizentra® Immune Globulin Subcutaneous (Human) 20% Liquid

Path

IgG dependency Test



Visits (weeks [wk])

BL = Baseline
R = Randomization

CSL

Path Study Progress

- 60 patients completed
- 114 / 174 randomised
- Expect to close recruitment in late 2015
- Last patient completing late 2016
- FDA and EMA submissions Q3/4 2017

Commercial Opportunities and Activities

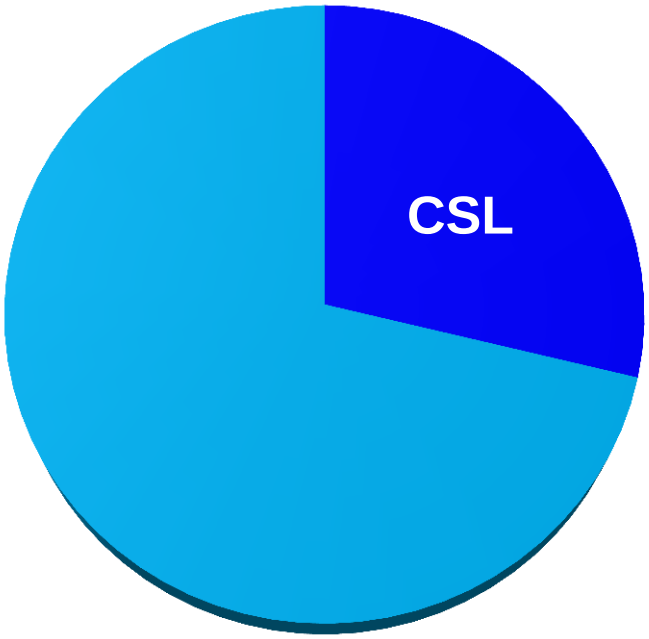
Global Immunoglobulin Market

- Ig volume continues to grow globally
- Increased competition particularly in SCIg
- CSL is well positioned

privigen®
Human Normal Immunoglobulin
IVIG therapy made simple

Hizentra®
Immune Globulin Subcutaneous (Human) 20%Liquid

2013/14 Sales (USD)



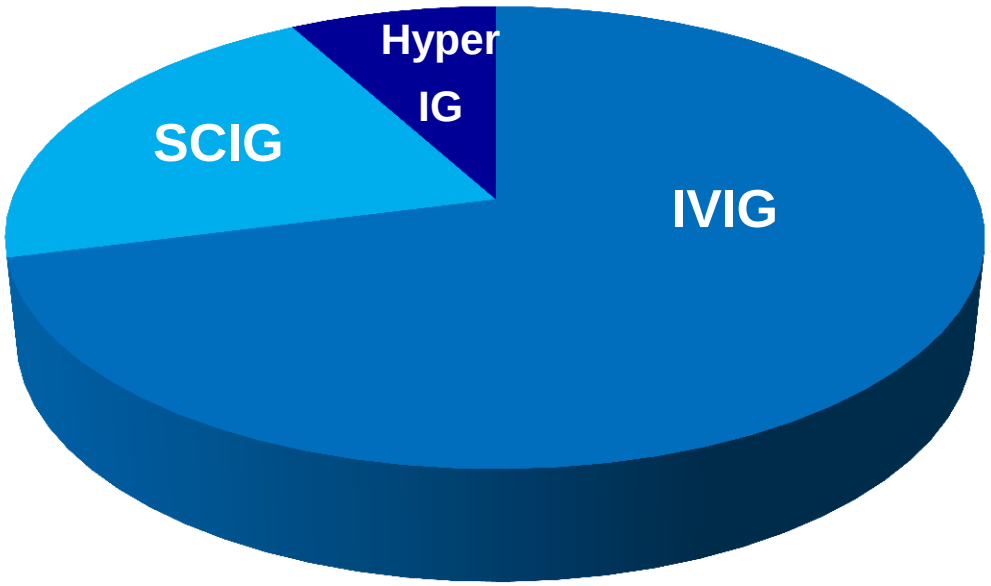
~ $8b

Sources: Company annual reports / earnings releases, CSL Estimates of Target Markets

CSL's Immunoglobulin Portfolio

- Increased presence in neurology in Europe
- Maximise patient convenience
- Geographical expansion

2013/14 Sales (USD)



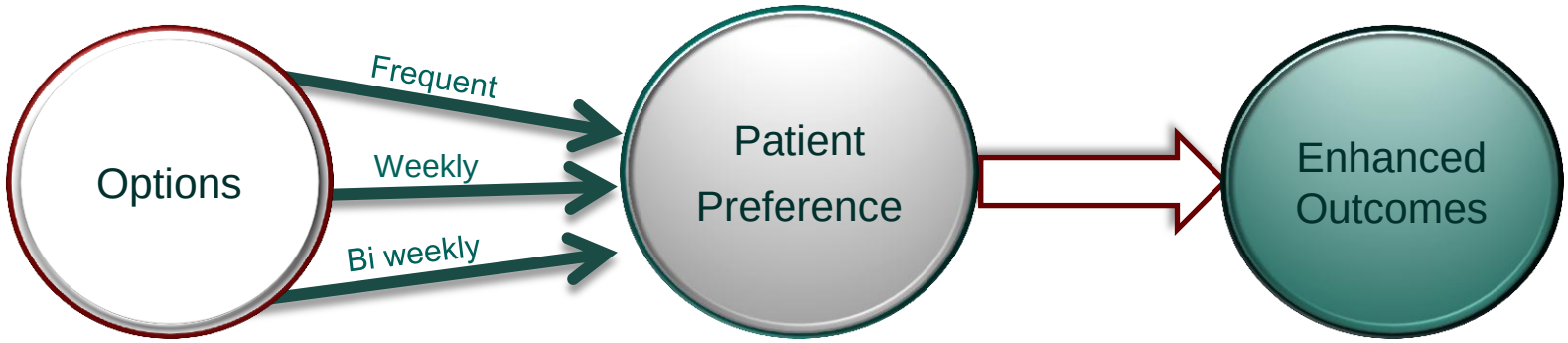
$2,320m

Immunoglobulins: Progress Achieved

Increased presence in neurology	• Privigen® CIDP launched in Europe and Canada • Ongoing development of Hizentra® in CIDP • Additional indications under evaluation
Maximise patient convenience	• Individualised therapy from daily to bi-weekly • Further activities ongoing
Geographical expansion	• Hizentra® biweekly approved in major regions • Hizentra® flexible dosing in EU • Hizentra® registered in 39 countries • Privigen® registered in 66 countries

Individualised Therapy

Hizentra®
Immune Globulin Subcutaneous (Human) 20% Liquid



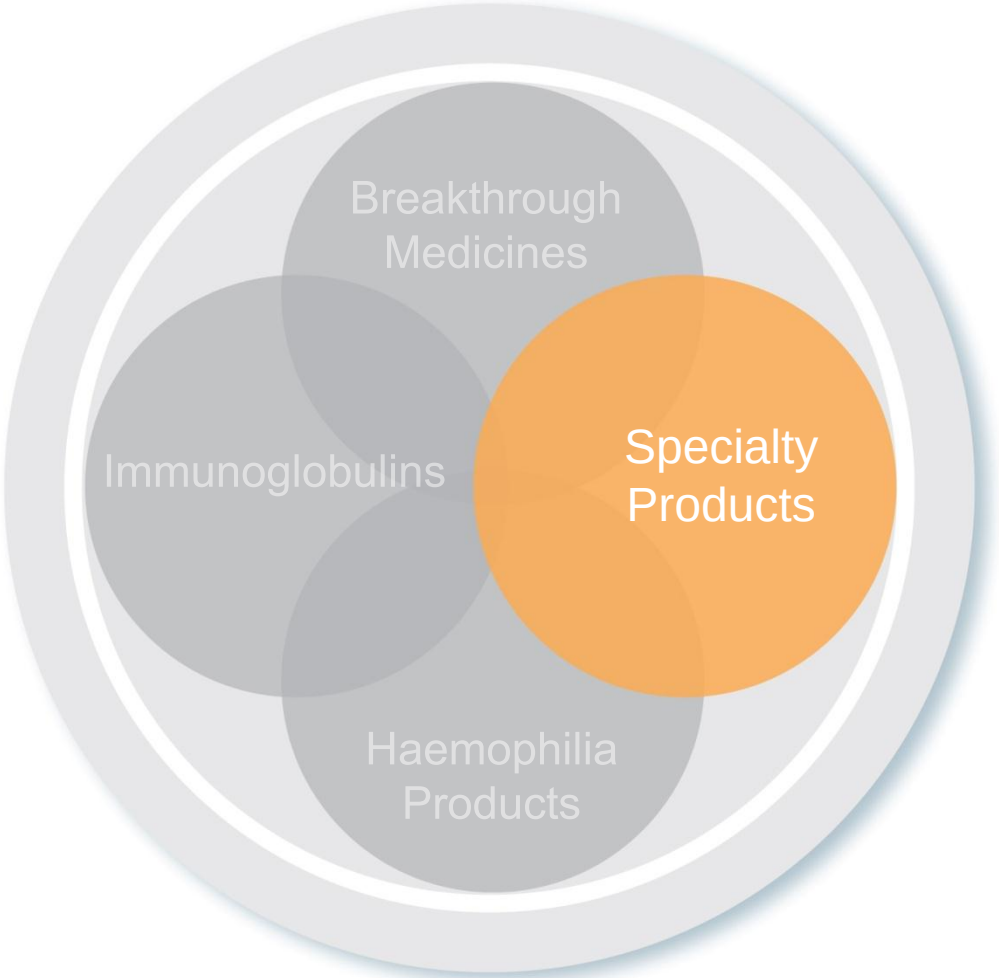
Advantages of individualised therapy with Hizentra®

- Dosing flexibility provides more freedom to patients, allowing them to manage their condition based upon their specific needs and lifestyle
- All dosing options with Hizentra® result in steady-state IgG levels, avoiding the monthly IVIG wear-off effects

CSL™

Specialty Products

Specialty Products



Leveraging high quality, broad product portfolio through:

- New markets
- Novel indications
- Novel modes of administration

Key Focus

- Beriplex® / Kcentra™
- Berinert®
- Zemaira®
- Fibrinogen

Kcentra™ (Beriplex®)

- Prothrombin Complex Concentrate = PCC
  - vitamin K-dependent coagulation factors (FII, FVII, FIX, FX)

Kcentra™ launched in April in the US as a first in class therapy to reverse the effects of vitamin K antagonists (e.g. Warfarin) for:

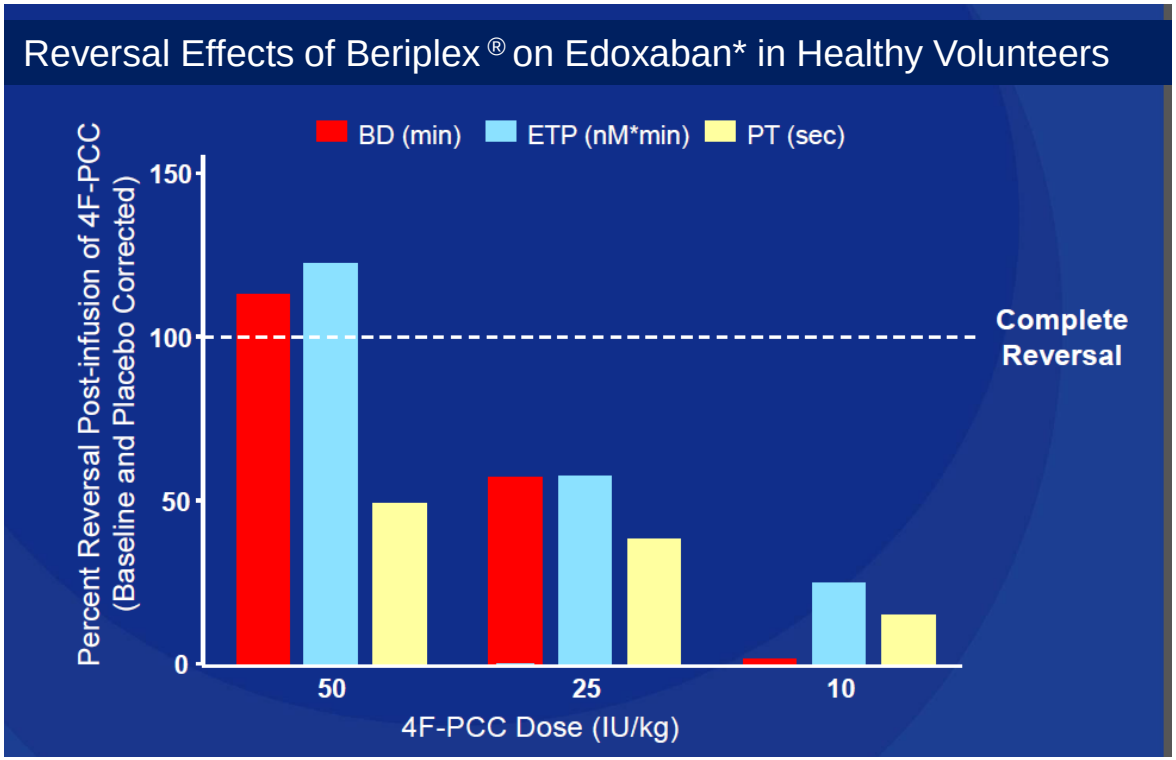
- Bleeding related to over-anticoagulation
- Patients needing urgent surgery
- Included in treatment guidelines

Clinical Program commenced in Japan to register Beriplex® for vitamin K antagonist reversal

- PMDA submission Q1 2016

Kcentra™ (Beriplex®)

- Potential clinical application for new oral anticoagulant reversal?



Key:

BD=bleeding duration

ETP=endogenous thrombin potential

PT=prothrombin time

- 50IU/kg Beriplex® dose reversed the anticoagulant effect of edoxaban

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT02047565. (Zahir H. *Circulation*. 2015;131:00-00. Published online November 17, 2014)

* Edoxaban - Daiichi Sankyo Pharma Development, Edison, NJ

Berinert®

Plasma derived, pasteurised & nanofiltered concentrate of C1 Esterase Inhibitor indicated for the treatment of acute abdominal, laryngeal or facial attacks of hereditary angioedema (HAE) in adults and adolescents

- Post marketing safety studies completed
  - No antibody generation
  - No increased thrombo-embolic risk

CSL830 (Subcutaneous C1-INH)

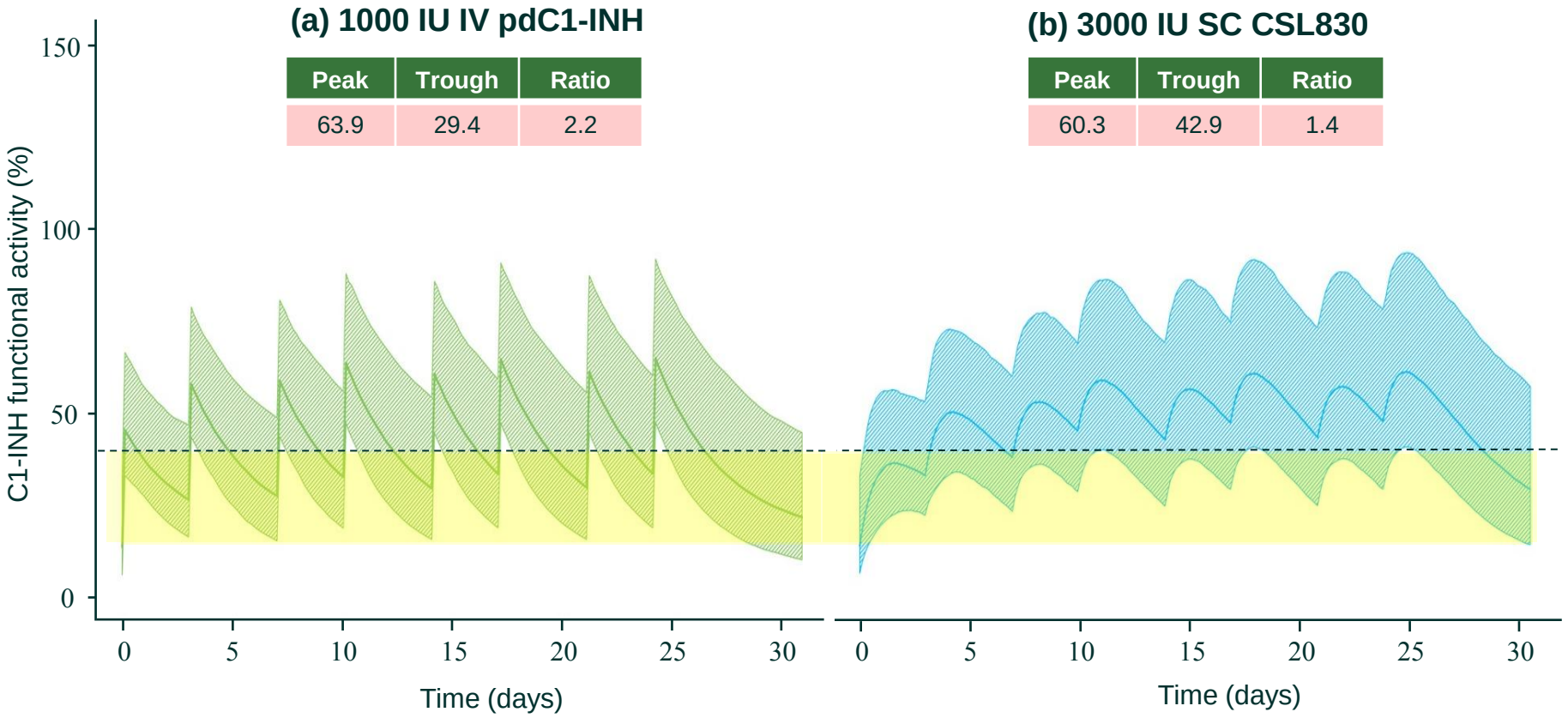
Plasma derived, pasteurised & nanofiltered highly concentrated C1 Esterase Inhibitor indicated for subcutaneous administration in the prophylaxis of hereditary angioedema (HAE) in adults and adolescents

- Patients with frequent attacks (50 to <100/year):
  - Treat acute attack, loss of life quality
- High frequency attacks (>100/year)
- Prophylaxis with intravenous C1 Esterase Inhibitor
  - Limited by venous access, break though attacks in some patients[1]

Zuraw B. *Allergy, Asthma & Clinical Immunology* 2010, **6**:23[1]

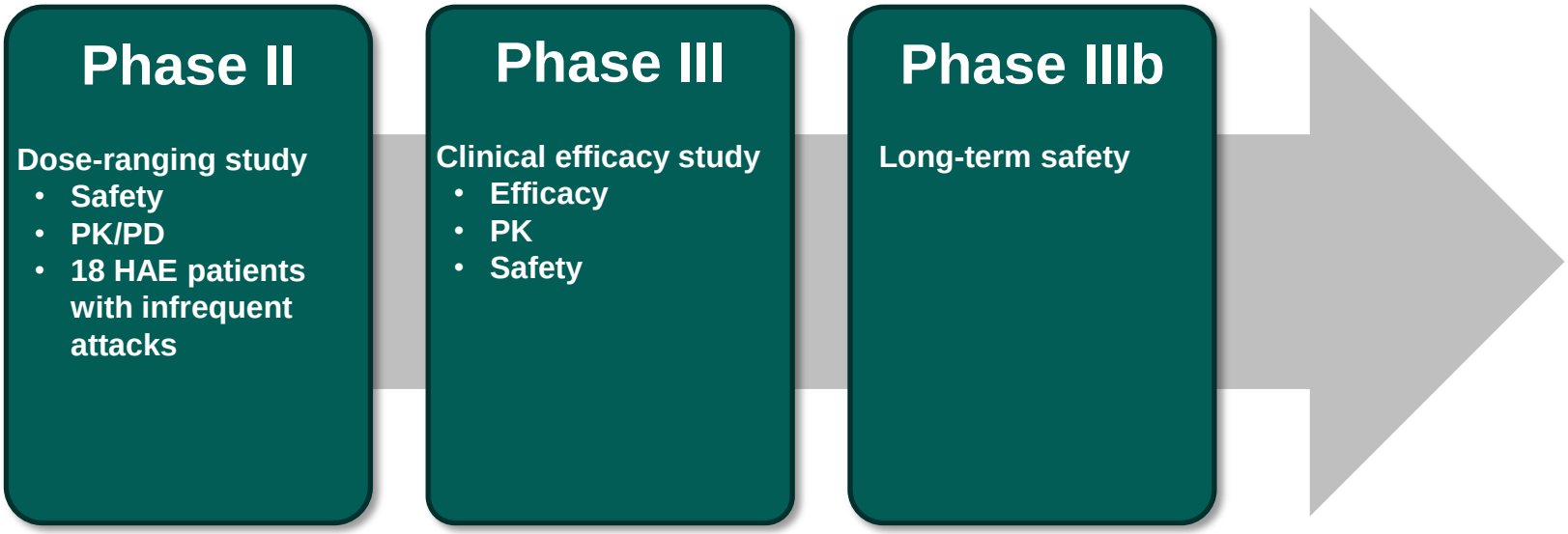
Vulnerable Period (time <40% C1-INH activity)

SC CSL830 maintains trough levels above “protective” C1 levels



Data on file CSL Behring
Submitted for publication

CSL830 Clinical Program



Completed | **Ongoing** | **Commencing Dec 14**

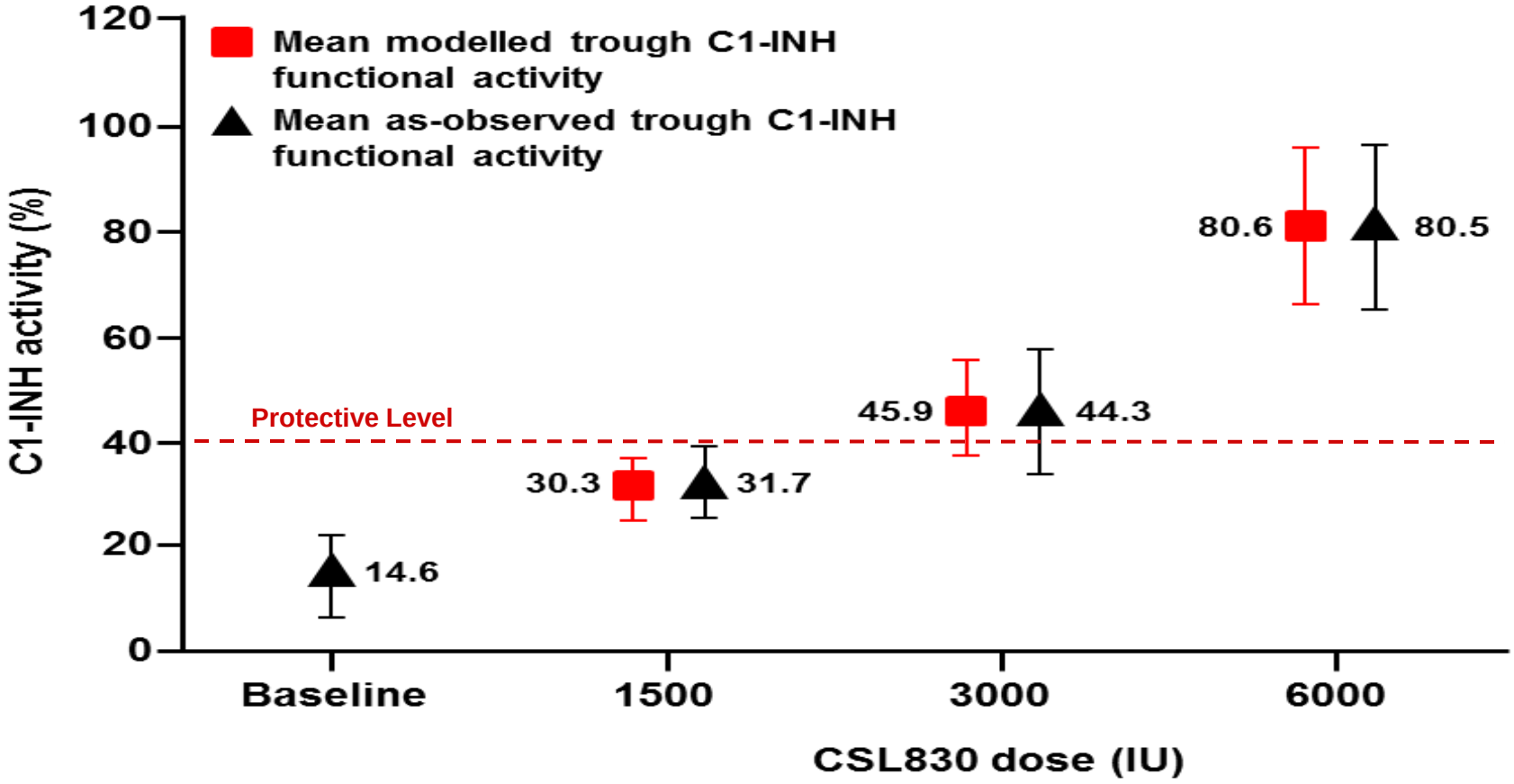
COMPACT

Clinical Studies for Optimal Management in Preventing Angioedema with low-volume subcutaneous C1-inhibitor Replacement Therapy

www.clinicaltrials.gov

CSL830 Phase II COMPACT Study Results

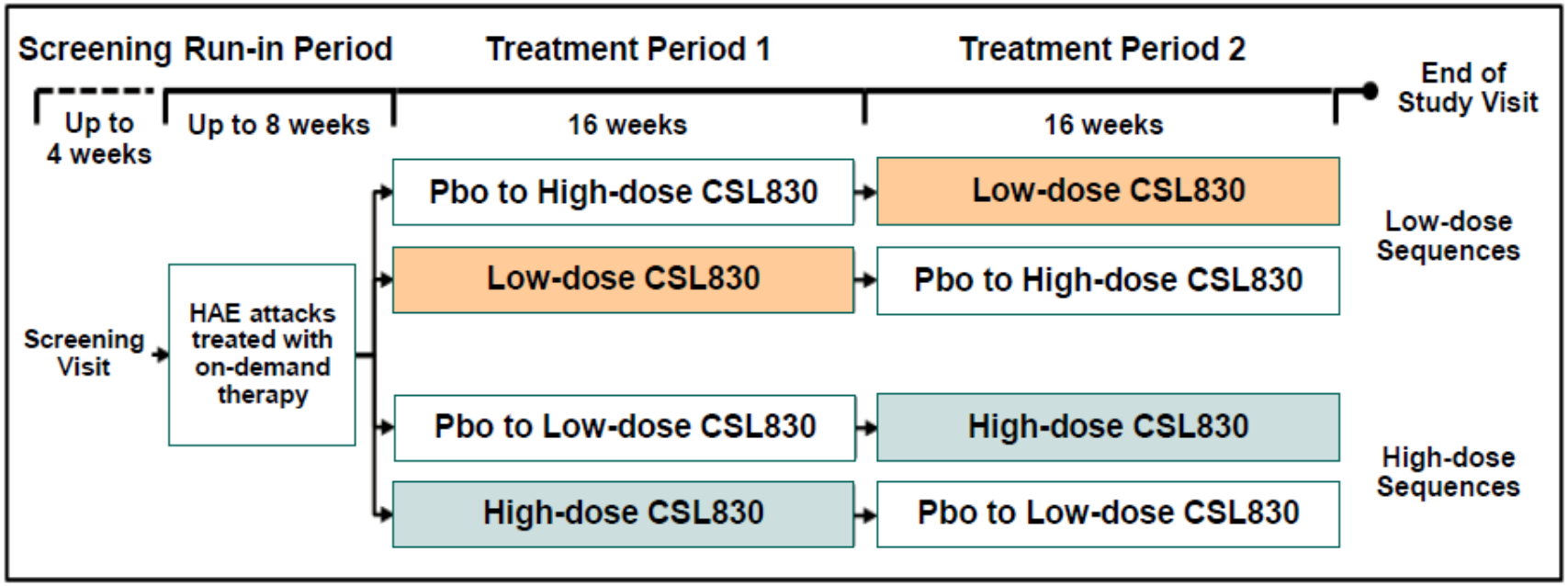
Primary Endpoint



Modified from Zuraw et al; EEACI 2014

CSL830 Phase III Study Design

COMPACT
Clinical Studies for Optimal Management in Preventing Angioedema with low-volume subcutaneous C1-inhibitor Replacement Therapy



***Pbo = Placebo**

Modified from Zuraw et al; EEACI 2014

CSL

CSL830 COMPACT Program Progress

- 84/100 patients randomised
- Last Patient visit Q4 2015
- Long term Safety study to commence Dec 2014
- Submission to FDA Q2/3 2016

COMPACT

Clinical Studies for Optimal Management in Preventing Angioedema with low-volume subcutaneous C1-inhibitor Replacement Therapy

CSL

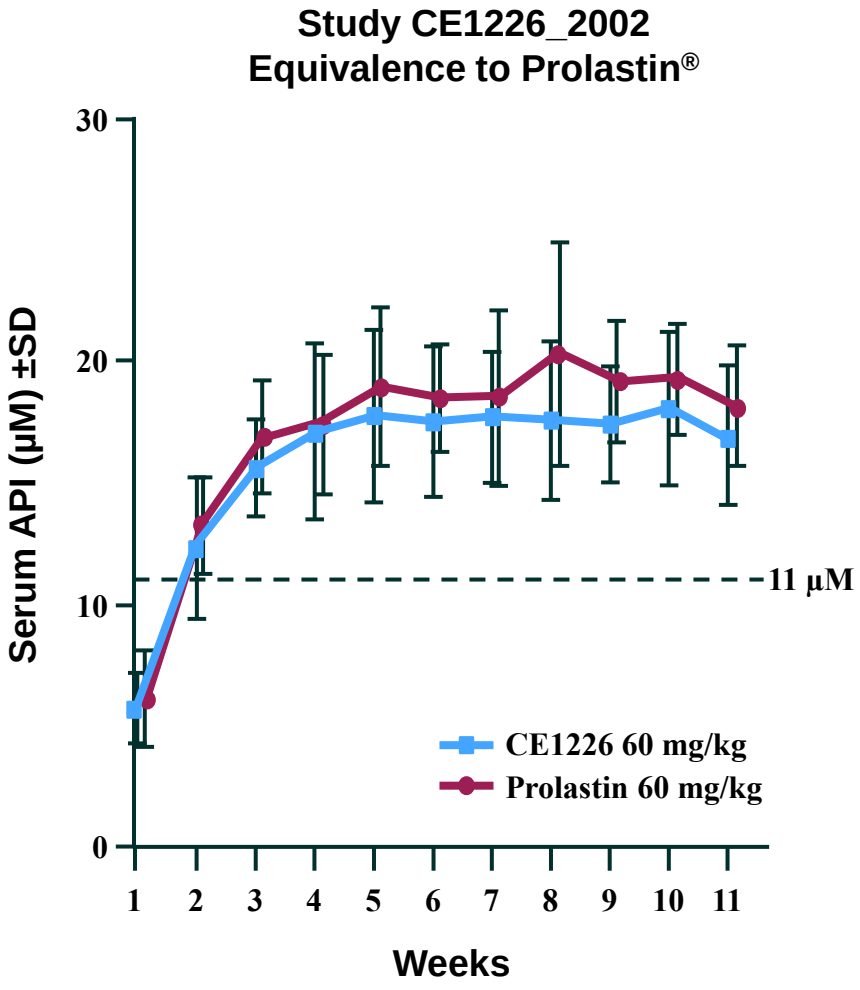
Zemaira®

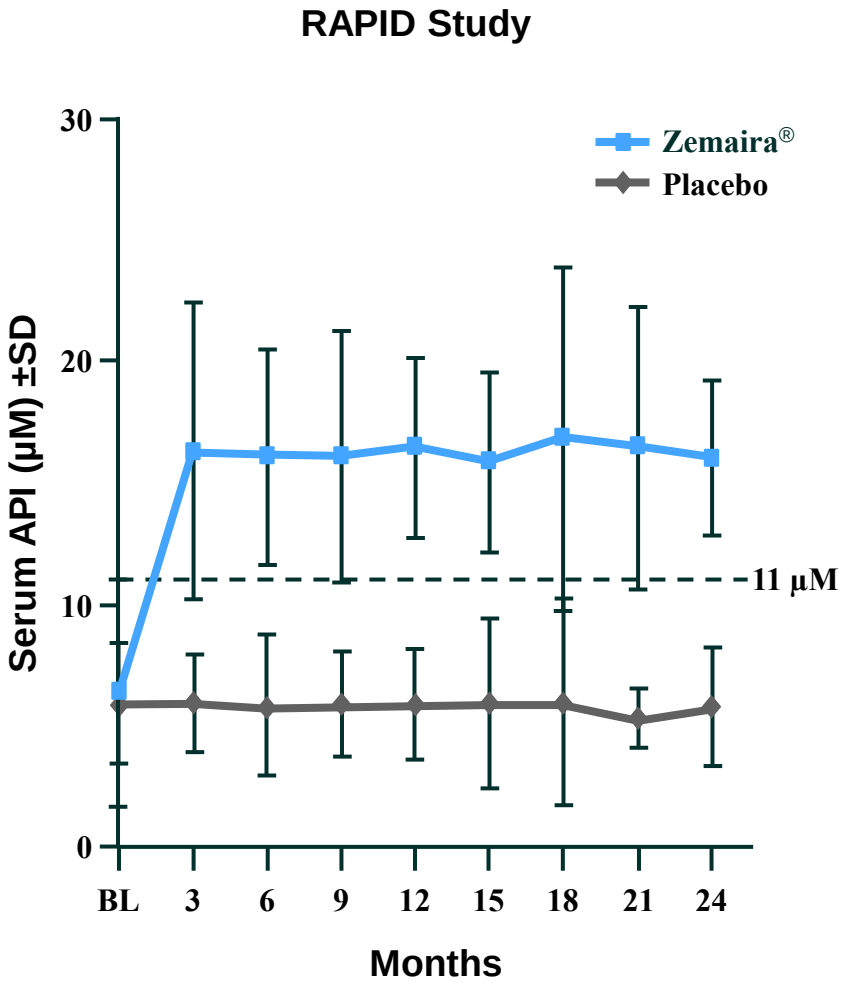
Zemaira is the first highly purified alpha-1 augmentation therapy approved by the FDA for chronic augmentation and maintenance therapy of adults with alpha-1 and emphysema

Seeking to broaden use through approval in EMA in 2015

- Completed RAPID trial in 2013
- Under review with EMA

Zemaira® Biochemical Efficacy

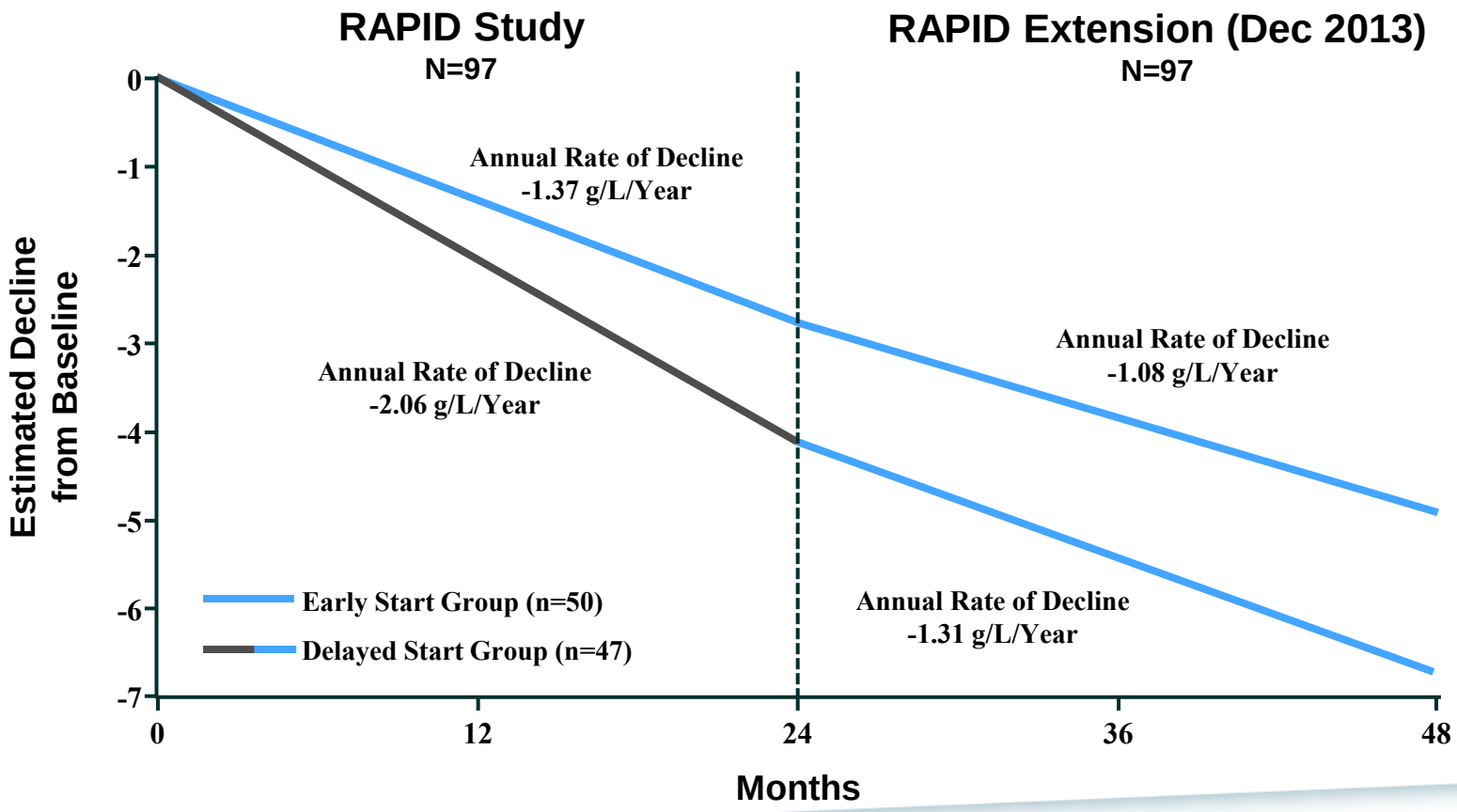




www.clinicaltrials.gov

Zemaira® Continues to Slow the Rate of Lung Density Decline Over 4 Years

Estimated Rate of Decline in Physiologically Adjusted P15 at TLC

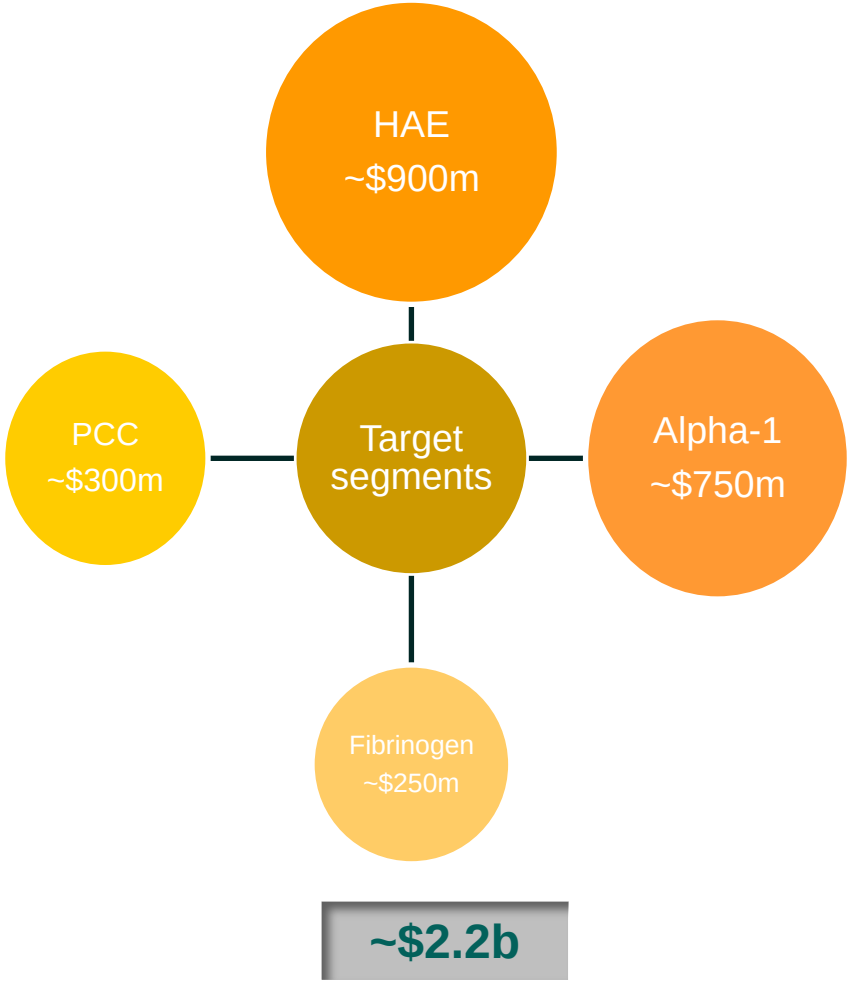


www.clinicaltrials.gov

Commercial Opportunities and Activities

Select Specialty Products – Global Markets

- Rare diseases
- Unmet medical need
- High value
- Increasing awareness

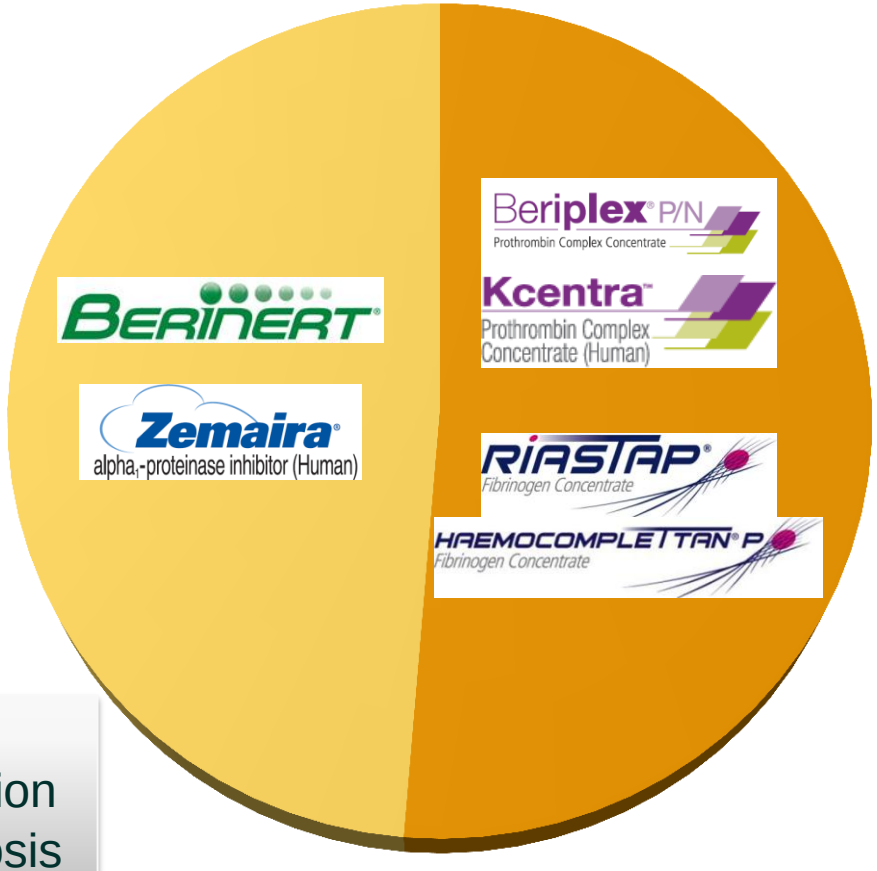


Sources: Company annual reports / earnings releases, CSL Estimates of Target Markets

CSL's Specialty Products Portfolio

2013/14 Sales (USD)

Other Specialty Products

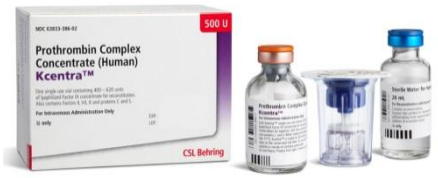


Peri-Operative Bleeding

- Increase demand
- Geographical expansion
- Education and diagnosis

$848m

Kcentra™



Kcentra™, Prothrombin Complex Concentrate (Human), is the first non-activated 4-factor PCC approved in the U.S. for the urgent reversal of vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with acute major bleeding or needing an urgent surgery or other invasive procedure

Sustain momentum in US

- Surgical indication and launch
- Hospital account expansion

Key tactics

- Pivotal publication in Lancet
- Broad customer education

Geographical expansion[1]

- Eastern Europe
- Japan

Life cycle management

- Improved virus filtration
- New 1000IU vial

1) Beriplex®

Berinert®

Berinert treats the fundamental cause of HAE symptoms by providing C1-Inhibitor deficient patients with the missing human protein[1]

Berinert has demonstrated that it provides fast relief of pain and swelling within 30 minutes[2]

Geographical expansion

- Asia
- Latin America
- Russia

Patient care and convenience

- Short term prophylaxis in Europe
- Self-administration education and expansion

Agostini et al. J Allergy Clin Immunol. 2004[1]
Craig et al. J Allergy Clin Immunol 2009[2]

Berinert® Key Features

Improved patient convenience

- Low volume formulation

New method of use

- subQ ➡ prophylaxis

COMPACT
Clinical Studies for Optimal Management in Preventing Angioedema with low-volume subcutaneous C1-inhibitor Replacement Therapy

New Indications

- Explore new indications (e.g. Transplantation)

Zemaira®

Zemaira
alpha$_1$-proteinase inhibitor (Human)

Indicated in the US for chronic augmentation and maintenance therapy in adults with alpha-1 deficiency and clinical evidence of emphysema

Has been shown to slow the progression of emphysema as measured by CT lung density

DNA_1 is the first and only test to confirm known and unknown variants of alpha-1 proteinase inhibitor

Increased diagnosis

- Approximately 100K patients in US
- 10% of patients diagnosed
- Established DNA_1 test

Geographical expansion

- EU registration process ongoing
- Launched in Brazil
- Dossier submitted in Mexico

Continued investment

- Expand US sales force
- Explore new formulations

RAPID data

- Publish in high impact journal
- Medical Affairs education

CSL

Q&A

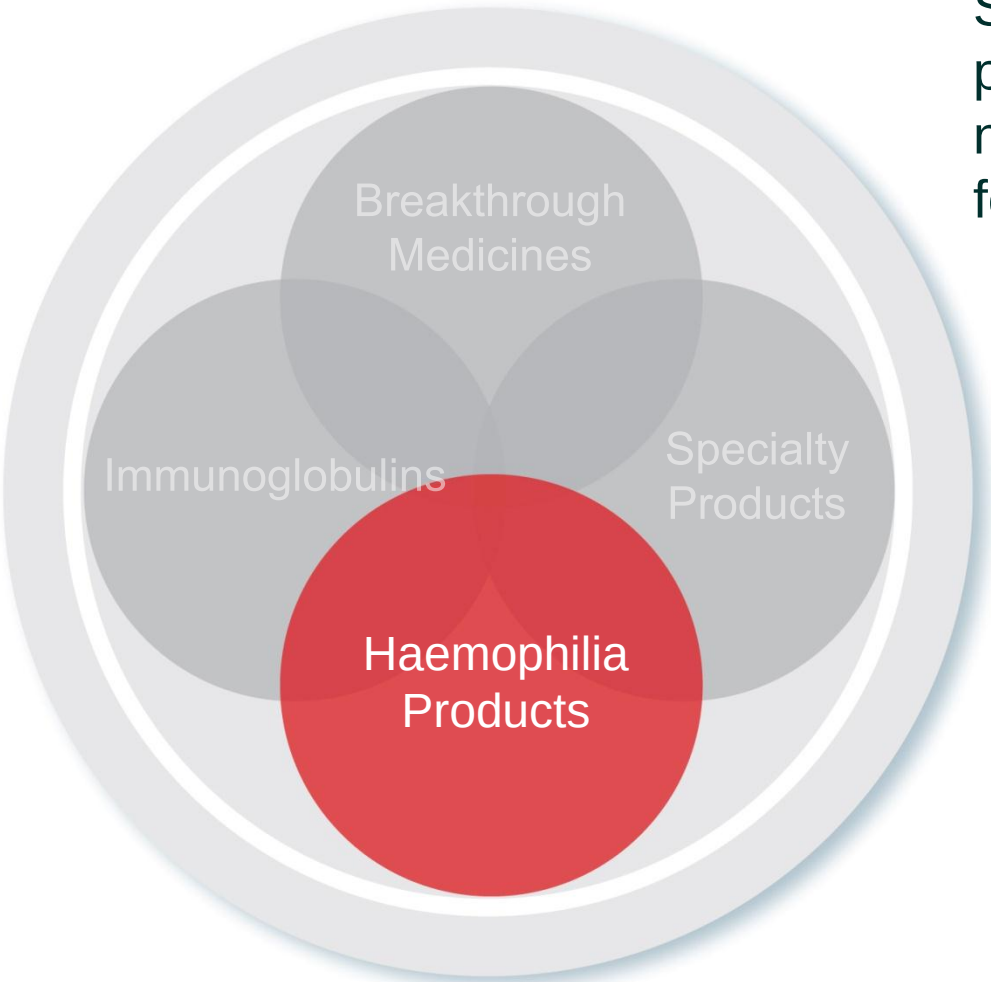
Break

R&D Briefing

December 3, 2014

Haemophilia Products

Haemophilia



Supporting and enhancing plasma products and developing novel recombinant portfolio with focus on:

- Scientific and product innovation
- Patient benefit

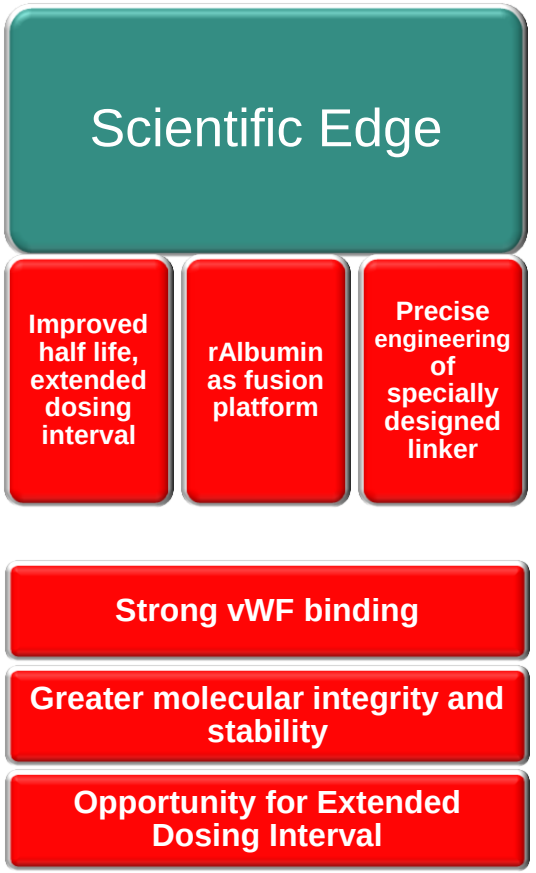
Key Focus

- Long acting rIX-FP
- Long acting rVIIa-FP
- rVIII-Single Chain
- Research into long acting rvWF-FP

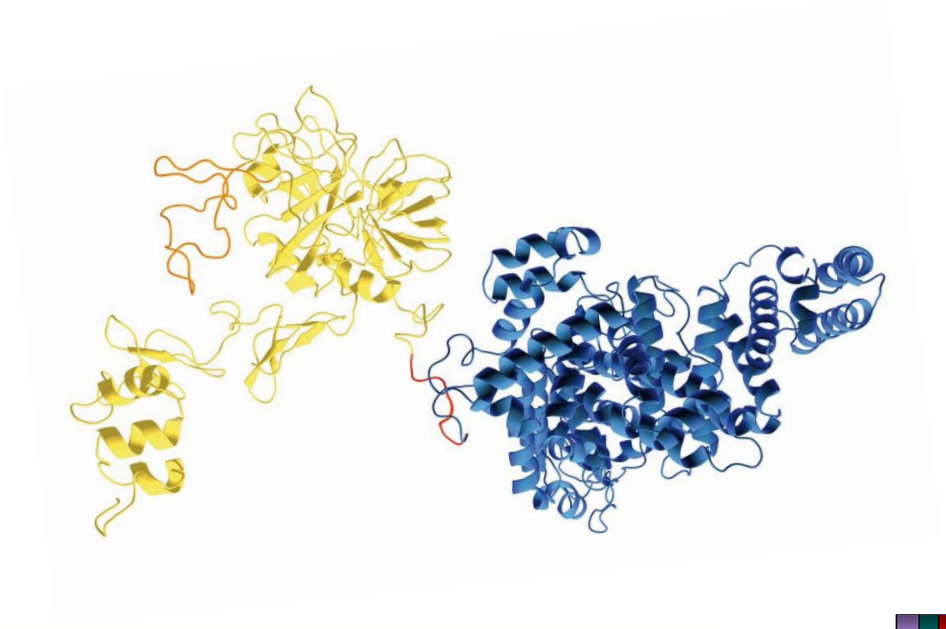
Innovation to Drive Growth

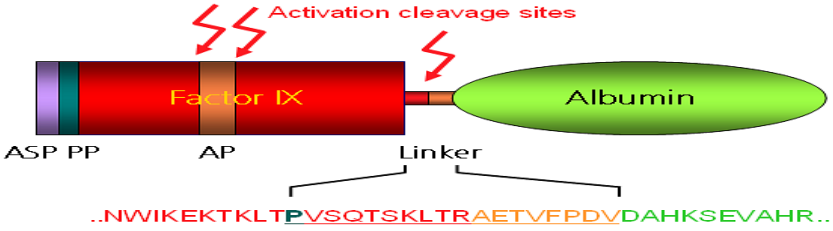
Patient benefit primary driver of innovation

- Albumin fusion technology
  - rIX-FP, rVIIa-FP, rvWF-FP
- Factor VIII
  - Innovative SingleChain design



PROLONG-9FP Clinical Development Program: rIX-FP





PROLONG 9 FP

www.clinicaltrials.gov

CSL™

blood

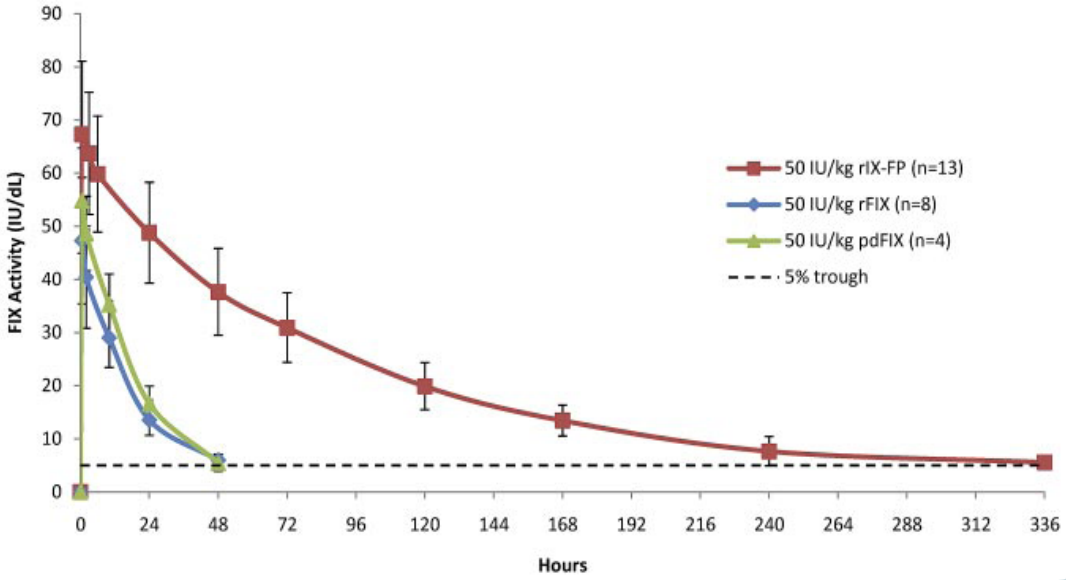
2012 120: 2405-2411
Prepublished online August 2, 2012;
doi:10.1182/blood-2012-05-429688

Safety and pharmacokinetics of a novel recombinant fusion protein linking coagulation factor IX with albumin (rIX-FP) in hemophilia B patients

Elena Santagostino, Claude Negrier, Robert Klamroth, Andreas Tiede, Ingrid Pabinger-Fasching, Christine Voigt, Iris Jacobs and Massimo Morfini

Compared with in market rFIX

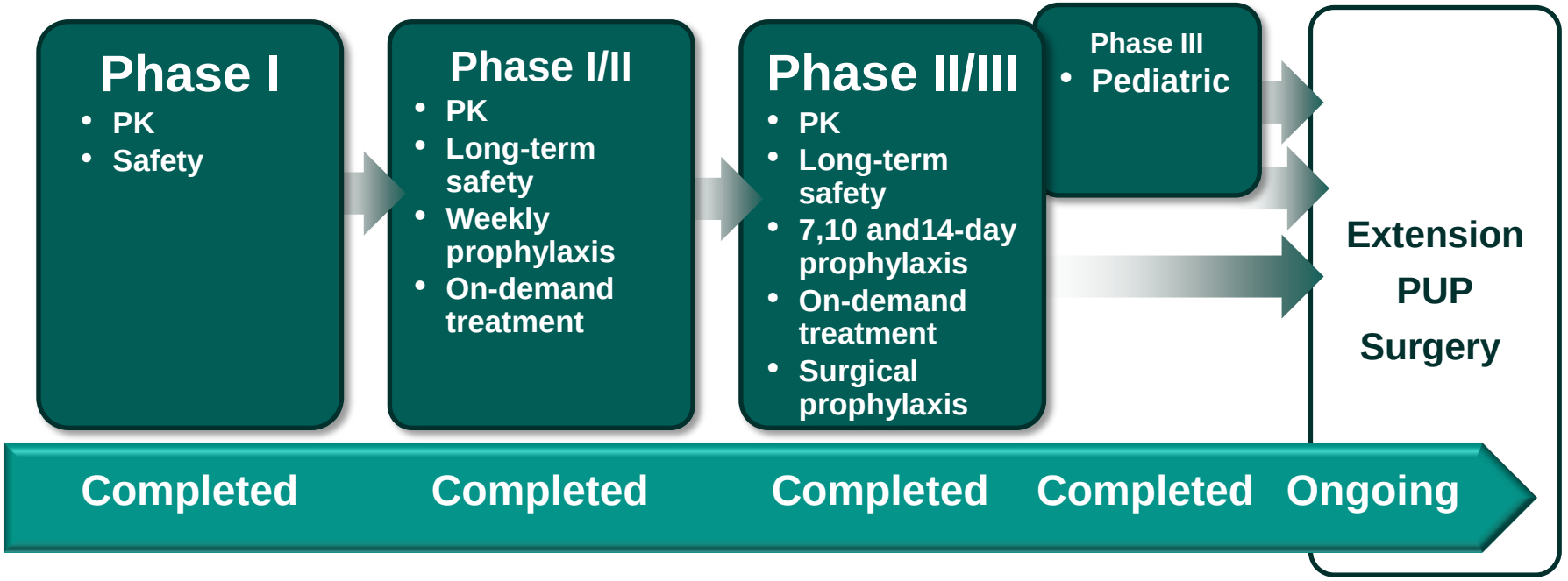
- 5.3-fold longer half-life (92hrs)
- ~ 45% higher incremental recovery
- ~7-fold larger AUC
- ~7-fold slower clearance



PROLONG 9 FP

CSL

PROLONG-9FP Clinical Development Program: rIX-FP



PROLONG 9 FP
www.clinicaltrials.gov

CSL

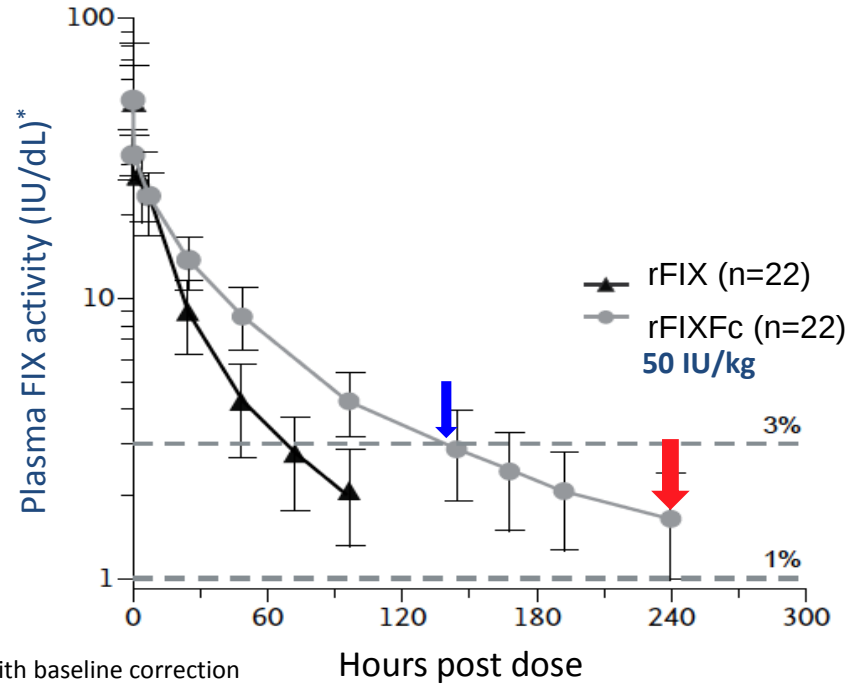
PROLONG-9FP Clinical Results Summary

- Excellent safety profile
  - Well tolerated
  - No inhibitors
  - No adverse events related to CSL654

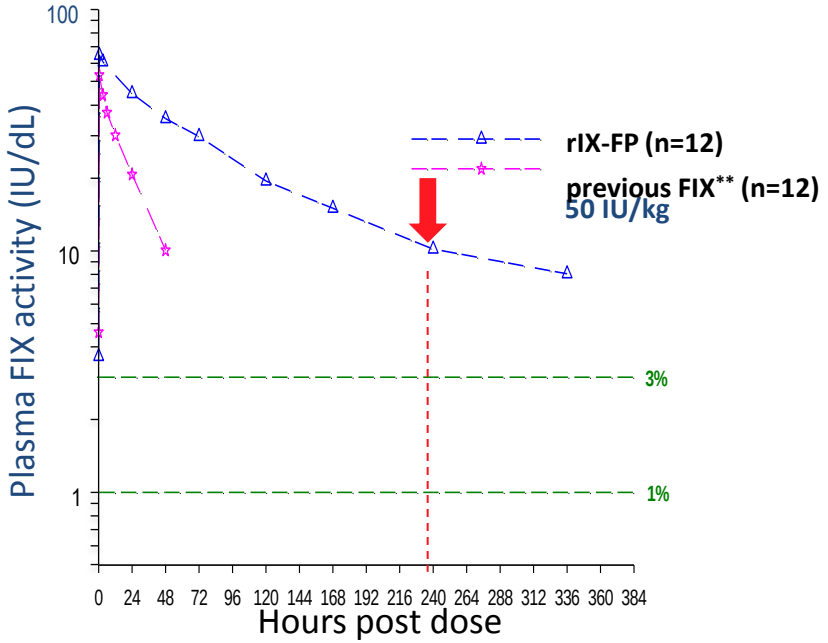
- Meets all criteria for registration
  - Effectively treats bleeding episodes
  - Offers benefit for prophylaxis
  - Effective in 7-day, 10-day and 14-day regimens

FIX Activity: rIX-FP vs. rFIXFc

rIX-FP shows higher activity at the 240 hour time point



*With baseline correction



**plasma-derived a

Plasma FIX activity-time profiles in ≥12-year olds

PROLONG 9 FP

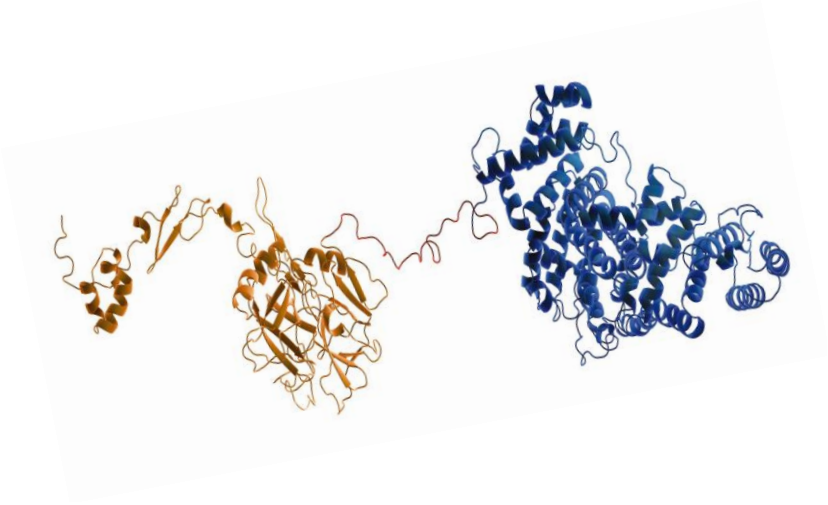
CSL

Powell et al. N Engl J Med 2013;
CSL Behring. Data on file.

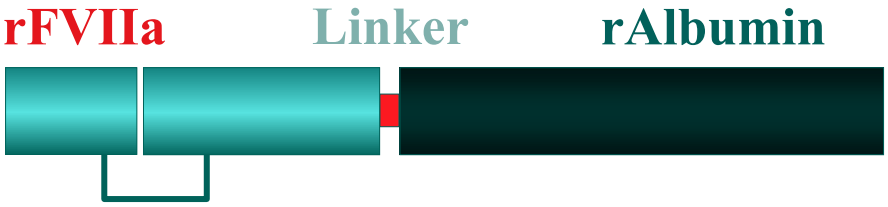
rIX-FP (CSL654) Clinical Development

- All patients now in extension study
- Dossier submission for adult and paediatric indications
  - FDA Dec 2014
  - EMA Q2 2015

rVIIa-FP (CSL689)



PROLONG 7 FP

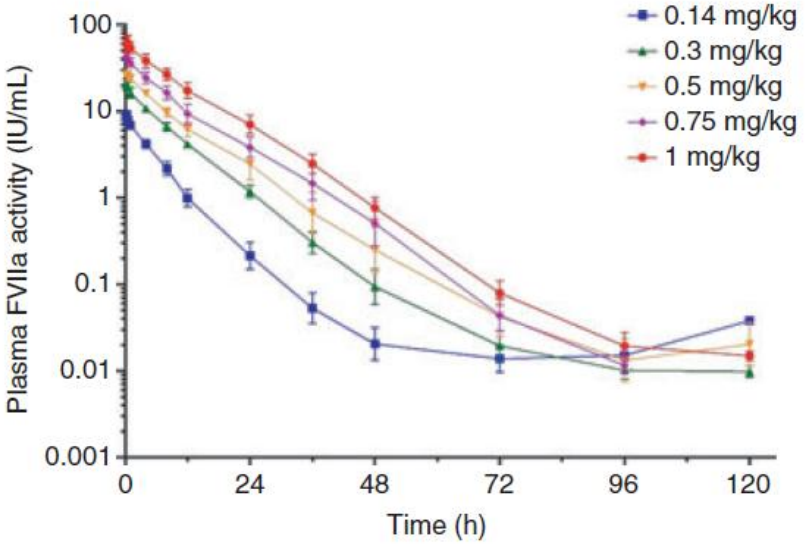


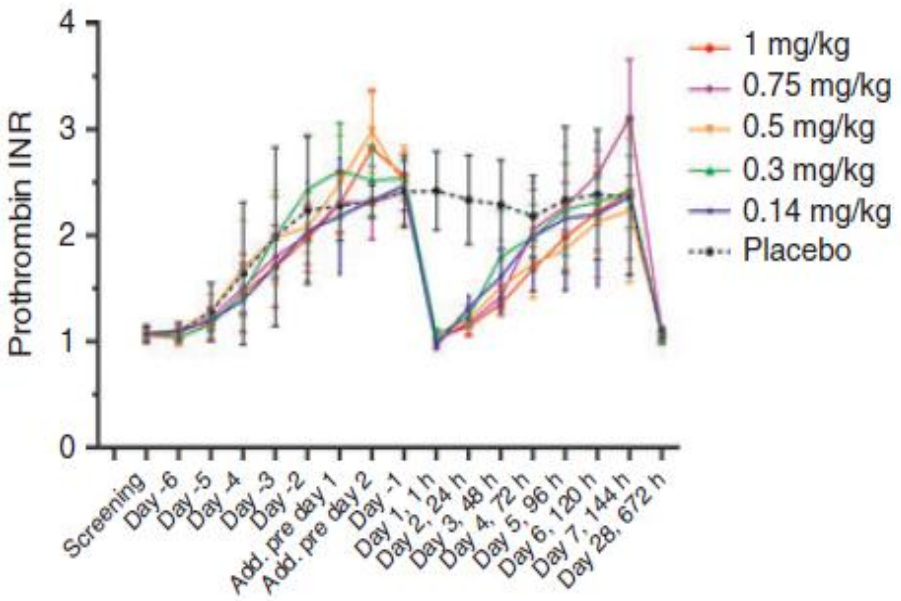
Journal of Thrombosis and Haemostasis, **11**: 1977–1985

ORIGINAL ARTICLE

Safety and pharmacokinetics of a recombinant fusion protein linking coagulation factor VIIa with albumin in healthy volunteers

G. GOLOR,* D. BENSEN-KENNEDY,† S. HAFFNER,* R. EASTON,† K. JUNG,‡ T. MOISES,‡ J.-P. LAWO,‡ C. JOCH‡ and A. VELDMAN‡



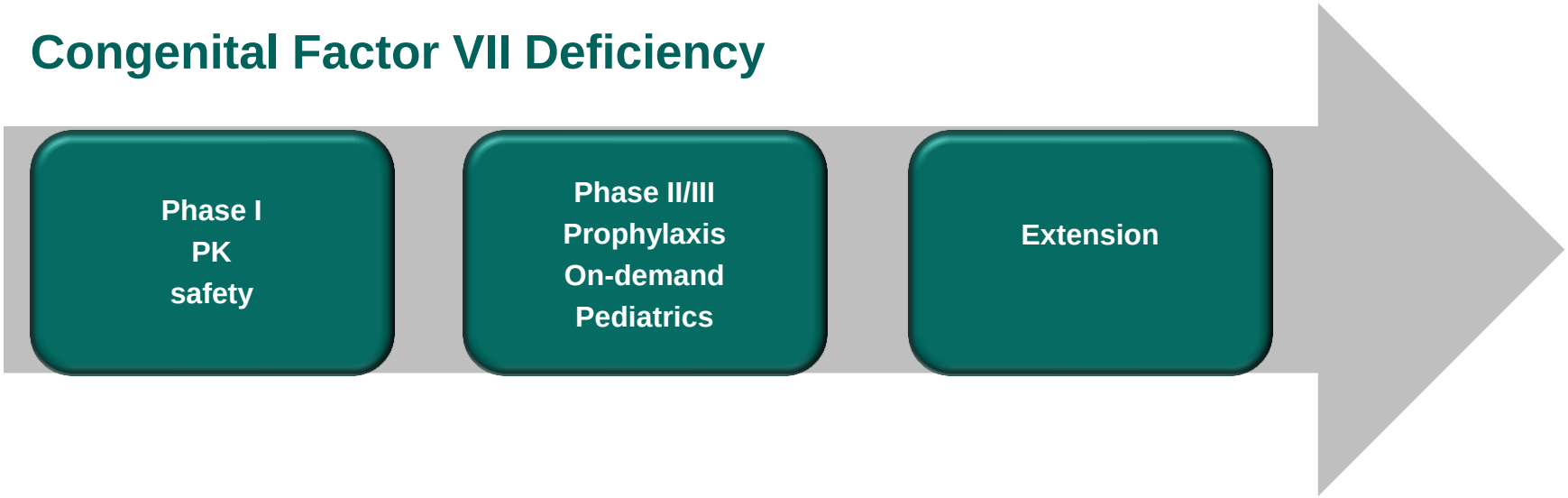


- Half-life = 8.5 hrs (vs rFVIIa ~2-3hrs)

PROLONG 7 FP CSL™

rVIIa-FP Clinical Development Program

Congenital Factor VII Deficiency



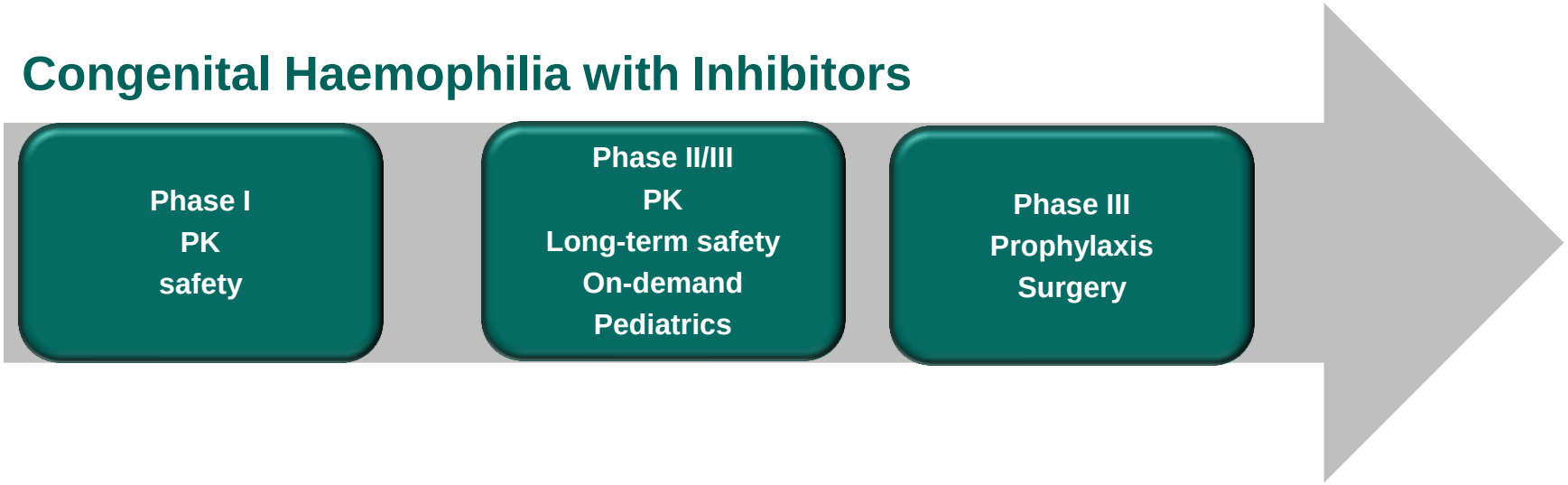
- Phase I PK/PD study in congenital FVII deficiency patients
  - PK and safety in patients
  - To commence December 2014

PROLONG 7 FP

CSL

rVIIa-FP Clinical Development Program

Congenital Haemophilia with Inhibitors

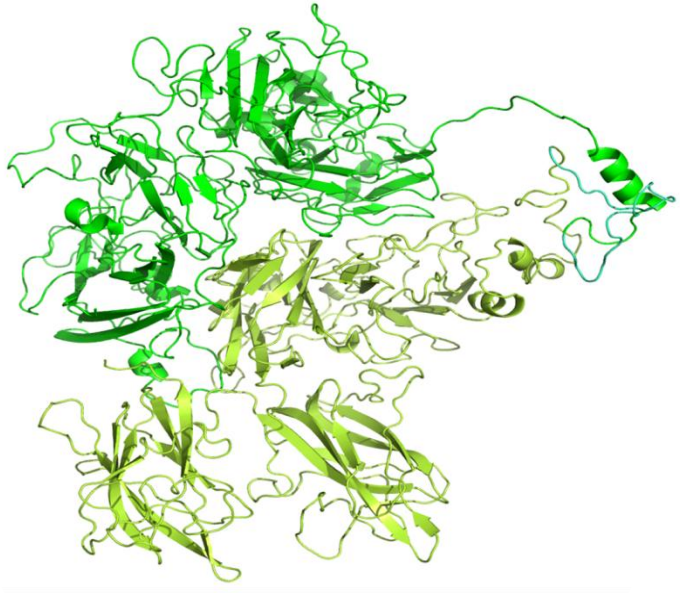


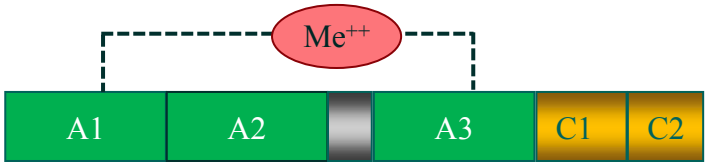
- Pivotal Phase II/III trial in haemophilia A & B patients with inhibitors
  - Dose finding, safety & efficacy on-demand therapy
  - To commence first half 2015

PROLONG 7 FP

CSL

rVIII-SingleChain (CSL627)



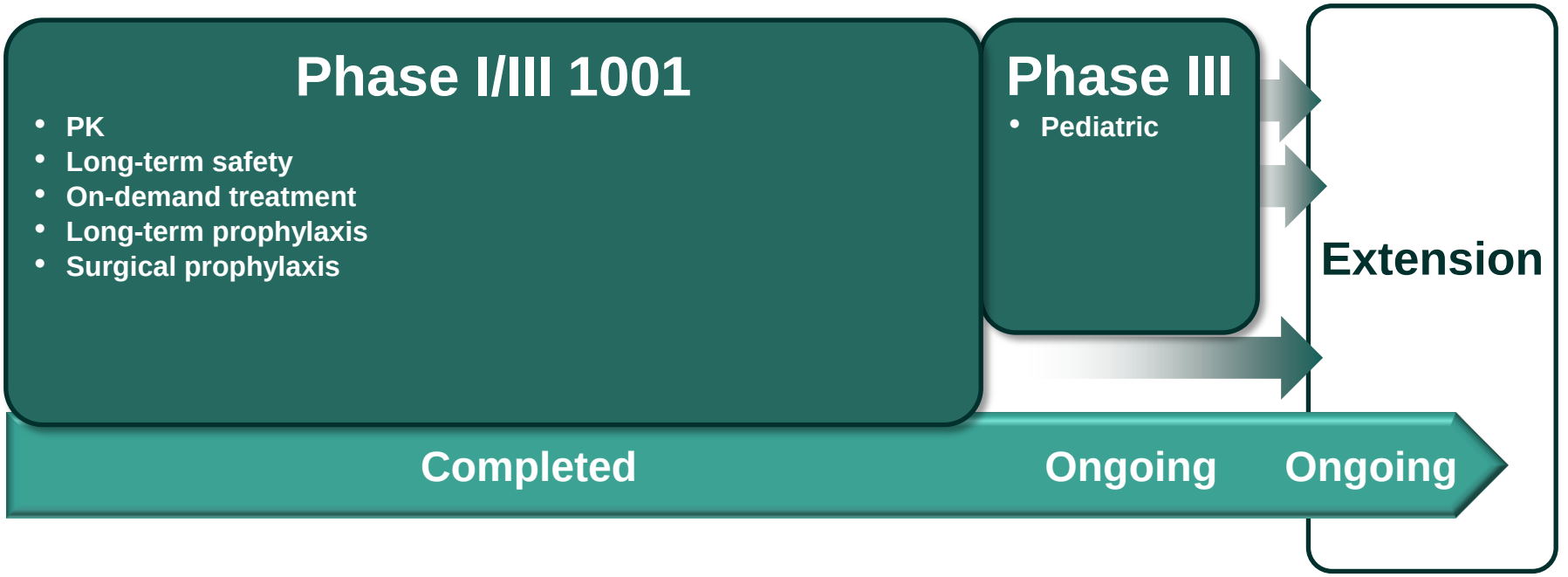


rVIII-SingleChain

AFFINITY
rVIII-SingleChain Clinical Trial Program

CSL

AFFINITY Clinical Development Program: rVIII-SingleChain

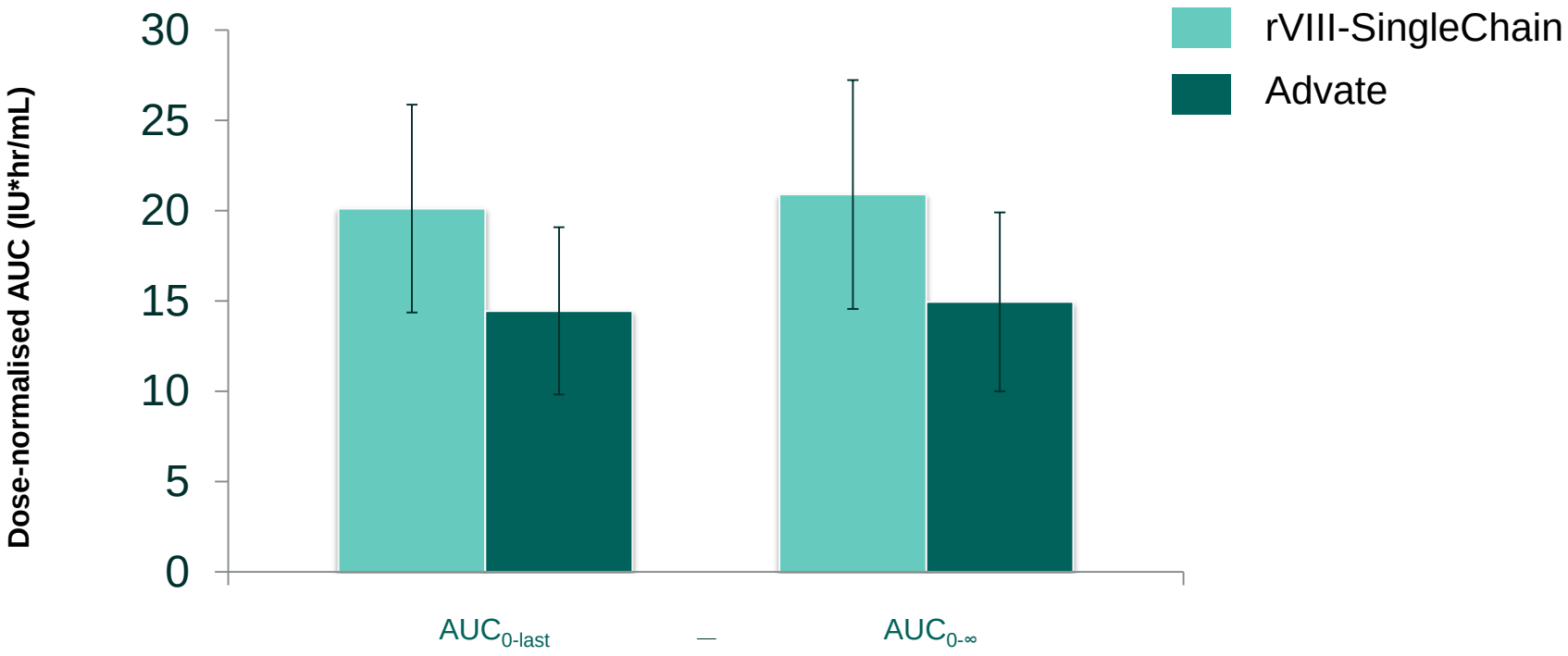


AFFINITY
rVIII-SingleChain Clinical Trial Program

www.clinicaltrials.gov

CSL

CSL627 PK Evaluation: Area Under the Curve

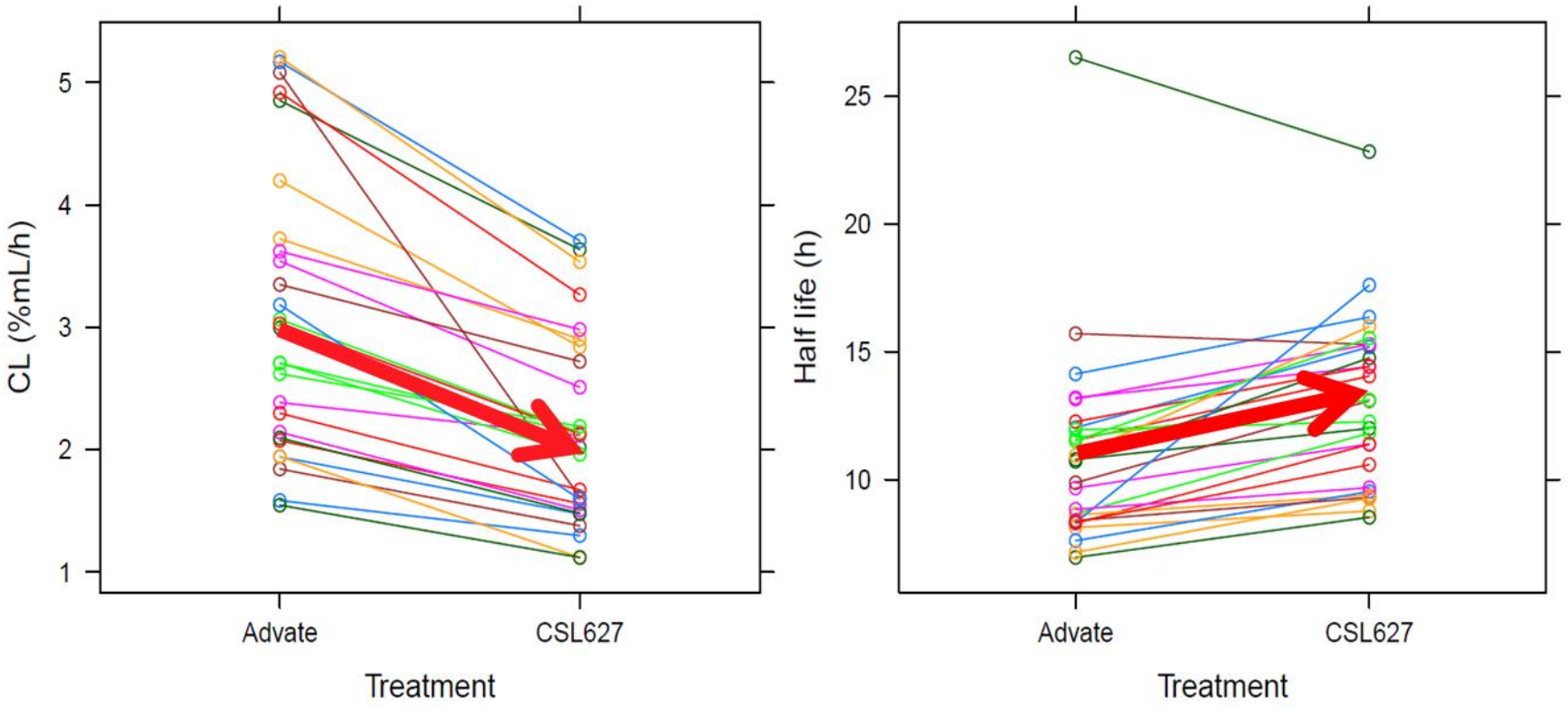


*Dose-normalised baseline-corrected FVIII activity $AUC_{0\text{-last}}$ and $AUC_{0\text{-}\infty}$ in plasma following a single intravenous administration of rVIII-SingleChain or Octocog alpha. FVIII activity determined by chromogenic assay and normalised by individual dose to 50 IU/kg. Data presented are mean ±SD n=27

AFFINITY rVIII-SingleChain Clinical Trial Program

www.clinicaltrials.gov CSL Behring. Data on file.

CSL627 PK Evaluation: Clearance and $t_{1/2}$



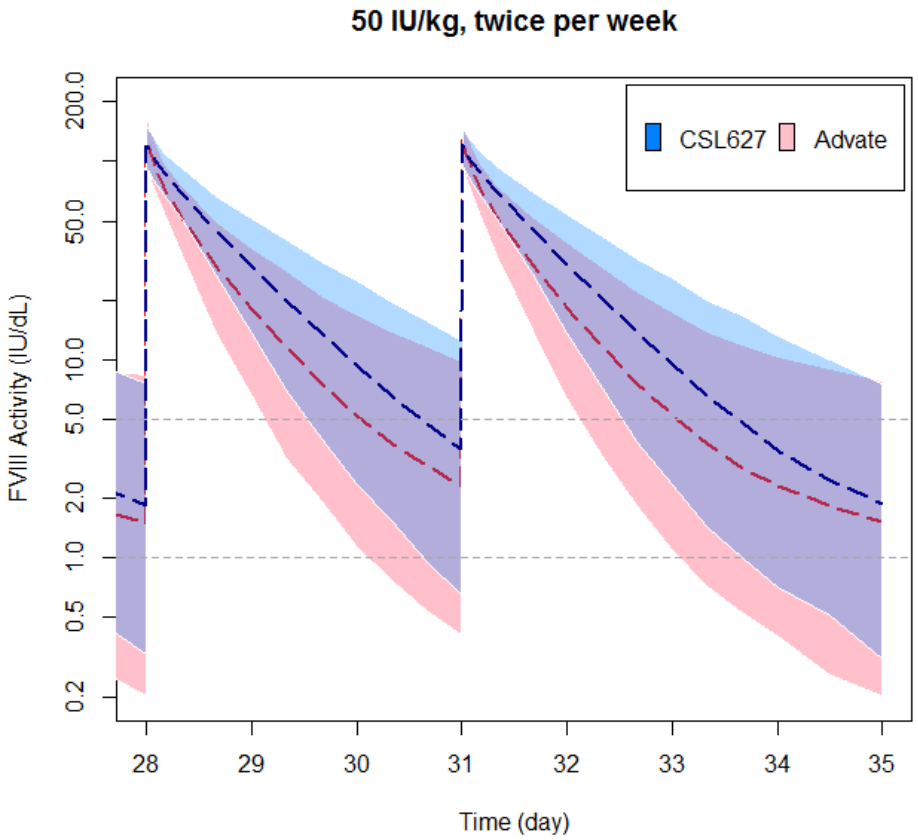
*Dose-normalised baseline-corrected FVIII activity Clearance and half-life in plasma following a single intravenous administration of rVIII-SingleChain or Octocog alpha. FVIII activity determined by chromogenic assay and normalised by individual dose to 50 IU/kg. n=27

CSL Behring. Data on file.

CSL627 PK Supports Dosing Twice-Weekly

Product	Time to 2% (hr)	Time to 1% (hr)
rVIII-SingleChain	78.0	91.9
Octocog alpha	65.2	77.2

Data presented are mean values. n=22



AFFINITY
rVIII-SingleChain Clinical Trial Program

CSL Behring. Data on file.

rVIII-SingleChain Phase I/III Study

- Very well tolerated
- No inhibitors
- All bleeding events effectively treated
- All surgeries successfully treated

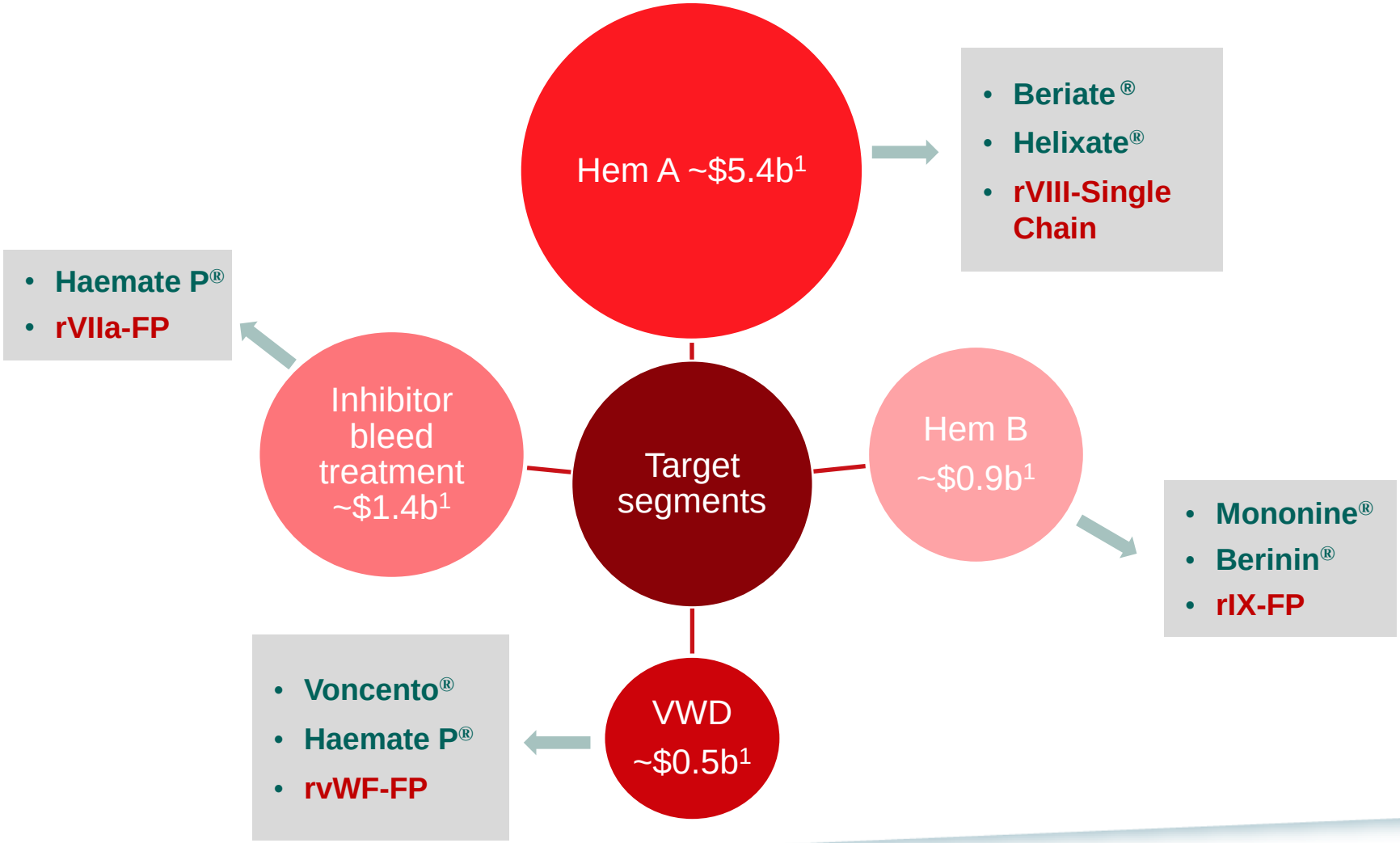
- Pivotal study primary endpoint reached
  - US dossier submission first half 2015
  - EMA dossier submission Q4 2015

AFFINITY
rVIII-SingleChain Clinical Trial Program

CSL™

Commercial Opportunities and Activities

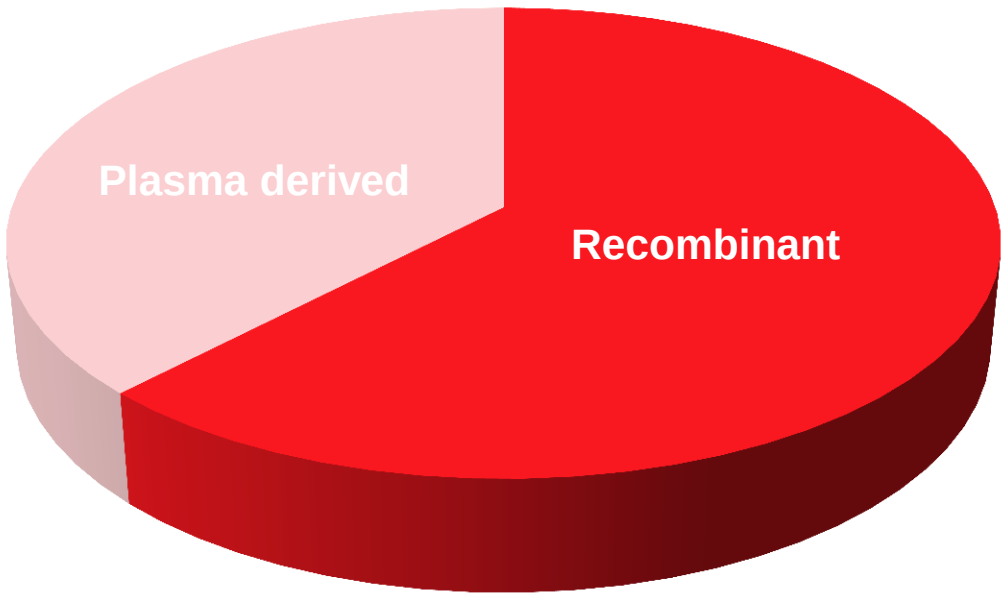
Coagulation: Key Market Segments (USD)



Sources: Company annual reports / earnings releases, CSL Estimates of Target Markets

Global Haemophilia Market (USD)

- Trend toward recombinants in major markets
- New longer-acting competition
- Pd highly competitive tender markets

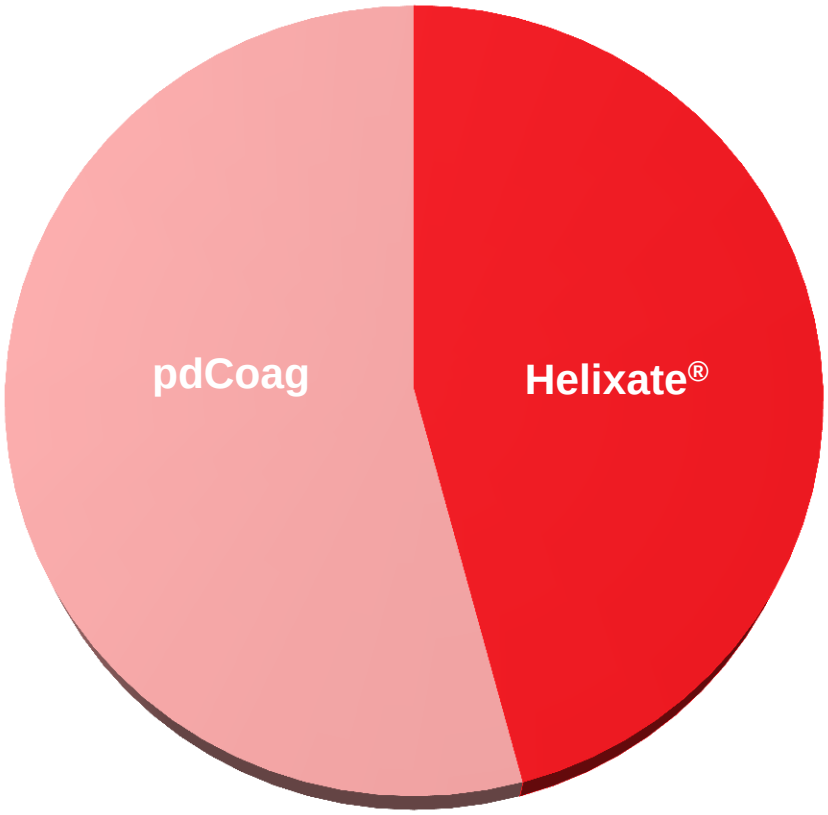


$8.2b

Sources: Company annual reports / earnings releases, CSL Estimates of Target Markets

CSL Coagulation Sales 2013/14 (USD)

- Broad portfolio presence
- Growth in developed and emerging markets
- Helixate® strong foundation for recombinant pipeline



$1,064m

rVIII-SingleChain (CSL627)

Single chain design with most of B-domain deleted

Covalent link between heavy and light chains

Single Chain Design

- Binds strongly to vWF
- Greater molecular integrity and stability
- Improved PK profile

Potential Differentiated Profile

- Effective bleeding control
- Favorable tolerability profile
- Low potential for inhibitors
- Longer lasting therapeutic effect
- Twice-weekly dosing

rIX-FP (CSL654)

Unique recombinant albumin fusion protein molecule

Enhanced pharmacokinetic profile including five-fold half-life extension, seven fold increase in AUC* and higher trough levels

Attributes of Albumin

- Natural protein
- Transports natural components
- Not associated with immune response
- Long half-life

Potential Differentiated Profile

- Effective bleeding control
- Favorable tolerability profile
- Minimising the potential for immunologic response
- Dosing interval 7 to 14 days

* Santagostino E et al. Blood 120: 2405-2411 (2012)

Coagulation: Growth Drivers

Increased diagnosis

- Estimated 1 in 1,000 people have inherited blood disorders
- 75% inadequate or no care; disorder not diagnosed

Awareness of benefits of prophylaxis

- Publications and presentations
- Benefits of long/longer acting products

Growth in recombinant market

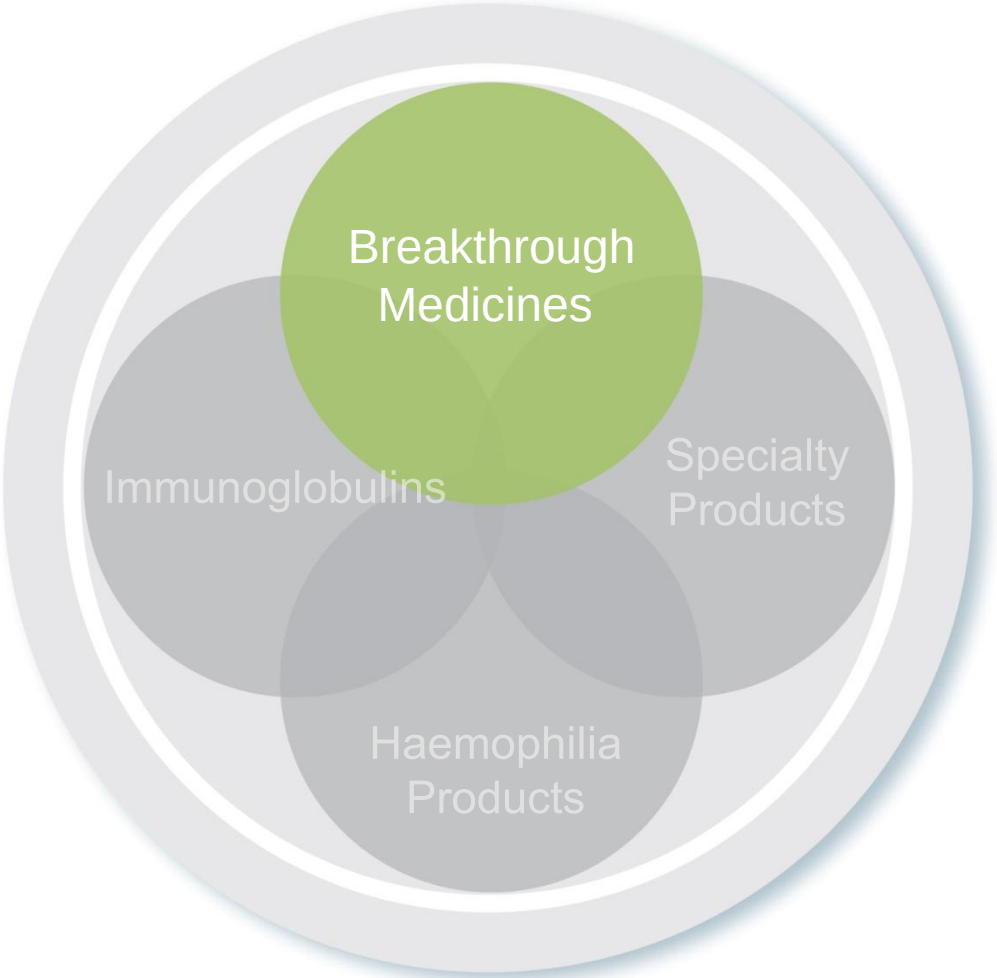
- Hemophilia B – long acting → rIX-FP
- Hemophilia A – longer acting → rVIII-SingleChain
- Inhibitors – long acting → rVIIa-FP

CSL leadership

- Strong heritage in therapeutic category
- Understanding of physician and patient community
- Robust pipeline of recombinant products

Breakthrough Medicines

Breakthrough Medicines



Leveraging clinical and technical insight in developing novel protein-based therapies

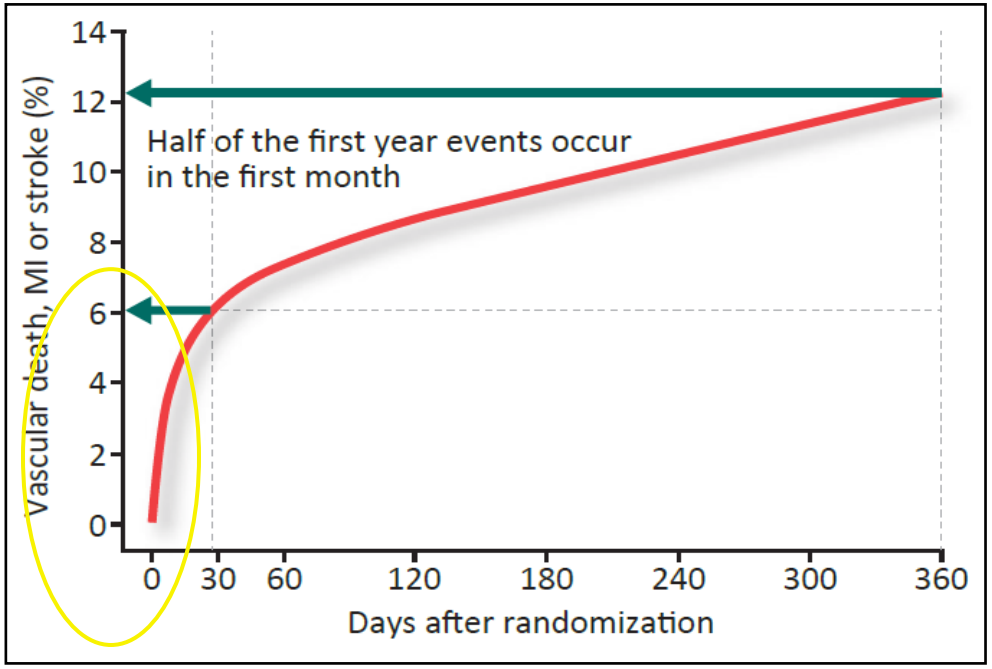
- Significant unmet need
- Multiple indications

Key Focus

- CSL112 (Apo AI)
- CSL346 (anti-VEGF-B mAb)
- FXII Antagonist

CSL112 (Apolipoprotein A-I)

- Reduction of early recurrent cardiovascular events represents a substantial unmet medical need

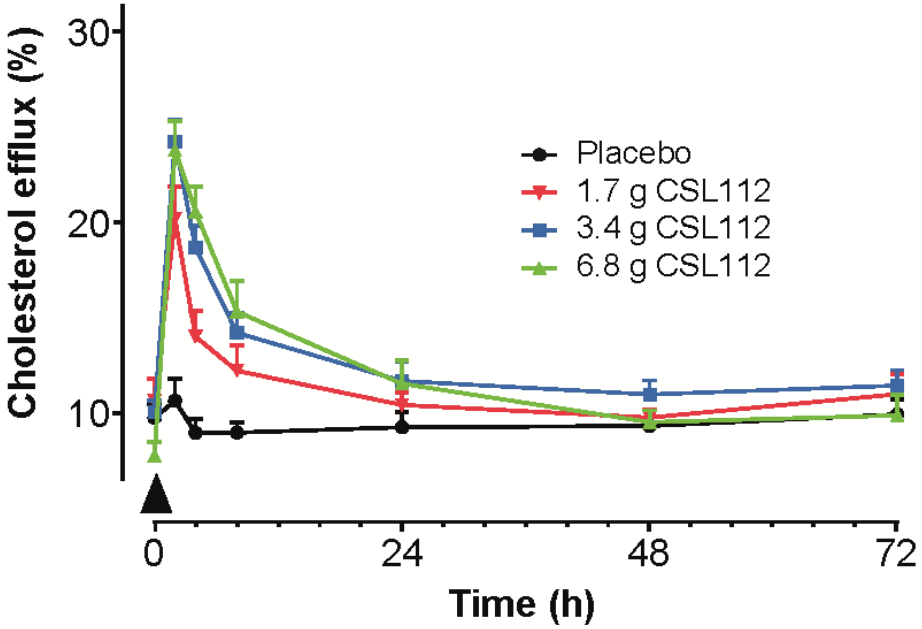


- Recurrent CV events occur early, are associated with high mortality and are inadequately addressed by available therapies

Figure adapted from PLATO Trial, Kohli P et al. Circulation 2013;127:673-680

CSL112

- Novel Mechanism of Action for Early Reduction of Recurrent CV Events
- Produces an immediate and robust increase in the efflux of cholesterol from cells, including lipid-rich macrophages in coronary arteries



- Expected to rapidly stabilise plaque and reduce the incidence of <u>early</u> recurrent cardiovascular events

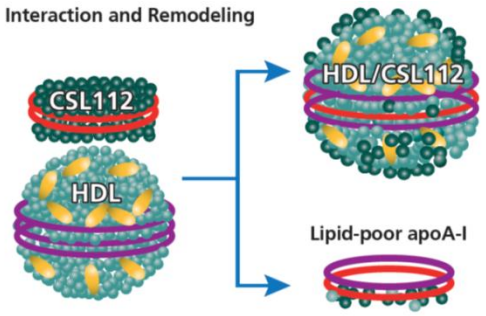
CSL112 AHA Presentations
Nov 18, 2014

American Heart Association. SCIENTIFIC SESSIONS 2014
Nov. 15–19 | CHICAGO, ILLINOIS

Further elucidation of mechanisms by which CSL112 may rapidly stabilise plaque at risk of rupture

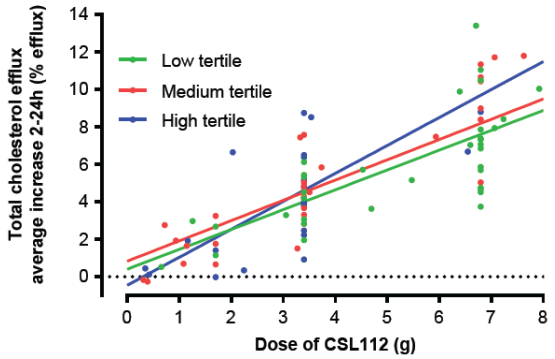
Mechanism of HDL Remodeling Induced by CSL112

- Prebeta-1 HDL levels correlate strongly with ABCA1 mediated cholesterol efflux
- Infusion of CSL112 rapidly produces large increases in prebeta-1 HDL



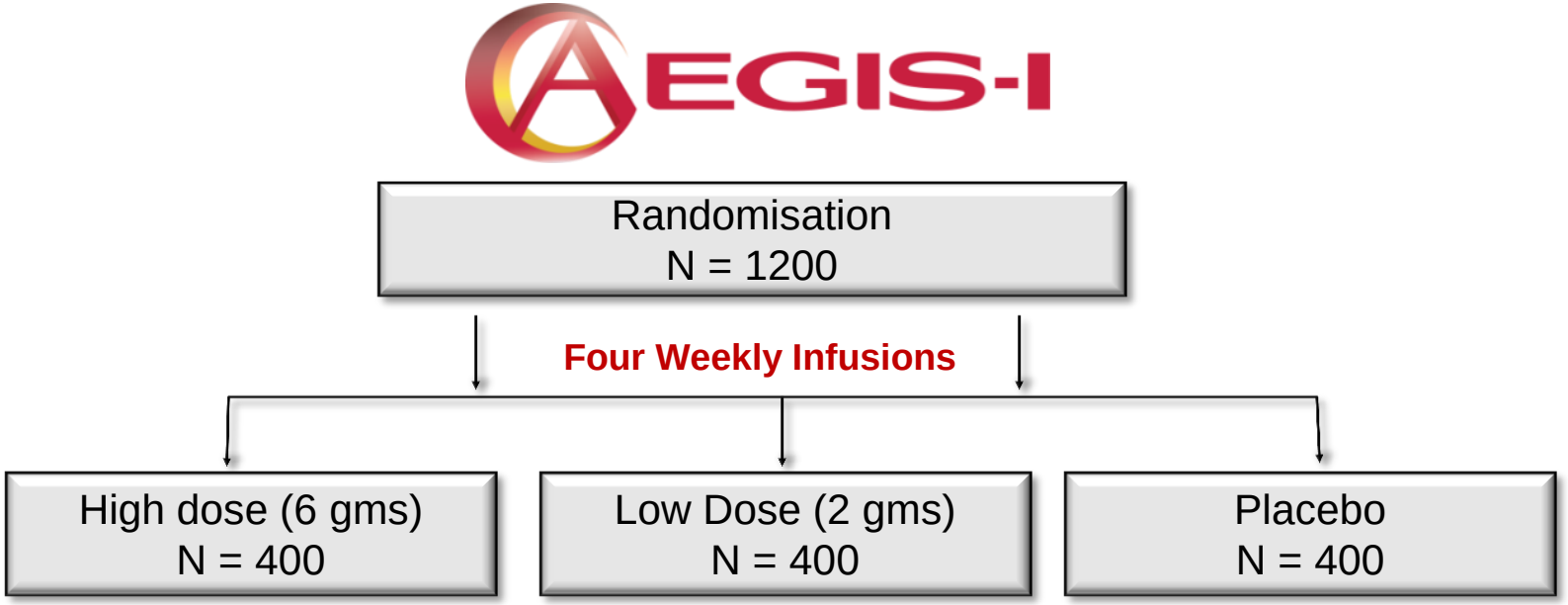
CSL112 Enhances Cholesterol Efflux In Patients with Low HDL Function

- CAD* patients have impaired ability to efflux cholesterol from cells
- CSL112 caused strong and quantitatively similar elevation in cholesterol efflux in patients with coronary artery disease and healthy subjects



*Coronary artery disease

CSL112
AHA announcement of Phase 2b start



Administrated in acute MI setting

Primary endpoint: liver and renal safety

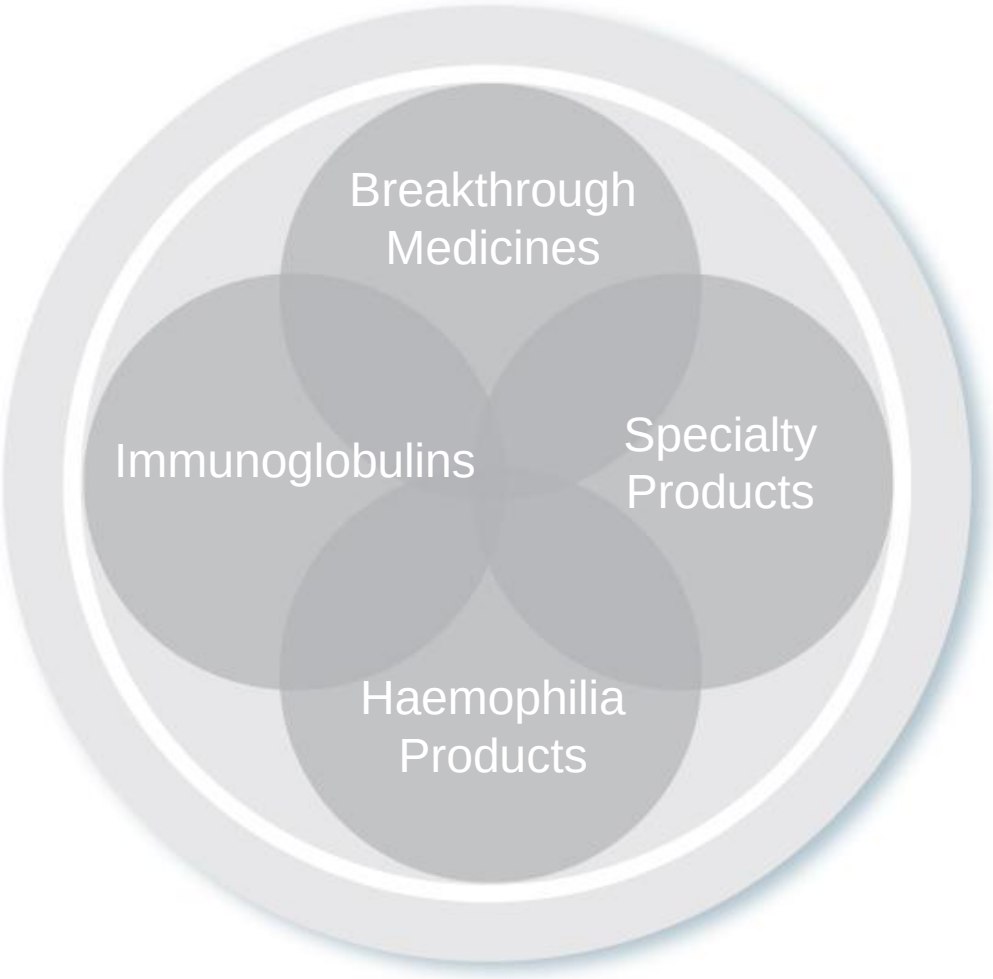
To be followed by Phase 3 morbidity/mortality trial

Target indication

Reduction of early atherothrombotic events in acute MI patients at high risk of recurrent events

Licensing and Collaborations

Licensing



Optimising value of IP Portfolio and assets

- Partner high opportunity products
  - GARDASIL®
  - Mavrilimumab (GM-CSFRα - Medi/AZ)
  - Periodontal disease (Sanofi)
  - CSL362 (Janssen)
  - CSL334 (ASLAN)
- ISCOMATRIX® adjuvant

GARDASIL®

- Impact of Australia's HPV Vaccination Program

Genital warts

- 93% reduction in genital warts in females less than 21 years
- 82% reduction in genital warts in heterosexual males less than 21 years
- Rates of treatment for genital warts in private hospitals have also declined

Cervical disease

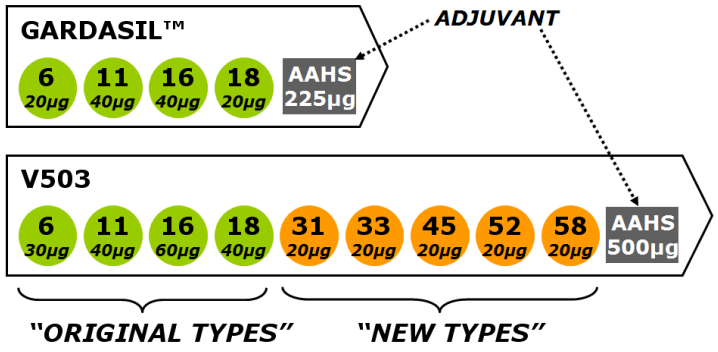
- Current Australian cervical screening program data show that rates of high grade cervical disease are declining in both the <20 year old age group and in women aged 20–24 years

HPV Prevalence

- Substantial fall in vaccine-targeted HPV types in vaccinated women
- Also lower prevalence of vaccine-targeted types in unvaccinated women, suggesting herd immunity

GARDASIL®

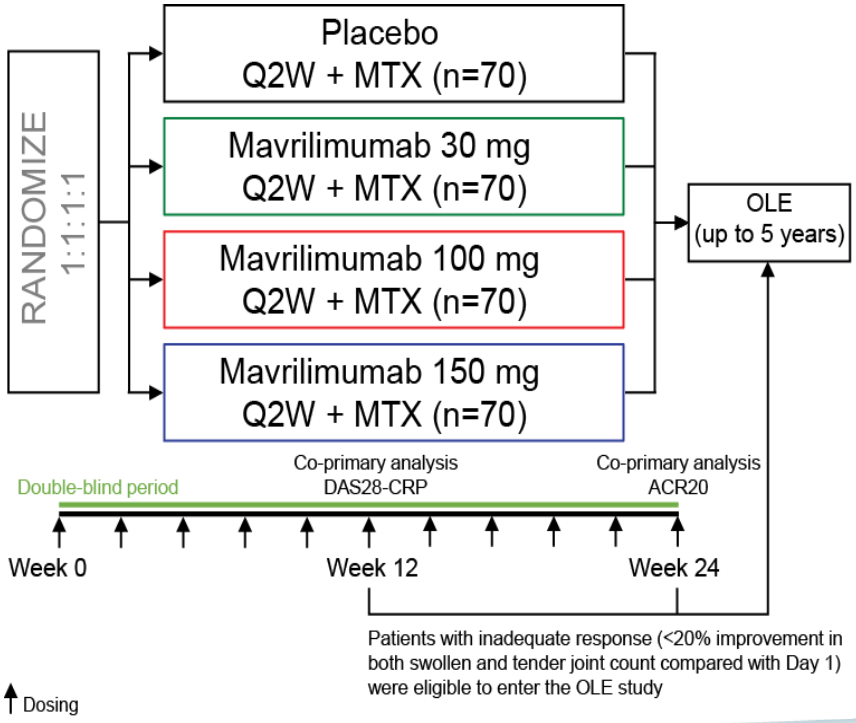
- Long term protection
  - Follow up studies up to 8 years demonstrate no break through disease
- V503: 9-Valent HPV Vaccine
  - Merck's 2nd generation HPV vaccine
  - Phase III data: prevented 97% cervical, vaginal and vulvar pre-cancers caused by additional 5 types
  - US - BLA Dec 2013 for 2015 launch
  - Australia - Submitted registration package to TGA June 2014



Mavrilimumab (GM-CSFRα mAb)

Phase IIb (EARTH EXPLORER 1) study:

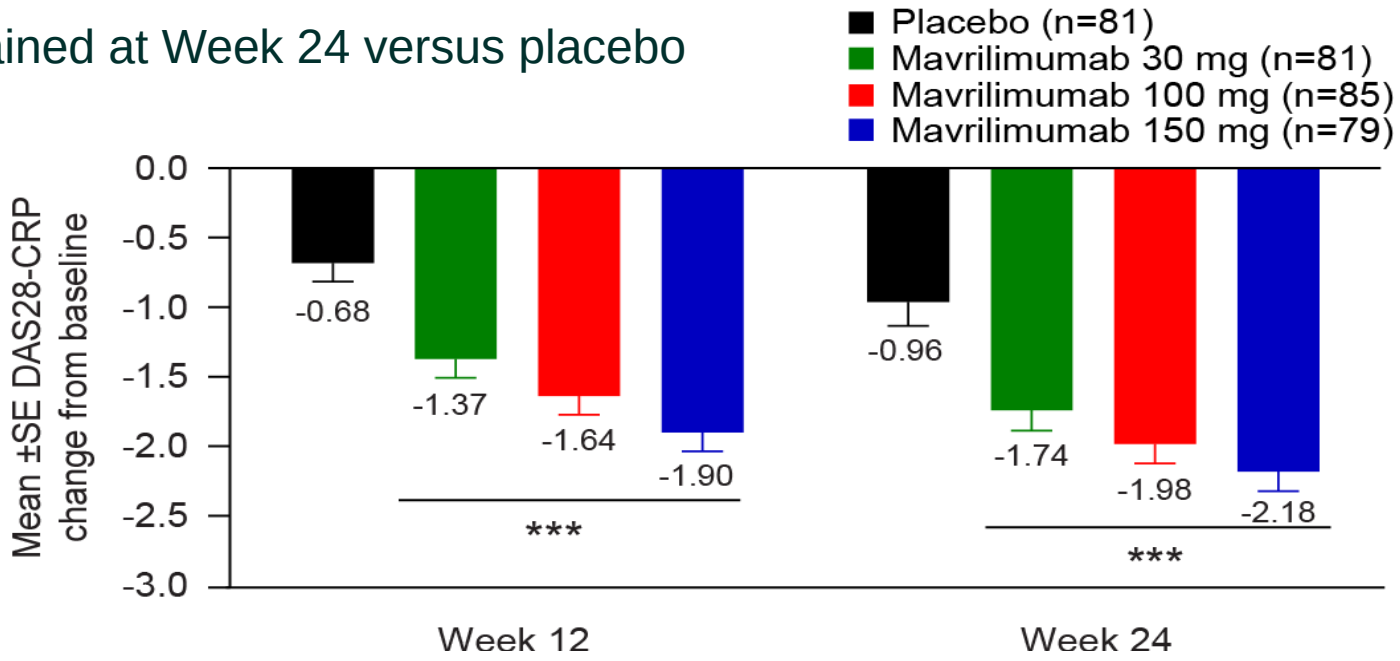
- 326 patients with moderate-to-severe RA and an inadequate response to at least one disease-modifying anti-rheumatic drug
- Dosing (30, 100, 150mg) every 2 weeks for 24 weeks
- Co-primary endpoints
  - Mean change from baseline in DAS28-CRP at Week 12
  - ACR20 response rate at Week 24
- Other endpoints
  - Multiple disease activity parameters
  - Safety and tolerability profile
- Patients eligible to enter open-label extension (OLE) study



Mavrilimumab

Phase IIb study met DAS28-CRP co-primary endpoint:

- At Week 12, a statistically significant difference in DAS28-CRP was seen for all doses of mavrilimumab versus placebo
- Sustained at Week 24 versus placebo



- A significantly greater percentage of mavrilimumab-treated patients met the ACR20 co-primary endpoint versus placebo for all doses

***p<0.001, mavrilimumab versus placebo

Mavrilimumab

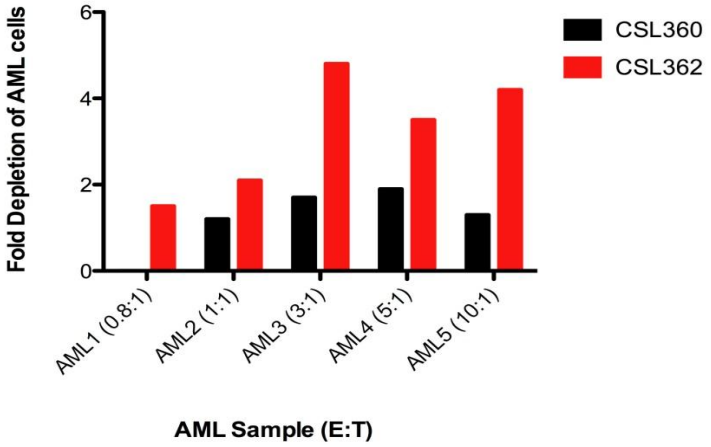
Phase IIb study conclusions:

- Study met both co-primary endpoints at all mavrilimumab doses
- All secondary endpoints (including ACR50, ACR70 response) achieved statistical significance for the 150 mg dose
- Rapid (after one week of initiation of treatment) and sustained improvement in multiple symptoms of RA observed in patients receiving mavrilimumab
- Improvements demonstrated in patient-reported outcomes (pain, health-related quality of life, physical function, fatigue)
- An acceptable safety and tolerability profile, with no apparent safety signals, demonstrated over the 24-week study period

CSL362 (anti-IL-3Rα mAb)

- Initial indication: Acute myeloid leukaemia
- Enhanced recruitment of tumour killing NK cells

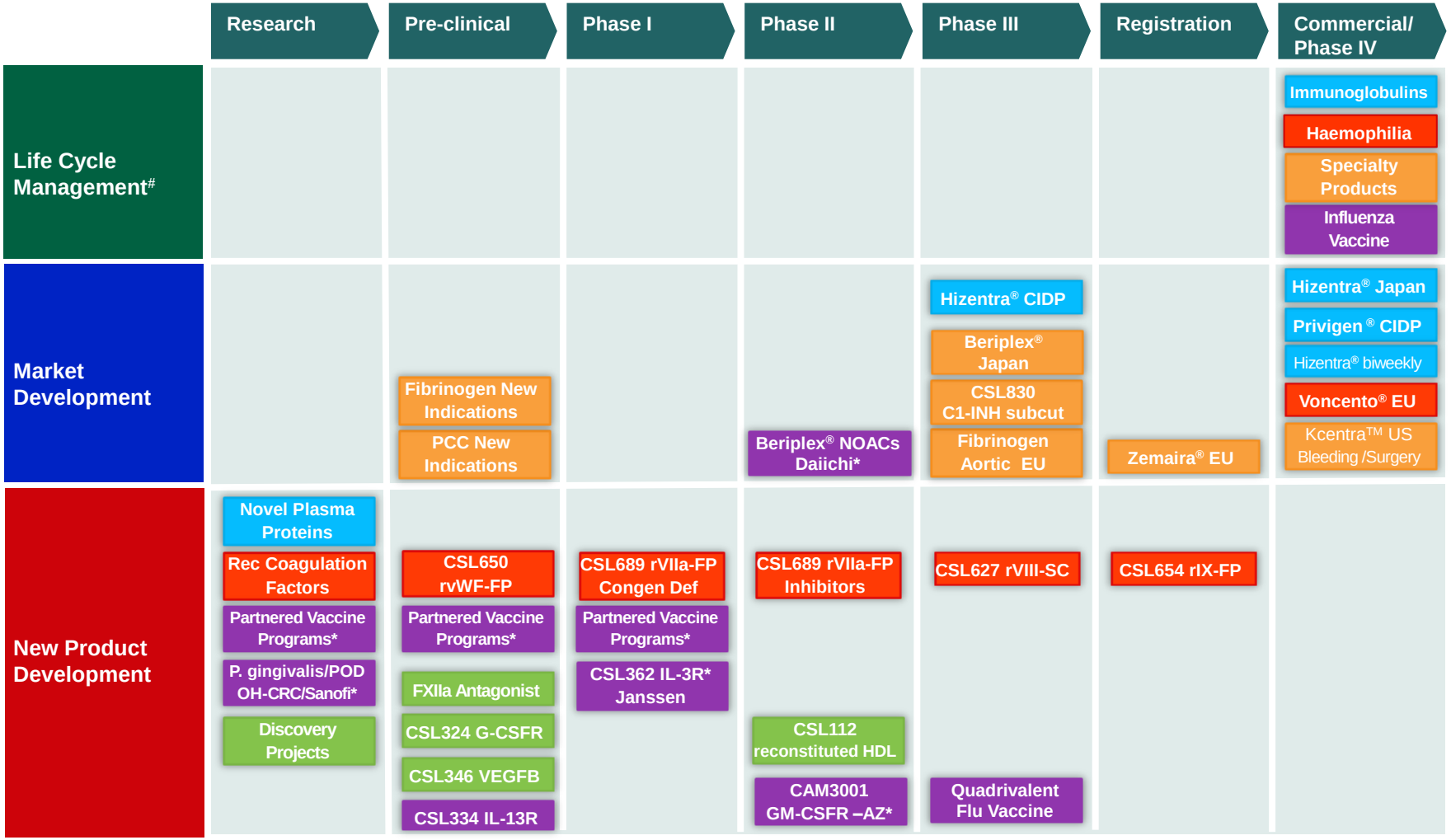
- Phase I study in progress
- Other high quality opportunities in autoimmunity eg. SLE



- Partnership with Janssen Biotech, Inc

Summary

Global R&D Portfolio December 2014

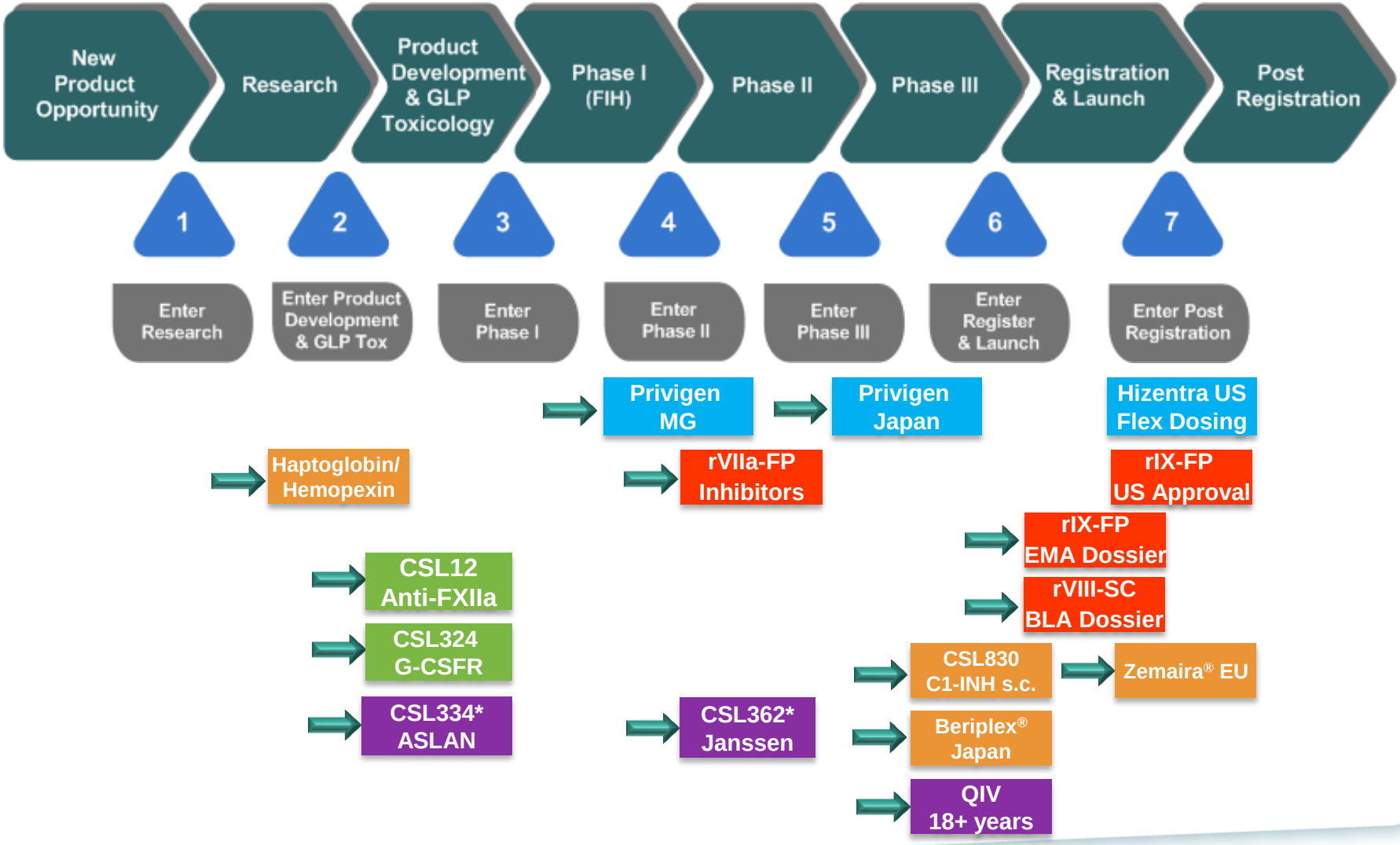


Core Capabilities: Immunoglobulins | Haemophilia | Specialty Products | Breakthrough Medicines | Vaccines & IP

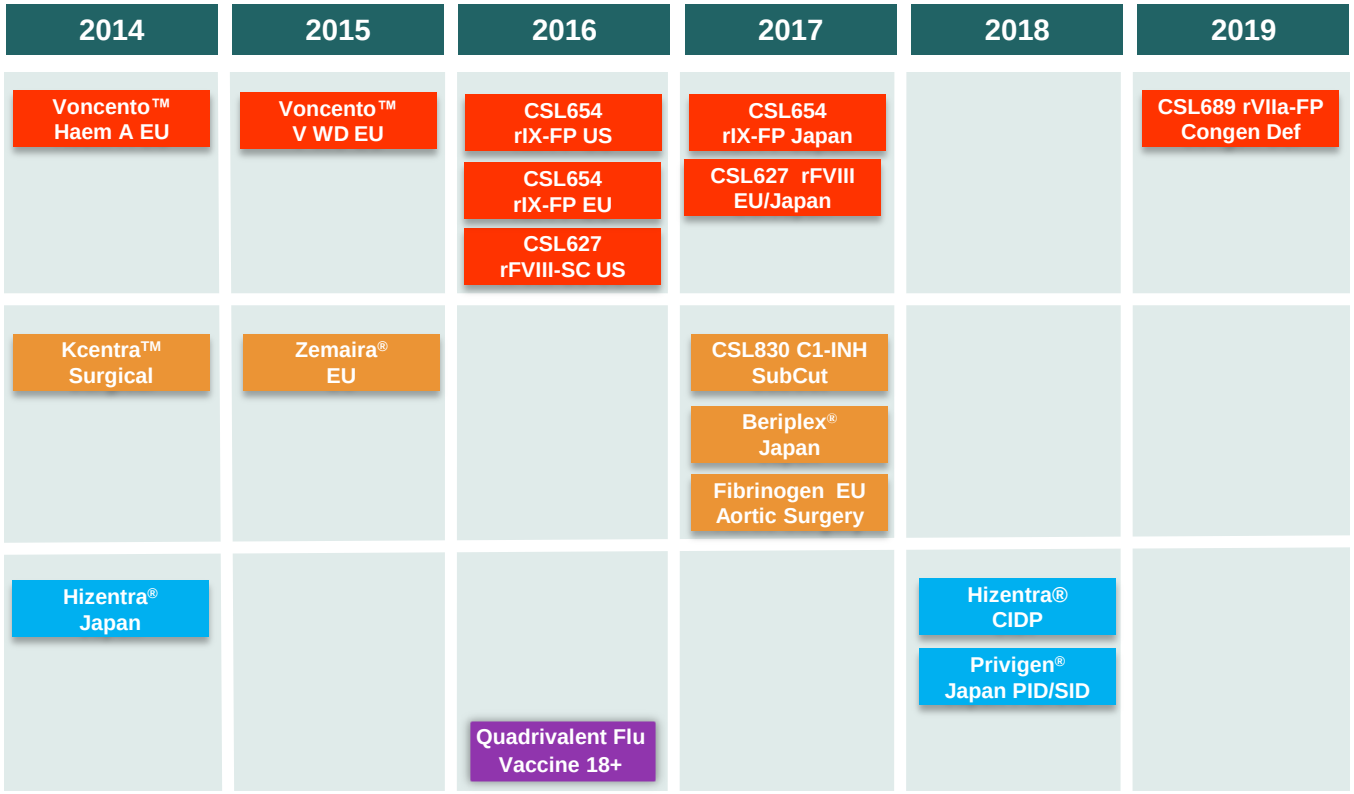
***Partnered Projects**

#LCM includes direct post marketing commitments as well as pathogen safety, capacity expansions, yield improvements, new packages and sizes for all registered products

Expected Progress in next 12 Months



Significant Target Launch Dates



Core Capabilities: Immunoglobulins | Haemophilia | Specialty Products | Vaccines & IP

* Calendar Years

2014 Highlights

Immunoglobulins	• Hizentra® flexible dosing registration in EU • Hizentra® CIDP orphan drug designation • Ongoing global Privigen CIDP registrations
Specialty Products	• Kcentra™ registration for surgical indication in US • Berinert® s.c. Pivotal Phase III rapid recruitment • Commencement of Beriplex™ Japan Phase III study
Haemophilia	• rIX-FP Phase III efficacy data supports 7-14 day dosing • rVIII-SingleChain Phase I/III supports twice-weekly dosing • rVIIa-FP congenital deficiency Phase I/II commenced
Breakthrough Medicines	• Commencement of CSL112 (Apo A-1) Phase IIb study • Anti-FXIIa mAb progressed into product development
Licensing & Vaccines	• Quadrivalent Flu (QIV-01) study 18+ yrs fully recruited • Mavrilimumab positive additional Phase II data

Q&A

Further Information

Presentation Playback

A playback of the Research and Development presentations will be available for a period of two weeks following the R&D Briefing. Investors wishing to listen to these presentations should contact CSL Investor Relations to arrange access.
Contact: maria.pikos@csl.com.au

Investor Relations:

Mark Dehring

Head of Investor Relations

Phone: +61 3 9389 2818

Email: mark.dehring@csl.com.au

Media:

Sharon McHale

Senior Director Public Affairs

CSL Limited

Phone: +613 9389 1506

Mobile: +614 0997 8314

Email: sharon.mchale@csl.com.au