

R&D Briefing

December 3, 2014

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Agenda December 2014 R&D Briefing

- Welcome
- Introduction & Highlights
- Protein Science Research
- Immunoglobulins & Specialty Products
 - Clinical Development
 - Commercial Opportunities
- Q&A

Mark Dehring

Andrew Cuthbertson

Andrew Nash

Charmaine Gittleson

Bob Repella

Break

- Coagulation/Haemophilia
 - Clinical Development
 - Commercial Opportunities
- Breakthrough Medicines & Licensing
- Summary
- Q&A

Charmaine Gittleson

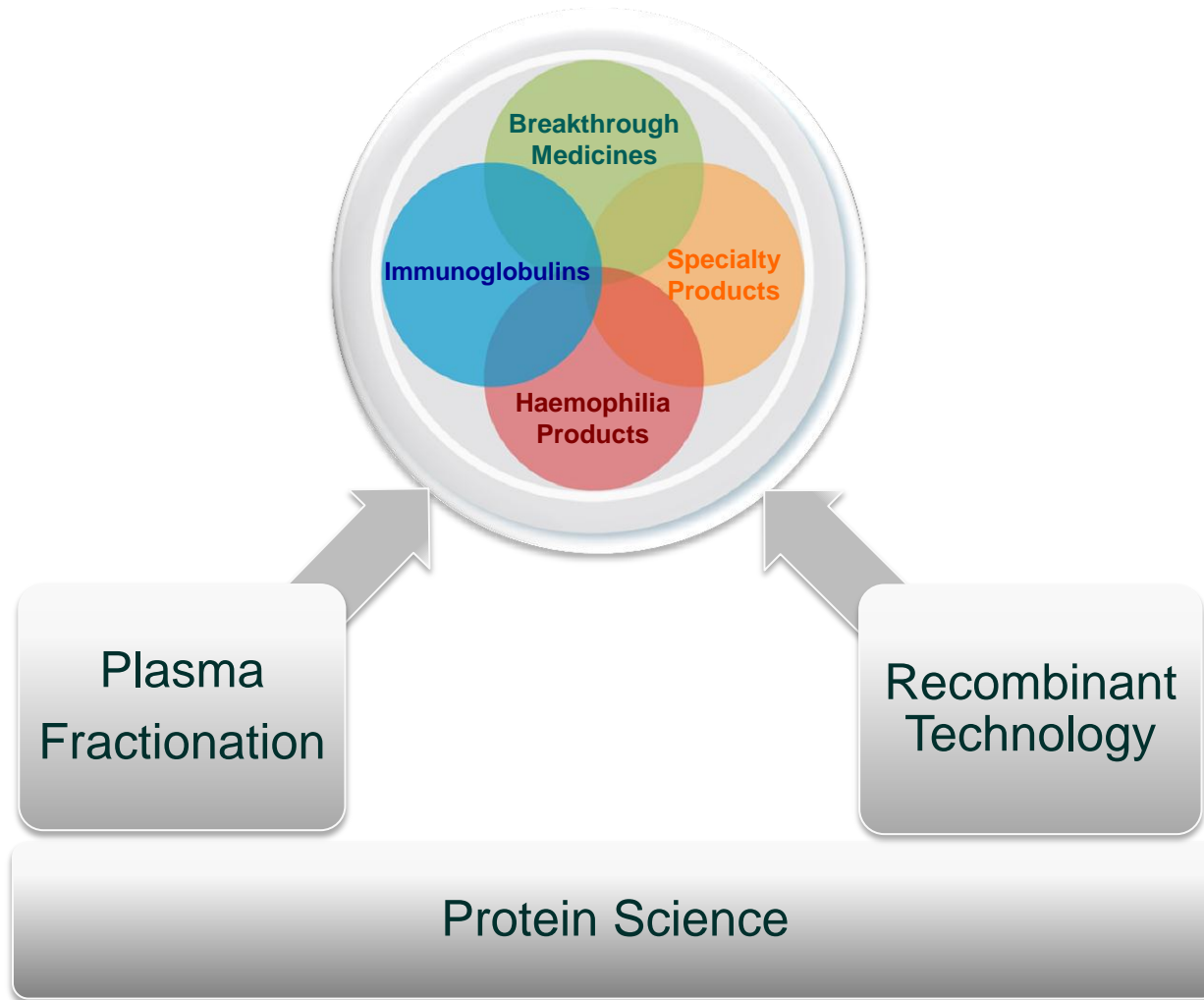
Bob Repella

Andrew Cuthbertson

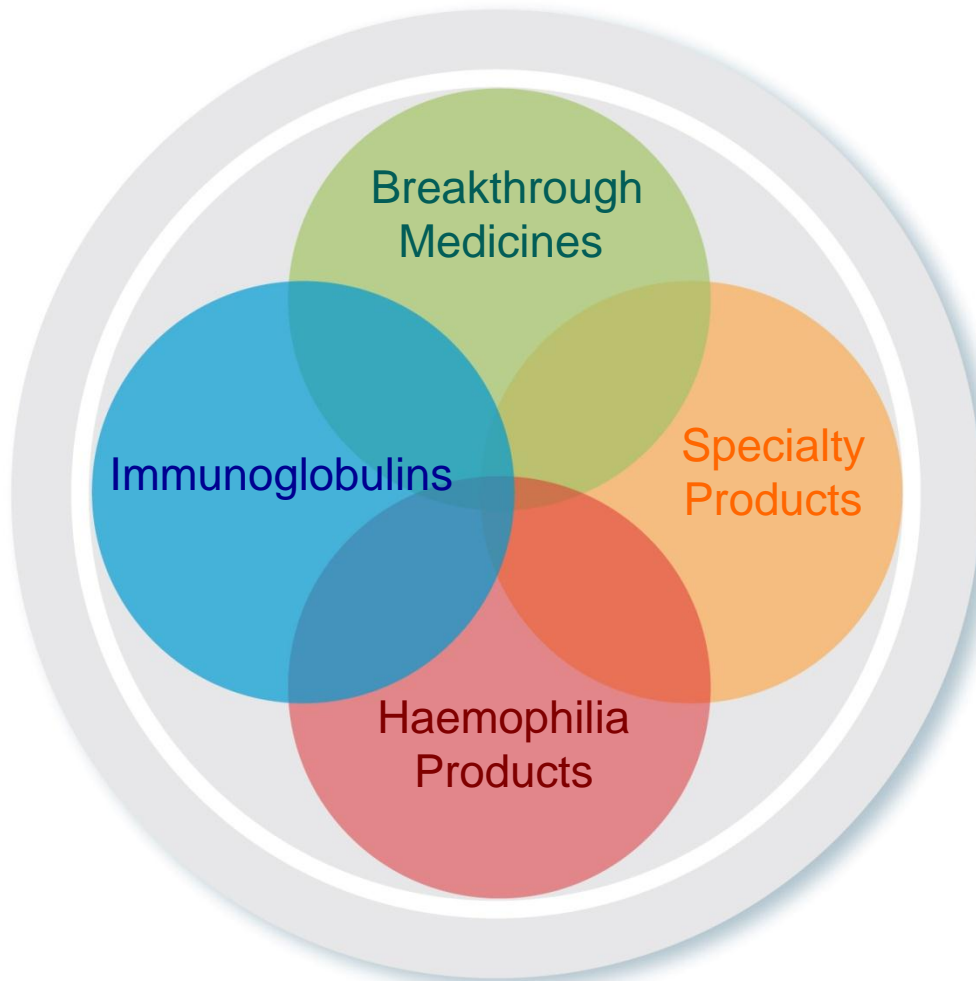
Andrew Cuthbertson

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

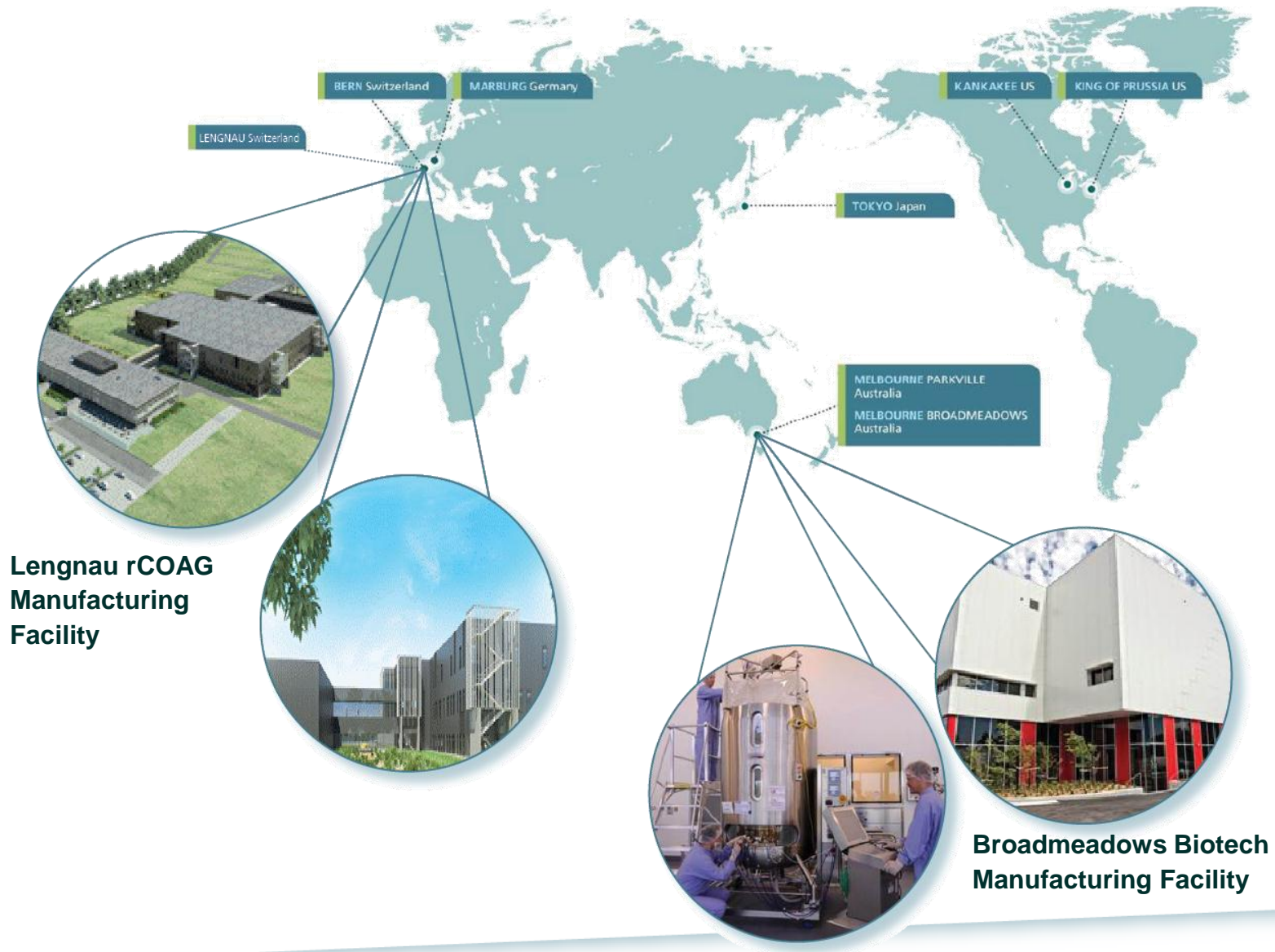
Leveraging Global Capabilities



- >1,100 scientists globally

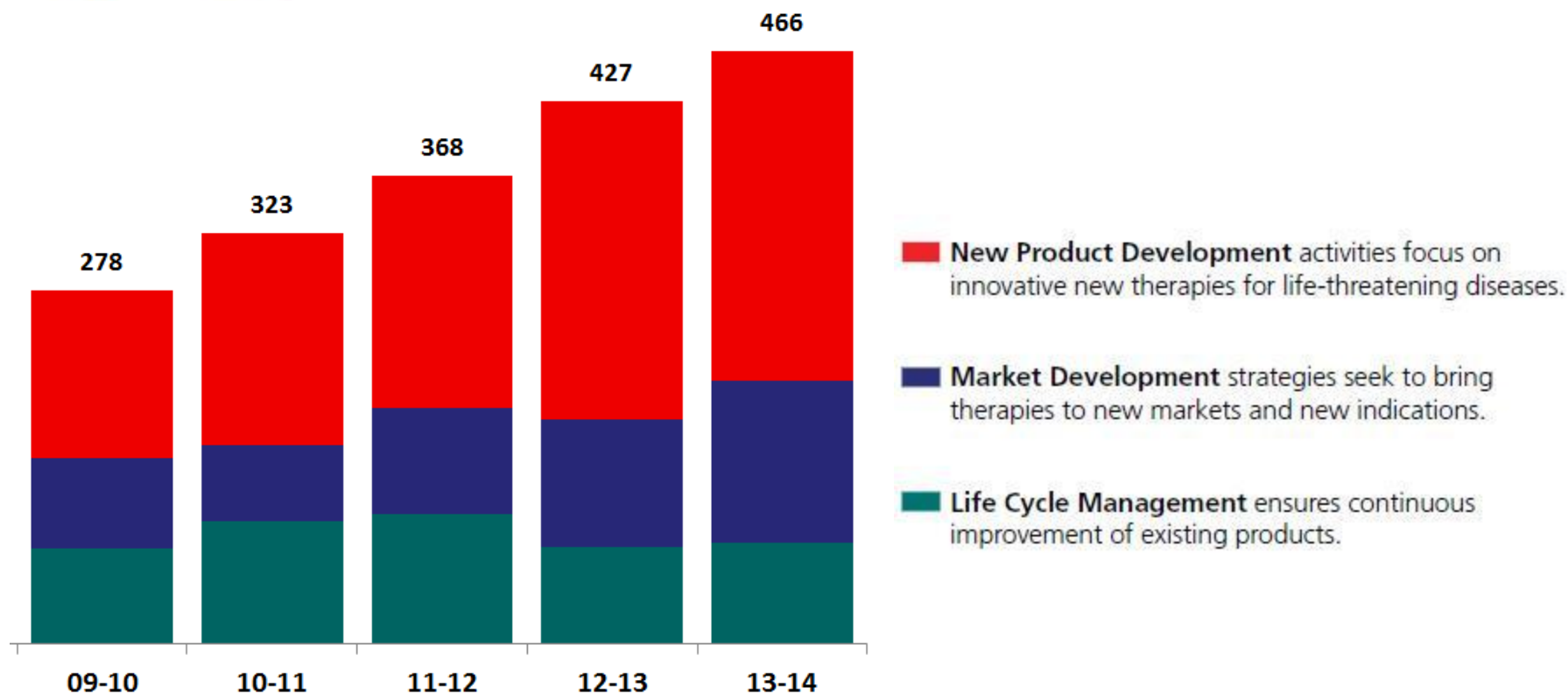


Building Global Recombinant Capabilities



R&D Investment

CSL RESEARCH AND DEVELOPMENT INVESTMENT
(US\$ MILLIONS)



Global R&D Portfolio

December 2013

	Research	Pre-clinical	Phase I	Phase II	Phase III	Registration	Commercial/ Phase IV
Life Cycle Management [#]							Immunoglobulins Haemophilia Specialty Products Influenza Vaccine
Market Development		Fibrinogen New Indications PCC New Indications			Hizentra [®] CIDP CSL830 C1-INH subcut Fibrinogen Aortic EU	Kcentra [™] US Surgery Zemaira [®] EU	Hizentra [®] Japan Privigen [®] CIDP Hizentra [®] biweekly Voncento [®] EU Kcentra [™] US Bleeding
New Product Development	Novel Plasma Proteins Rec Coagulation Factors Partnered Vaccine Programs* P. gingivalis/POD OH-CRC/Sanofi* Discovery Projects FXIIa Antagonist	CSL650 rVWF-FP Partnered Vaccine Programs* CSL324 G-CSFR CSL346 VEGFB CSL334 IL-13R	Partnered Vaccine Programs* CSL362 IL-3R* Janssen	CSL689 rVIIa-FP CSL112 reconstituted HDL CAM3001 GM-CSFR -AZ*	CSL627 rVIII-SC CSL654 rIX-FP		

Core Capabilities:

Immunoglobulins

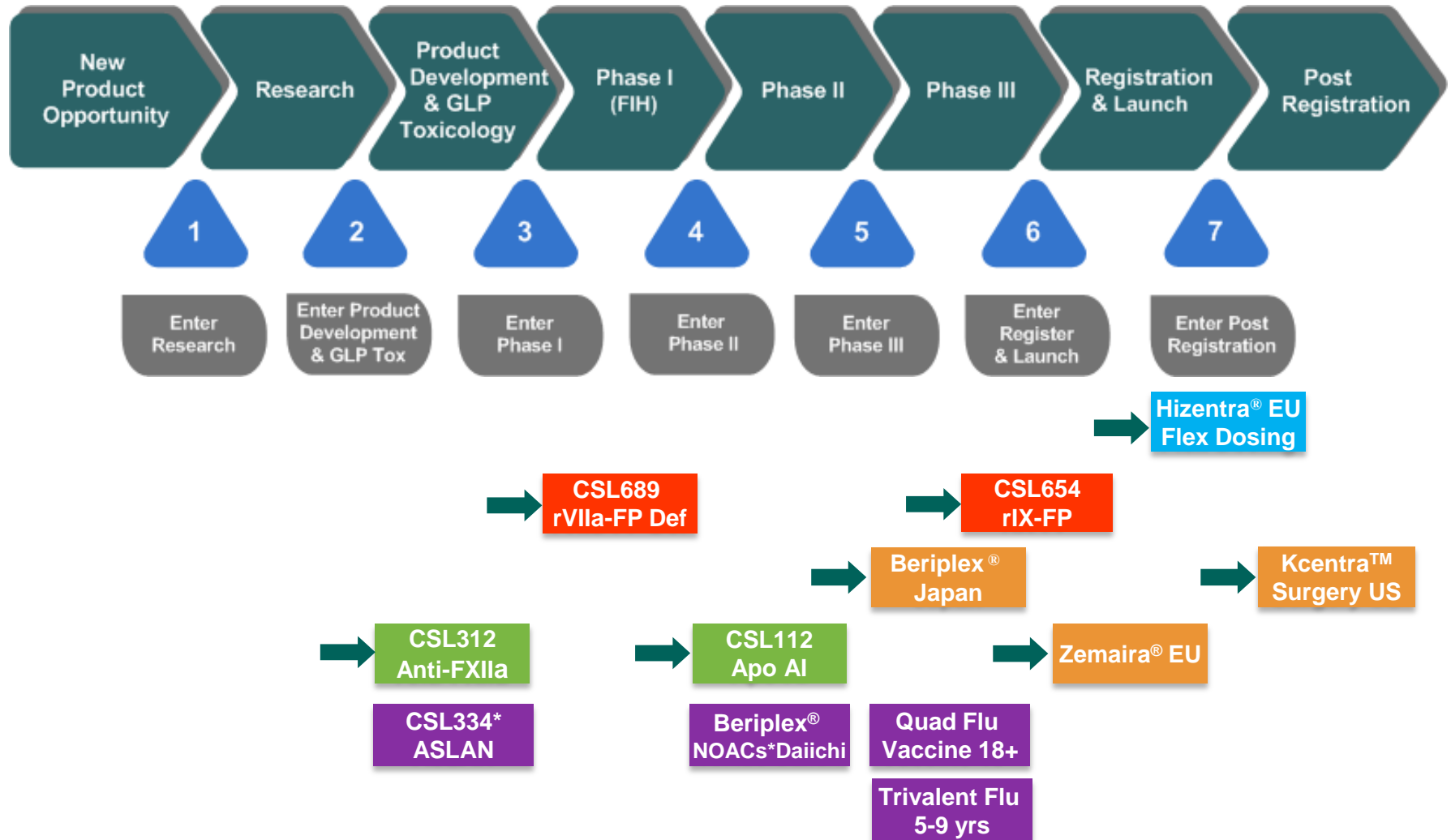
Haemophilia

Specialty Products

Breakthrough Medicines

Vaccines & IP

Progress through Stage Gates in 2014



	Research	Pre-clinical	Phase I	Phase II	Phase III	Registration	Commercial/ Phase IV
Life Cycle Management [#]							Immunoglobulins Haemophilia Specialty Products Influenza Vaccine
Market Development		Fibrinogen New Indications PCC New Indications		Beriplex [®] NOACs Daiichi*	Hizentra [®] CIDP Beriplex [®] Japan CSL830 C1-INH subcut Fibrinogen Aortic EU	Zemaira [®] EU	Hizentra [®] Japan Privigen [®] CIDP Hizentra [®] biweekly Voncento [®] EU Kcentra [™] US Bleeding /Surgery
New Product Development	Novel Plasma Proteins Rec Coagulation Factors Partnered Vaccine Programs* P. gingivalis/POD OH-CRC/Sanofi* Discovery Projects	CSL650 rVWF-FP Partnered Vaccine Programs* FXIIa Antagonist CSL324 G-CSFR CSL346 VEGFB CSL334 IL-13R	CSL689 rVlla-FP Congen Def Partnered Vaccine Programs* CSL362 IL-3R* Janssen	CSL689 rVlla-FP Inhibitors CSL112 reconstituted HDL CAM3001 GM-CSFR –AZ*	CSL627 rVIII-SC Quadrivalent Flu Vaccine	CSL654 rIX-FP	

Core Capabilities:

Immunoglobulins

Haemophilia

Specialty Products

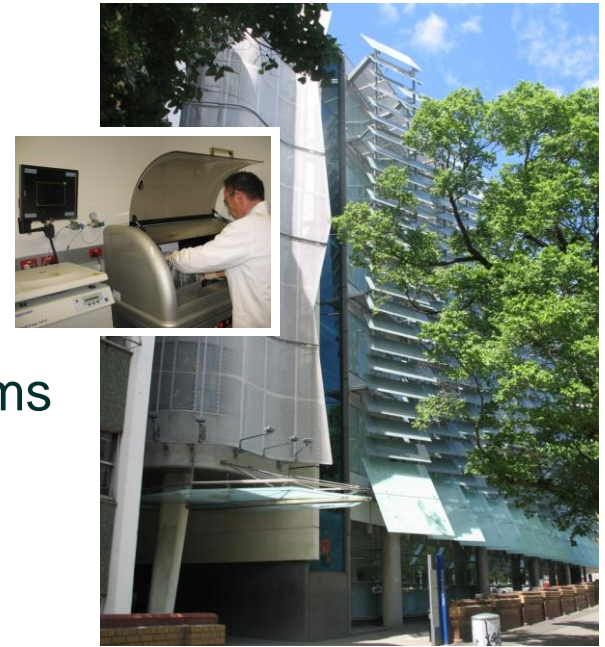
Breakthrough Medicines

Vaccines & IP

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				<i>P.ging</i> 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 III / launch manufacturing



Patient



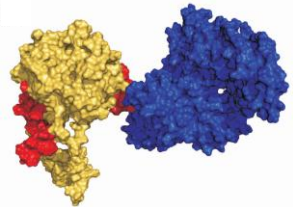
Market



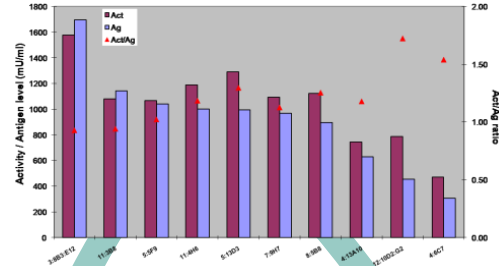
Phase I / II manufacturing

CSL654 (rIX-FP) – Discovery to Development

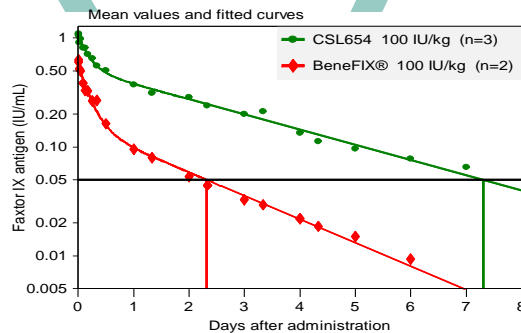
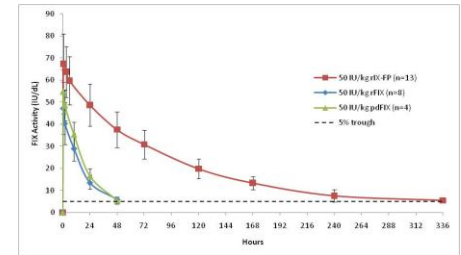
Factor IX fused to human albumin (CSL654)



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



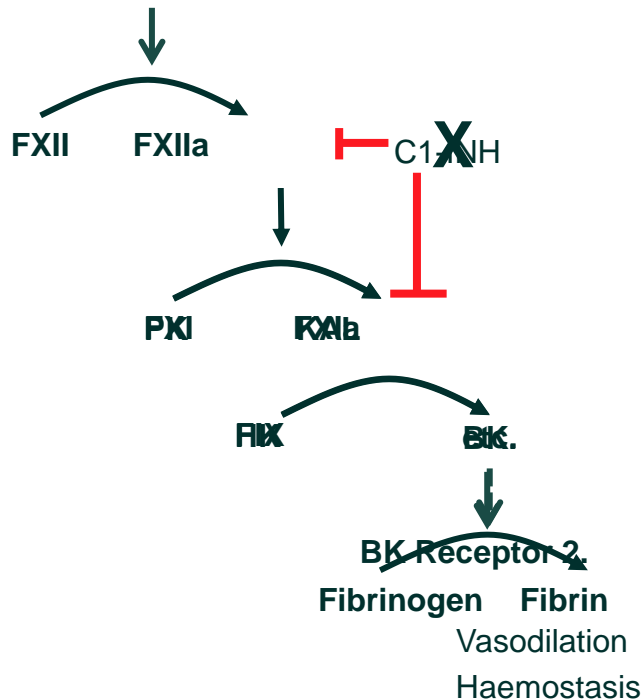
500L fed batch fermentation

Market

CSL312 (FXIIa antagonist mAb)

Contact activation (intrinsic) pathway

Damaged surface



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

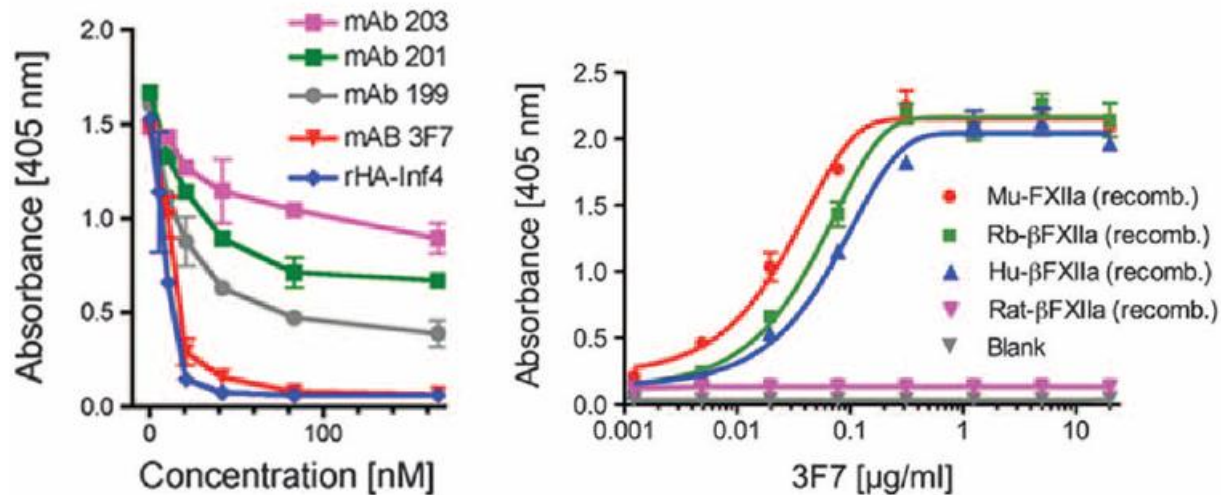
Opportunity

- Improve clinical outcomes and patient QoL by enabling prophylaxis

CSL312 (FXIIa antagonist mAb)

Generation & characterisation of a human FXIIa antagonist mAb

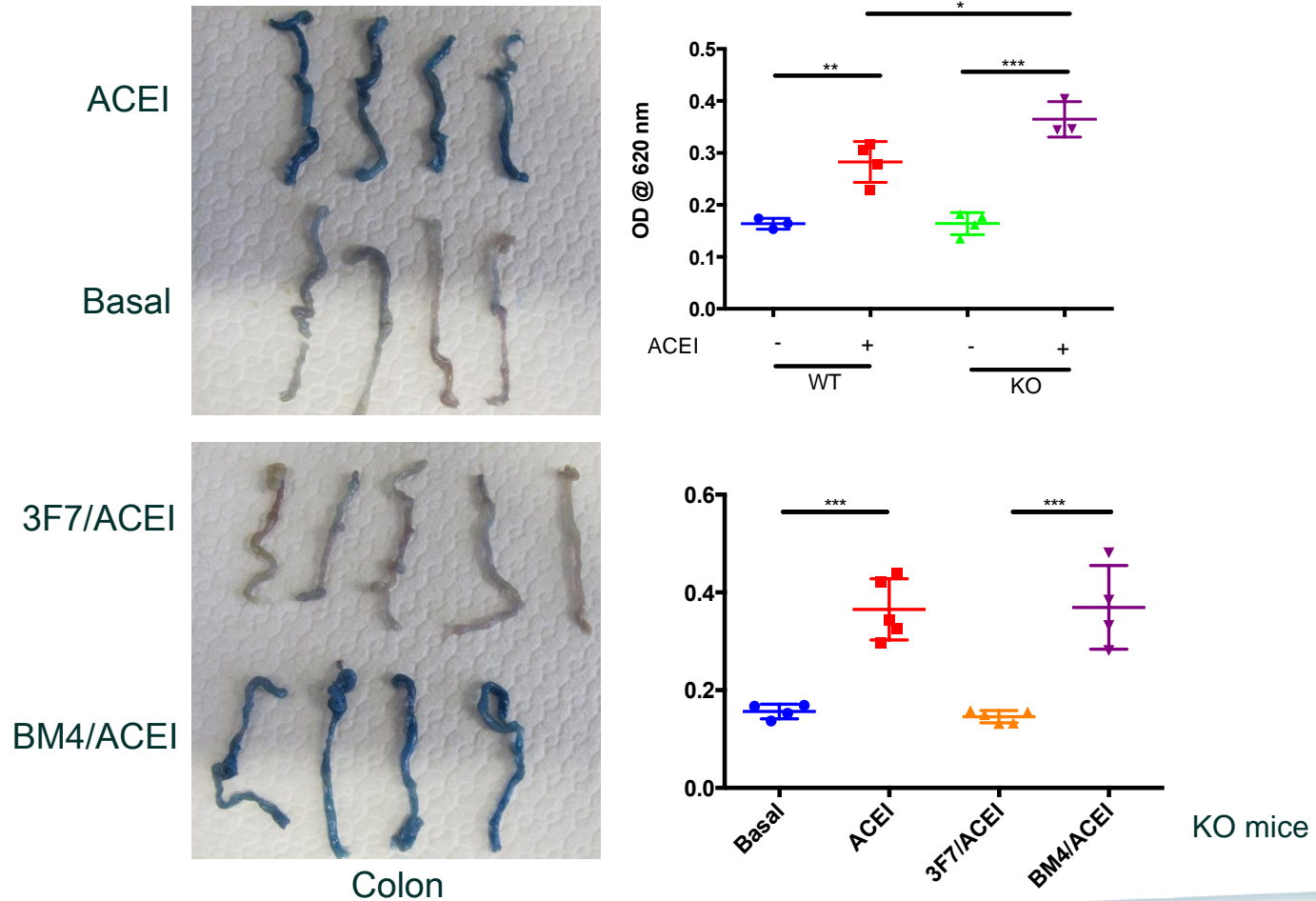
- screening of human Ab (Fab) phage display library



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

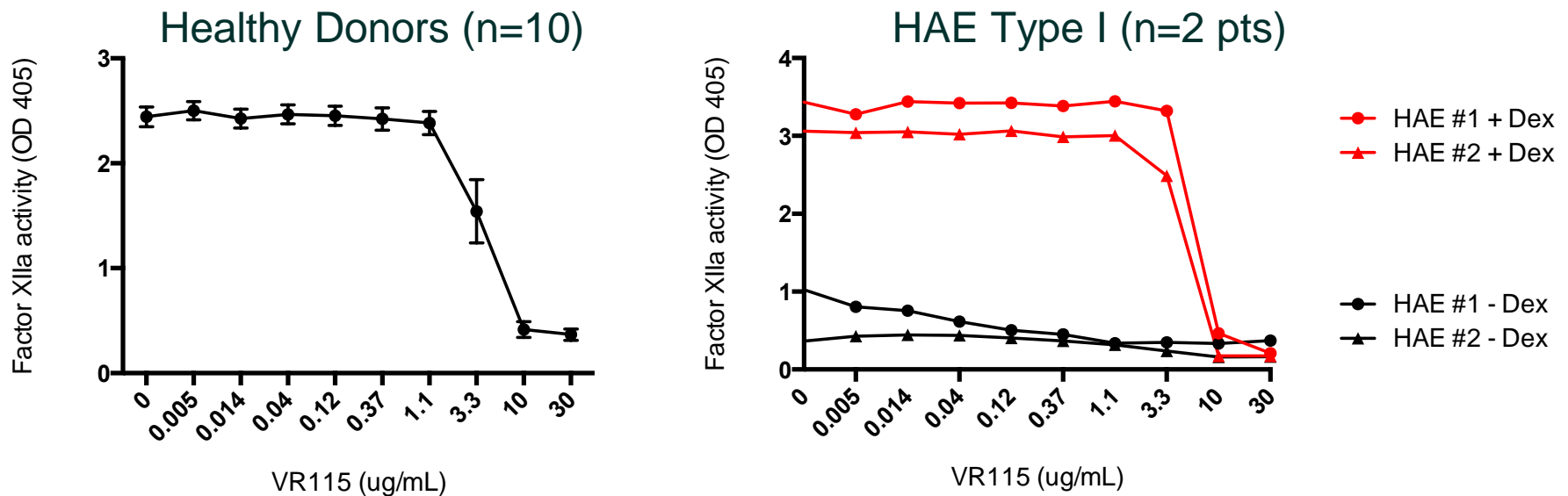
CSL312 – Hereditary Angioedema

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



CSL312 – Hereditary Angioedema

CSL312 inhibits Factor XIIa activity in human plasma



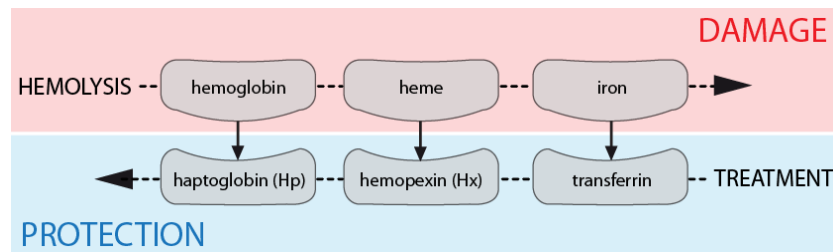
Current status

- 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

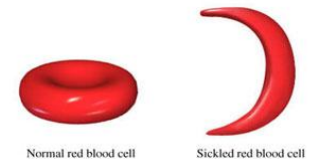
- Mutation in β -Hb gene, aggregation of β -Hb, sickle-shaped RBC
- Obstruct microvasculature, prone to lysis and release of Hb / heme

Diverse manifestations

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

Aetiology

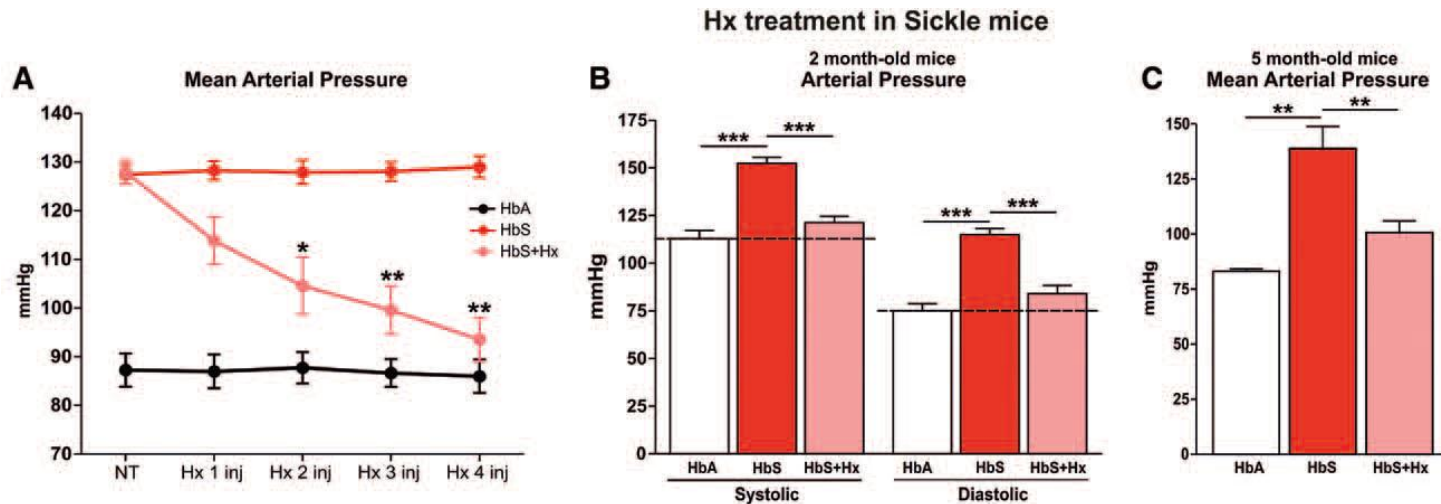
- Chronic low level and acute higher level exposure to Hb and heme
 - Vasoconstriction, vascular damage / local inflammation
 - Vaso-occlusive crisis
 - mechanical and heme induced obstruction of capillaries
- **Hp is absent and Hx significantly depleted in SCD patients**



Haptoglobin (Hp) / Hemopexin (Hx)

Hx therapy normalises blood pressure in SCD mice

- Transgenic mice that express human α -globin 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



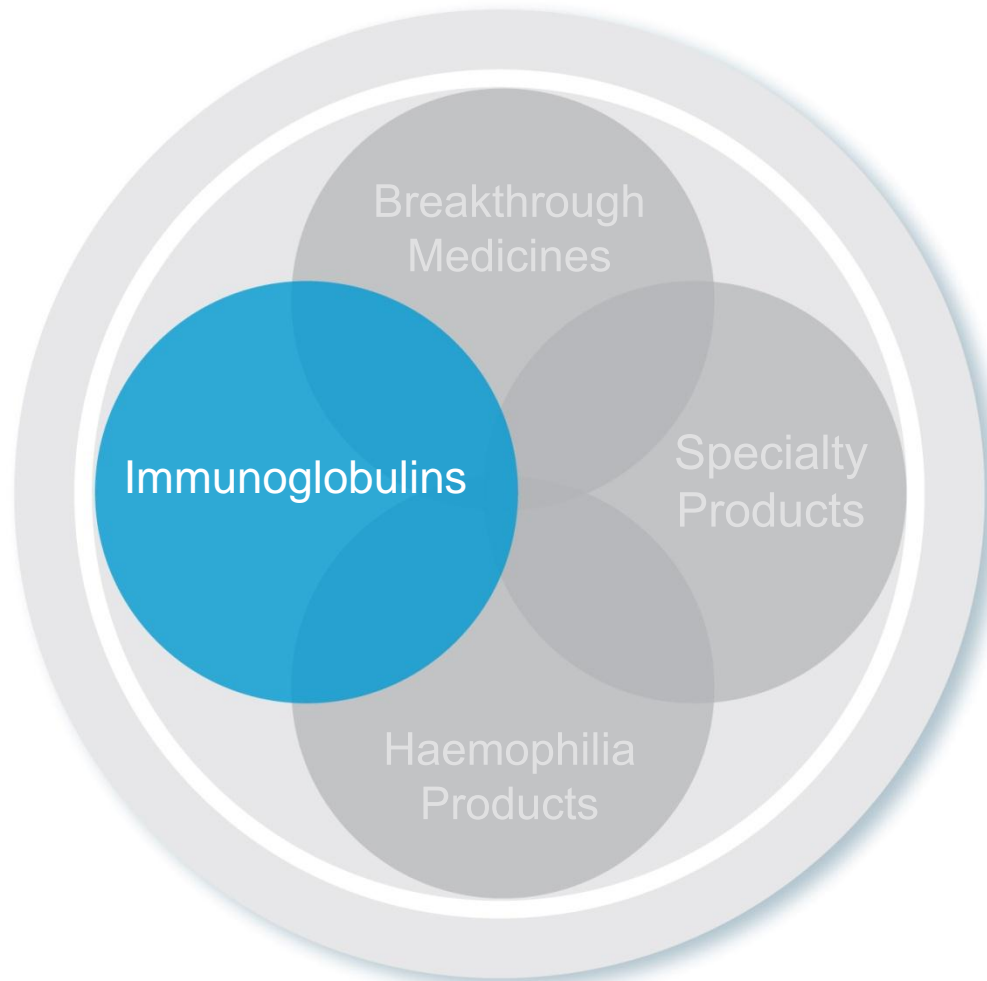
Vinchi *et al.*, Circulation 2013

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[®]

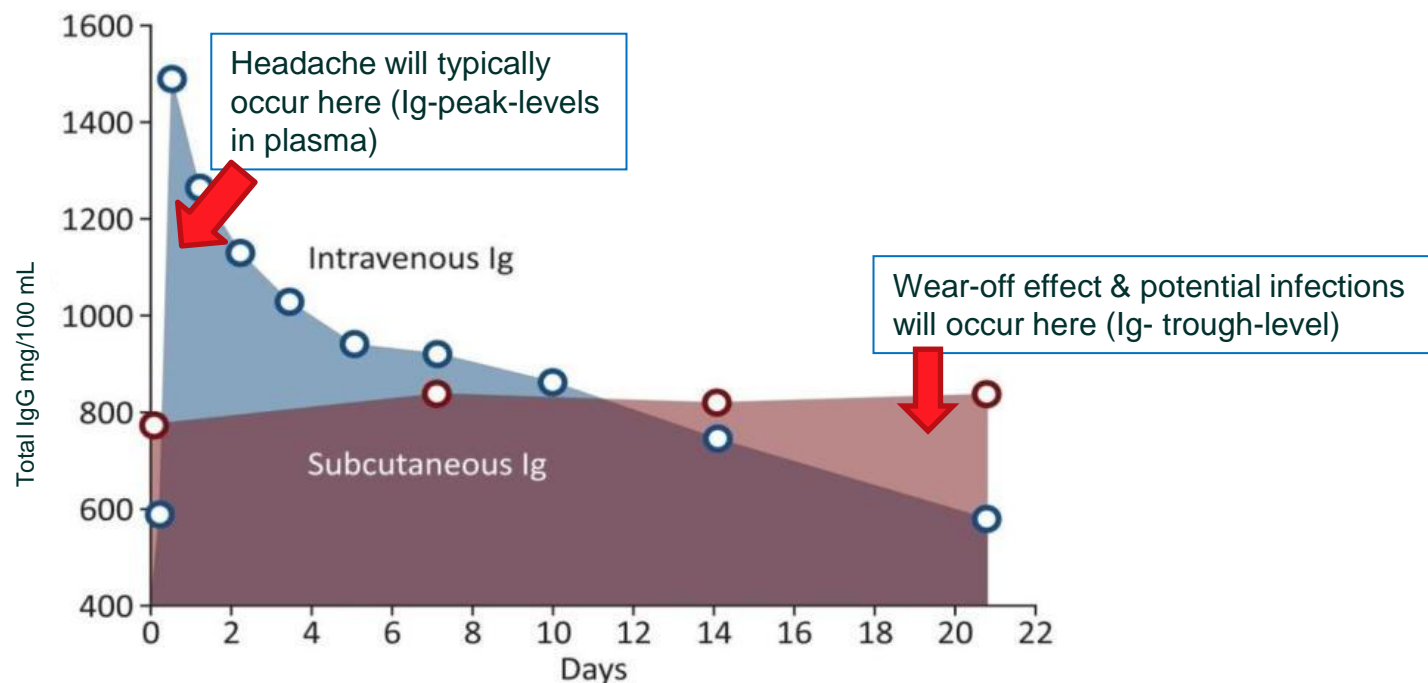


The first and only 10% liquid intravenous immunoglobulin (IVIg) therapy that is proline stabilised with room temperature storage up to 36 months



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

Benefits of Hizentra®: Steady-State Kinetics



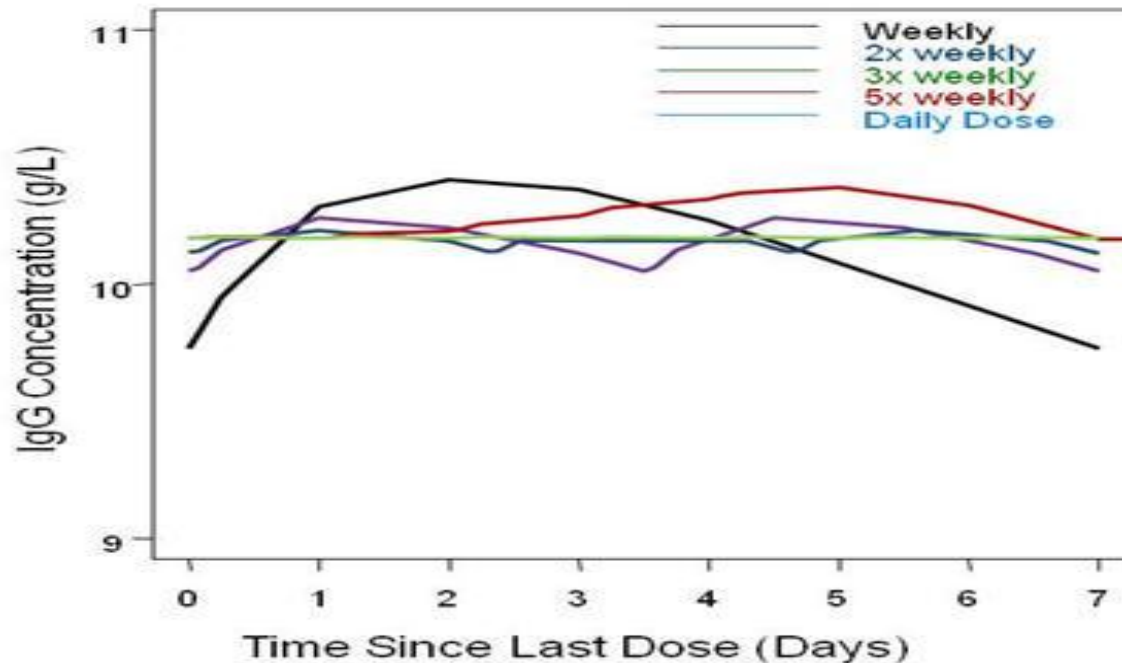
Pharmacokinetic Profile of IVIG vs. SCIG

- 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

Hizentra® Schedules Beyond Biweekly

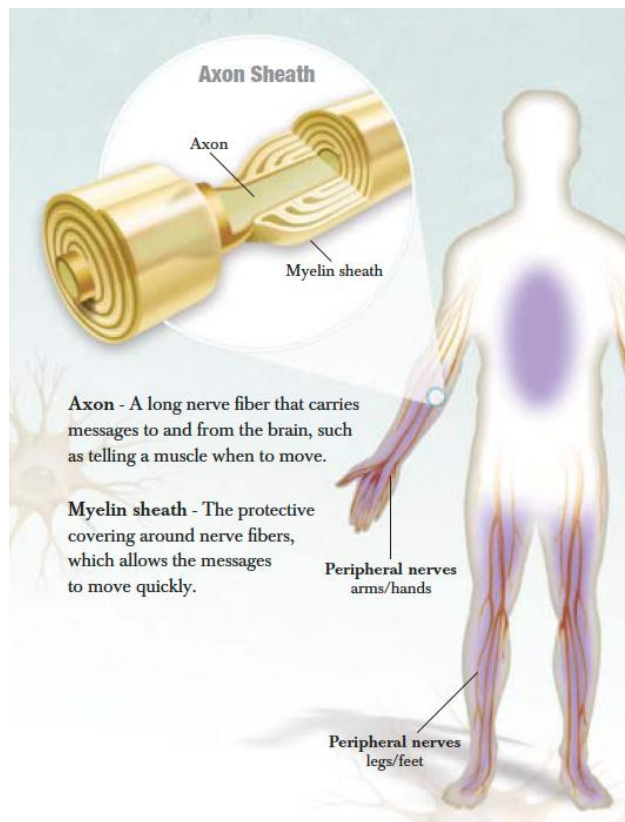
Individualised dosing strategies for patient protection

Medians of various scenarios *



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

Strengthening Presence in Neurology



Chronic Inflammatory Demyelinating Polyneuropathy

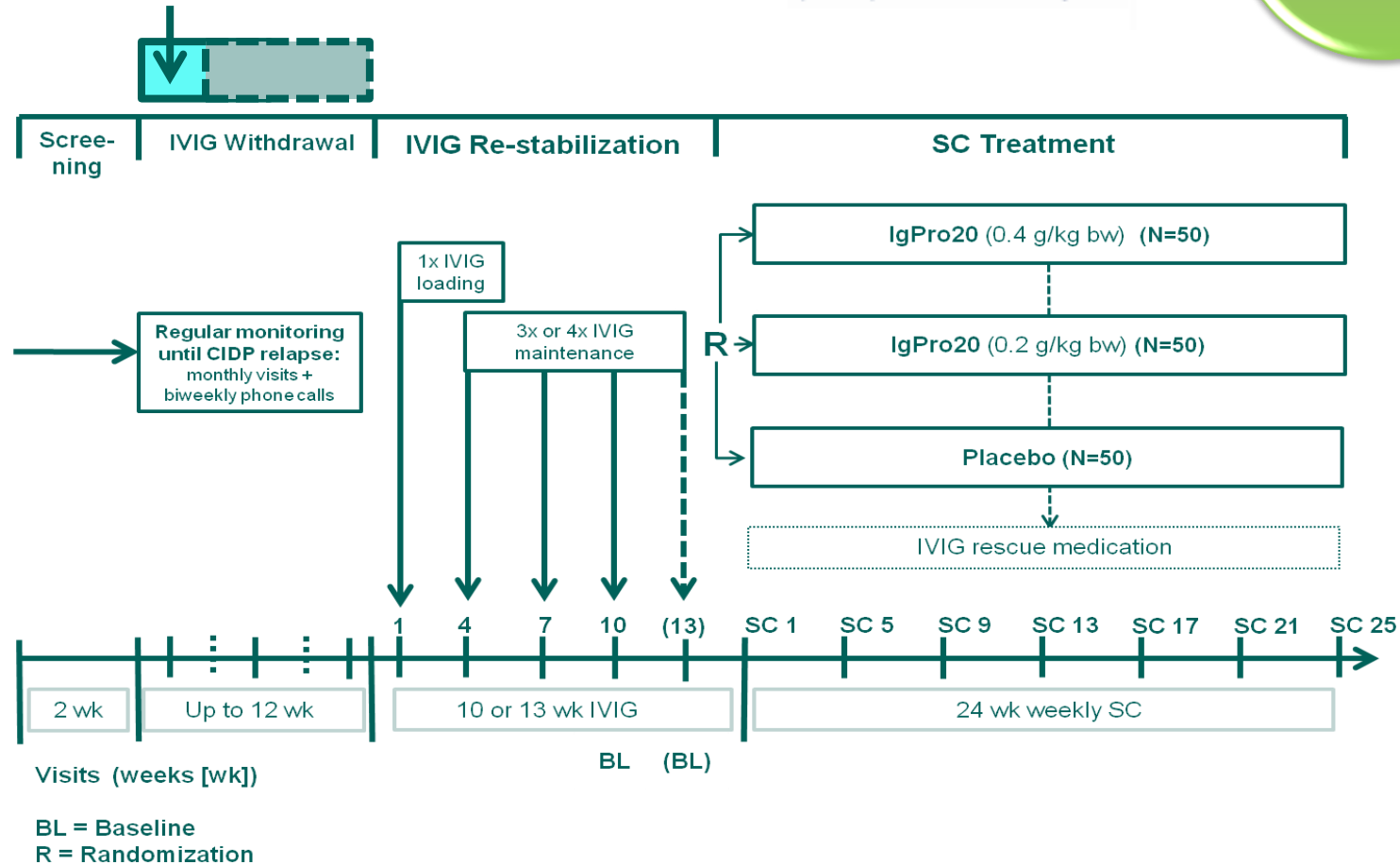
- Increased use of Privigen® across Europe and Canada in patients with CIDP
- Hizentra® CIDP orphan designation in the US
- Ongoing progress in Hizentra® Path study



Path Phase III Study Design



IgG dependency Test



Path Study Progress



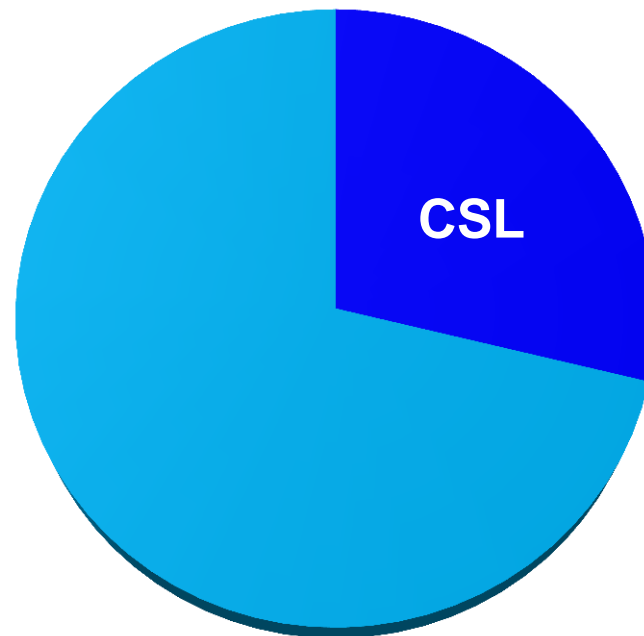
- 60 patients completed
- 114 / 174 randomised
- Expect to close recruitment in late 2015
- Last patient completing late 2016
- FDA and EMA submissions Q3/4 2017

Commercial Opportunities and Activities

Global Immunoglobulin Market

2013/14 Sales (USD)

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

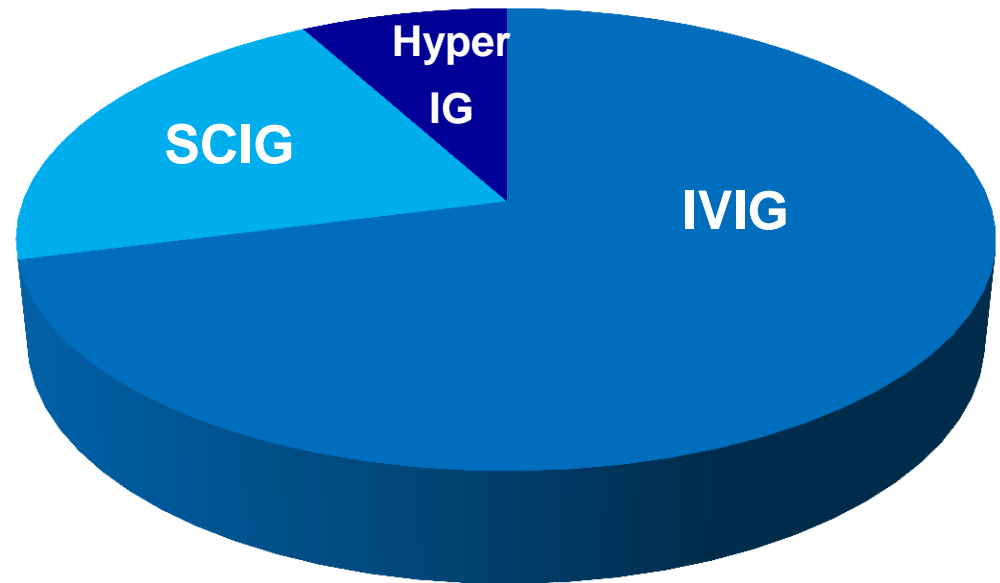


~ \$8b

CSL's Immunoglobulin Portfolio

2013/14 Sales (USD)

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



\$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

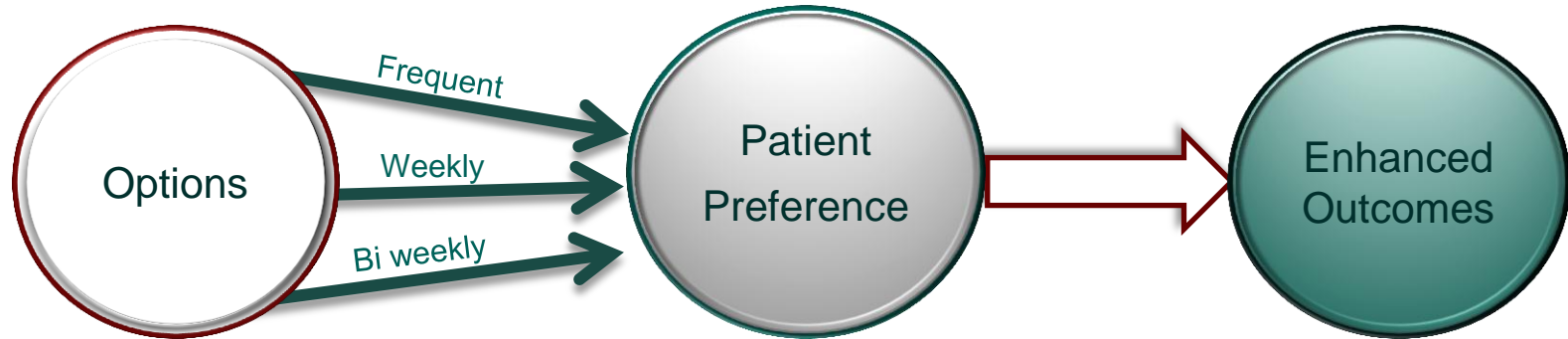
Maximise patient convenience

- 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

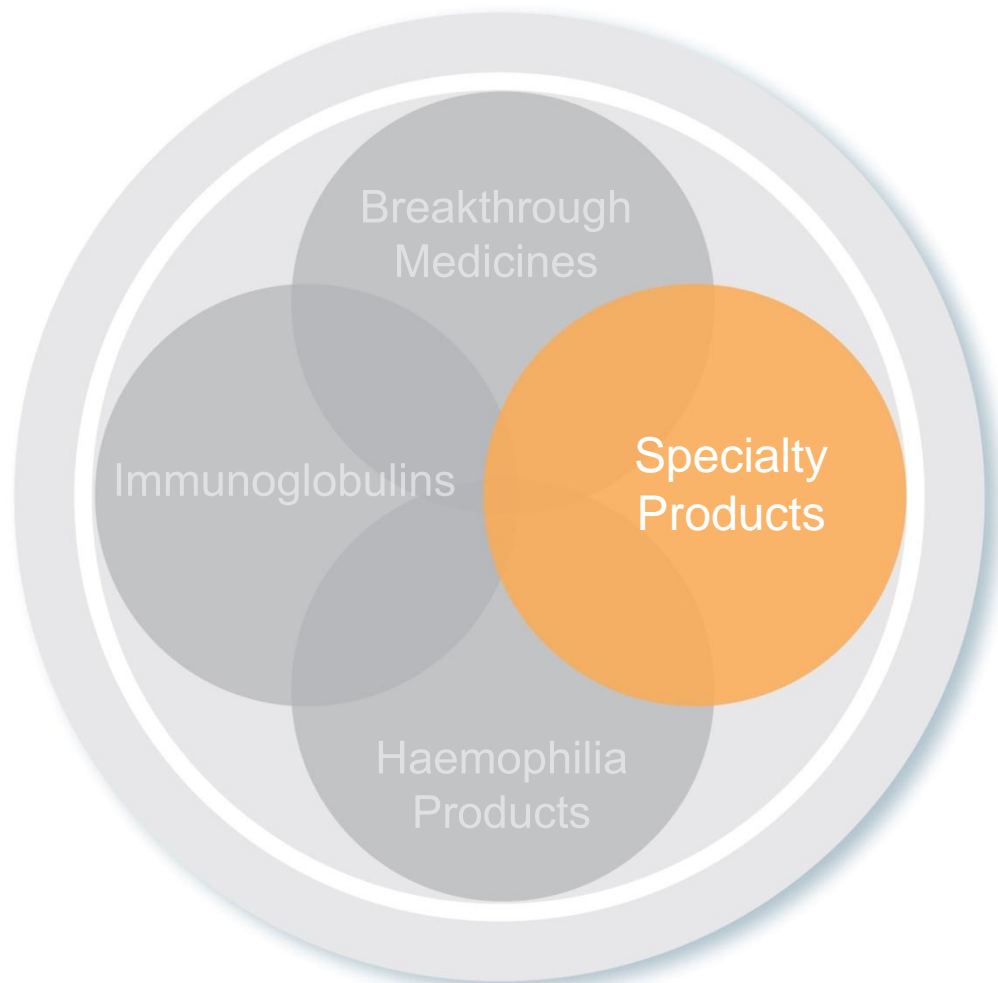


Advantages of individualised therapy with Hizentra[®]

- 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

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

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

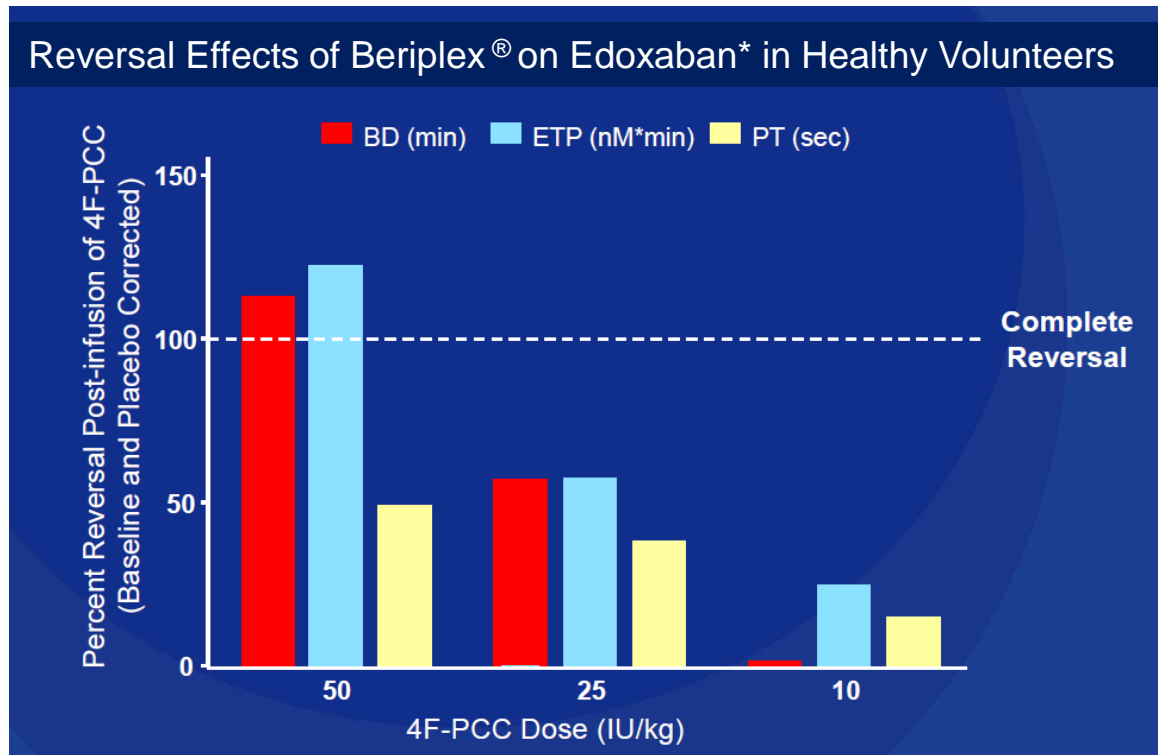
Kcentra™ launched in April in the US as a first in class therapy to reverse the effects of vitamin K antagonists (e.g. Warfarin) for:

- 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

- Potential clinical application for new oral anticoagulant reversal?



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

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

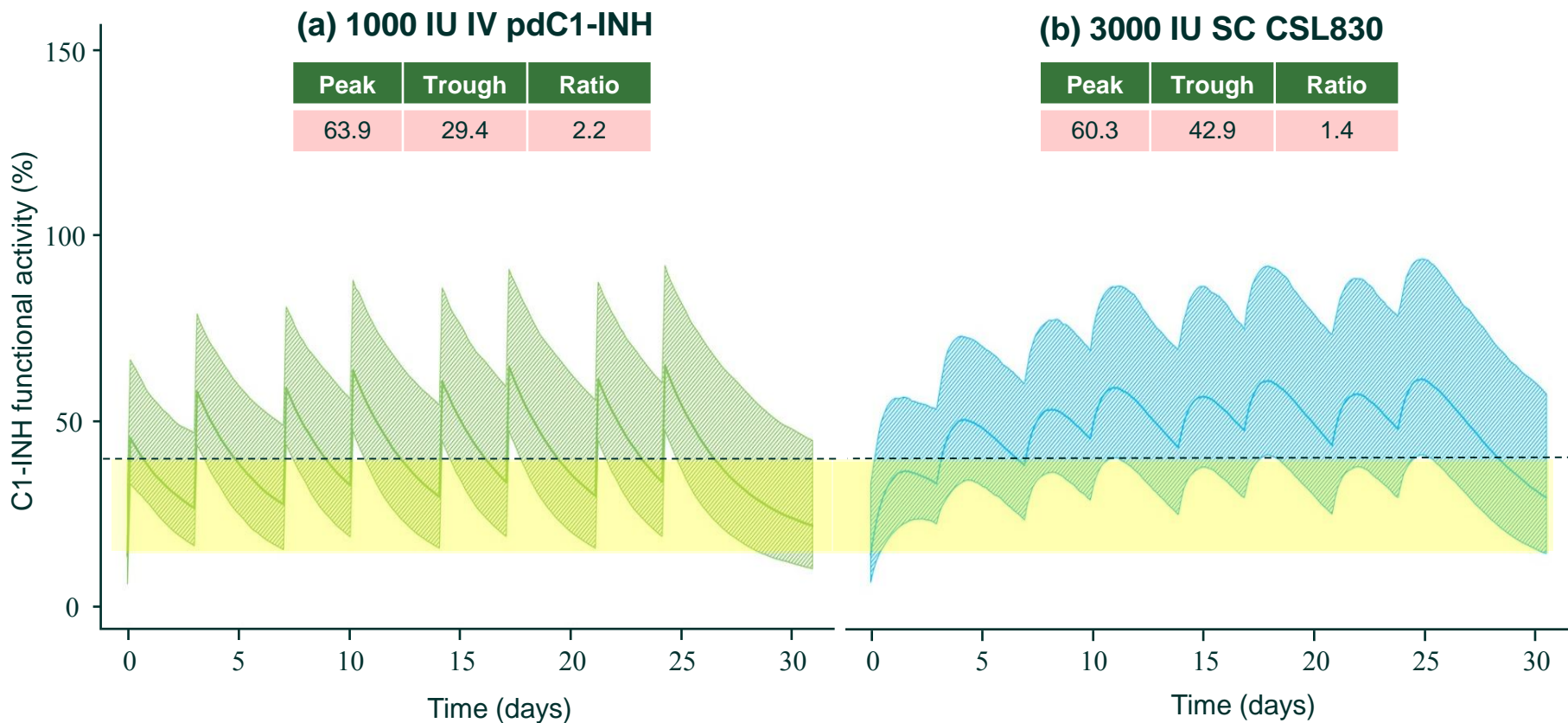
CSL830 (Subcutaneous C1-INH)

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 through attacks in some patients¹

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

SC CSL830 maintains trough levels above “protective” C1 levels



CSL830 Clinical Program

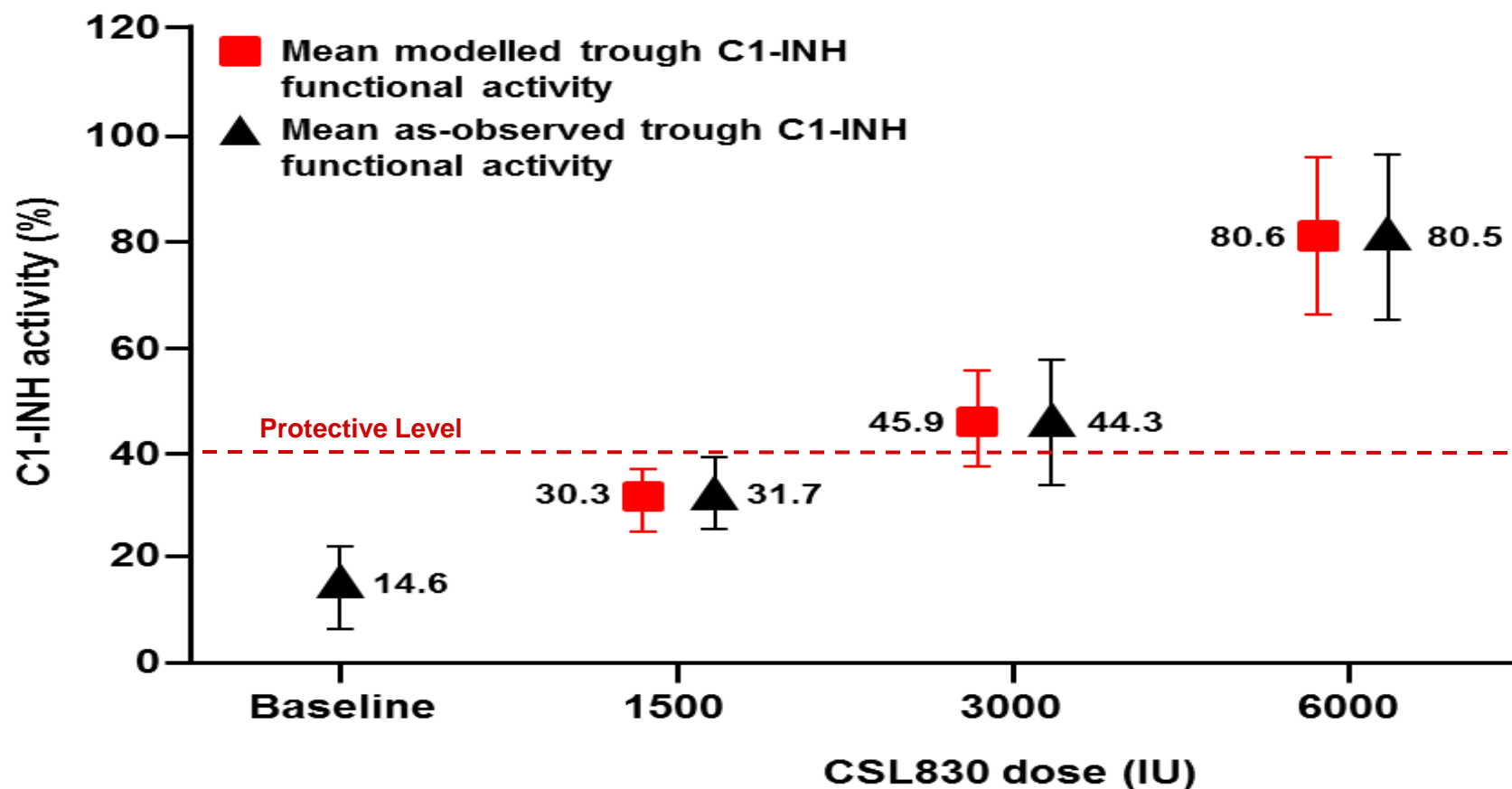


COMPACT

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

CSL830 Phase II COMPACT Study Results

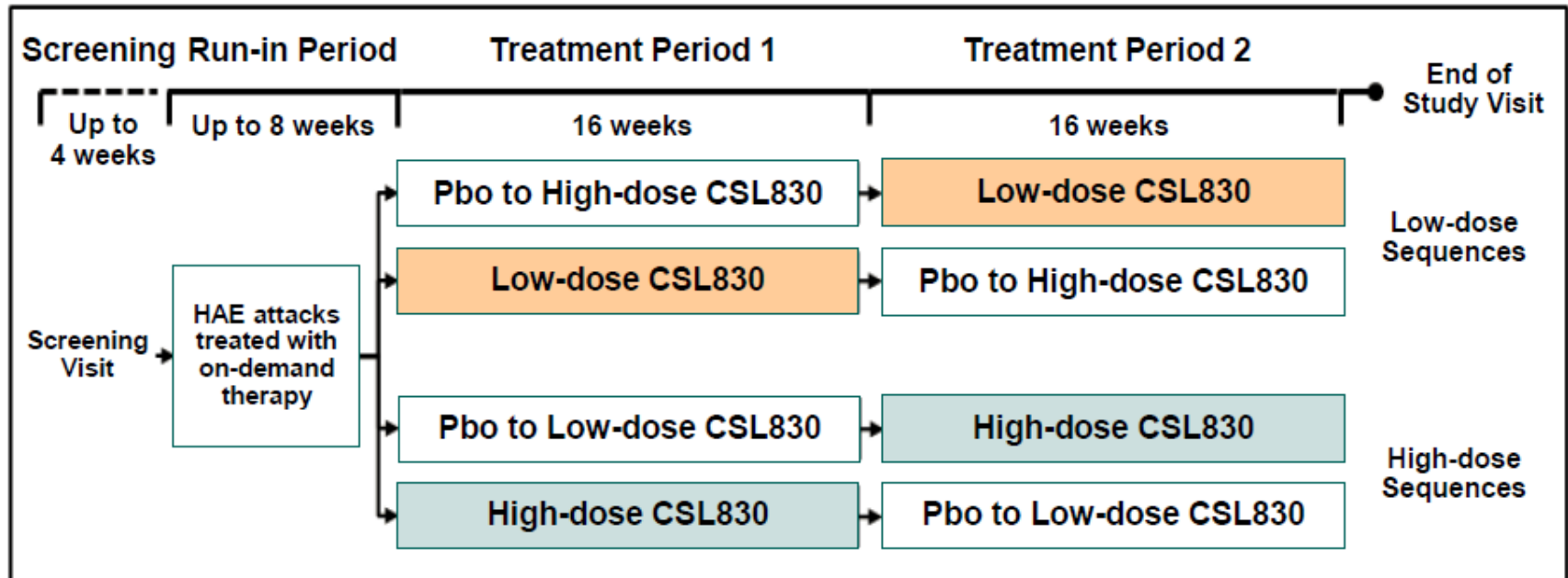
Primary Endpoint



CSL830 Phase III Study Design

COMPACT

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



*Pbo = Placebo

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

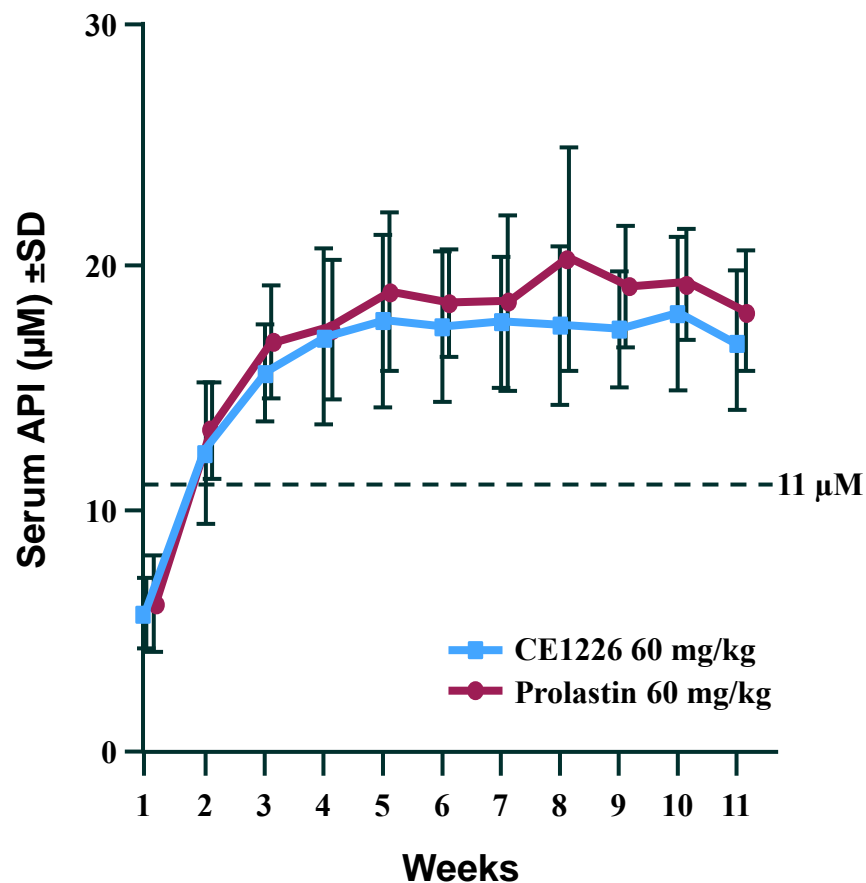
Zemaira is the first highly purified alpha-1 augmentation therapy approved by the FDA for chronic augmentation and maintenance therapy of adults with alpha-1 and emphysema

Seeking to broaden use through approval in EMA in 2015

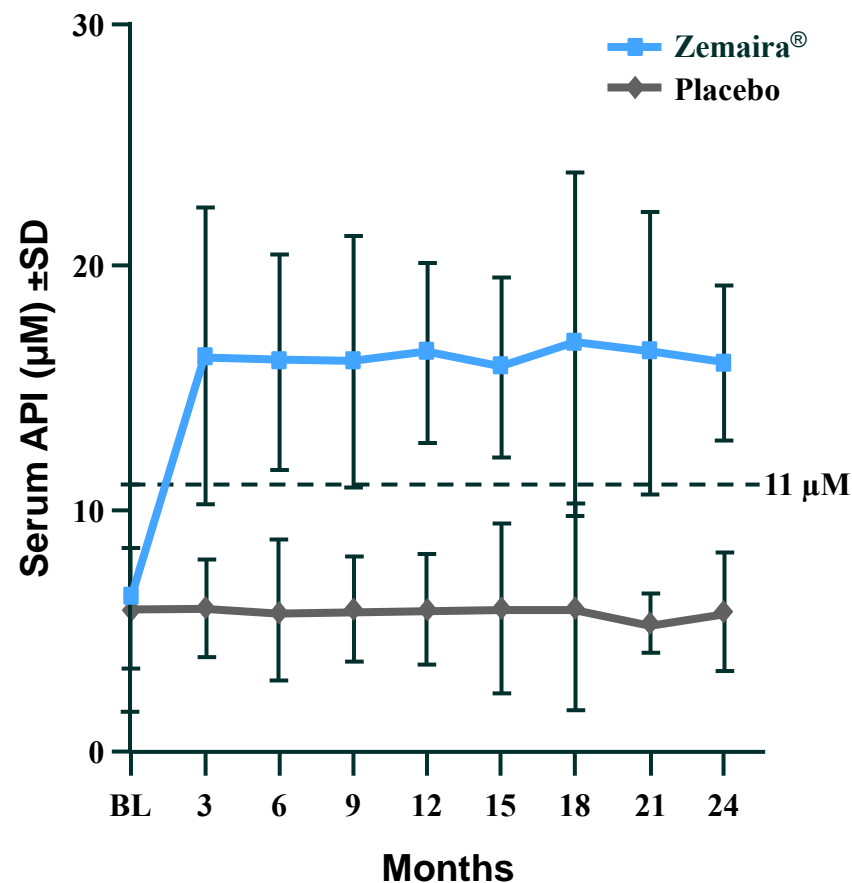
- Completed RAPID trial in 2013
- Under review with EMA

Zemaira® Biochemical Efficacy

Study CE1226_2002
Equivalence to Prolastin®

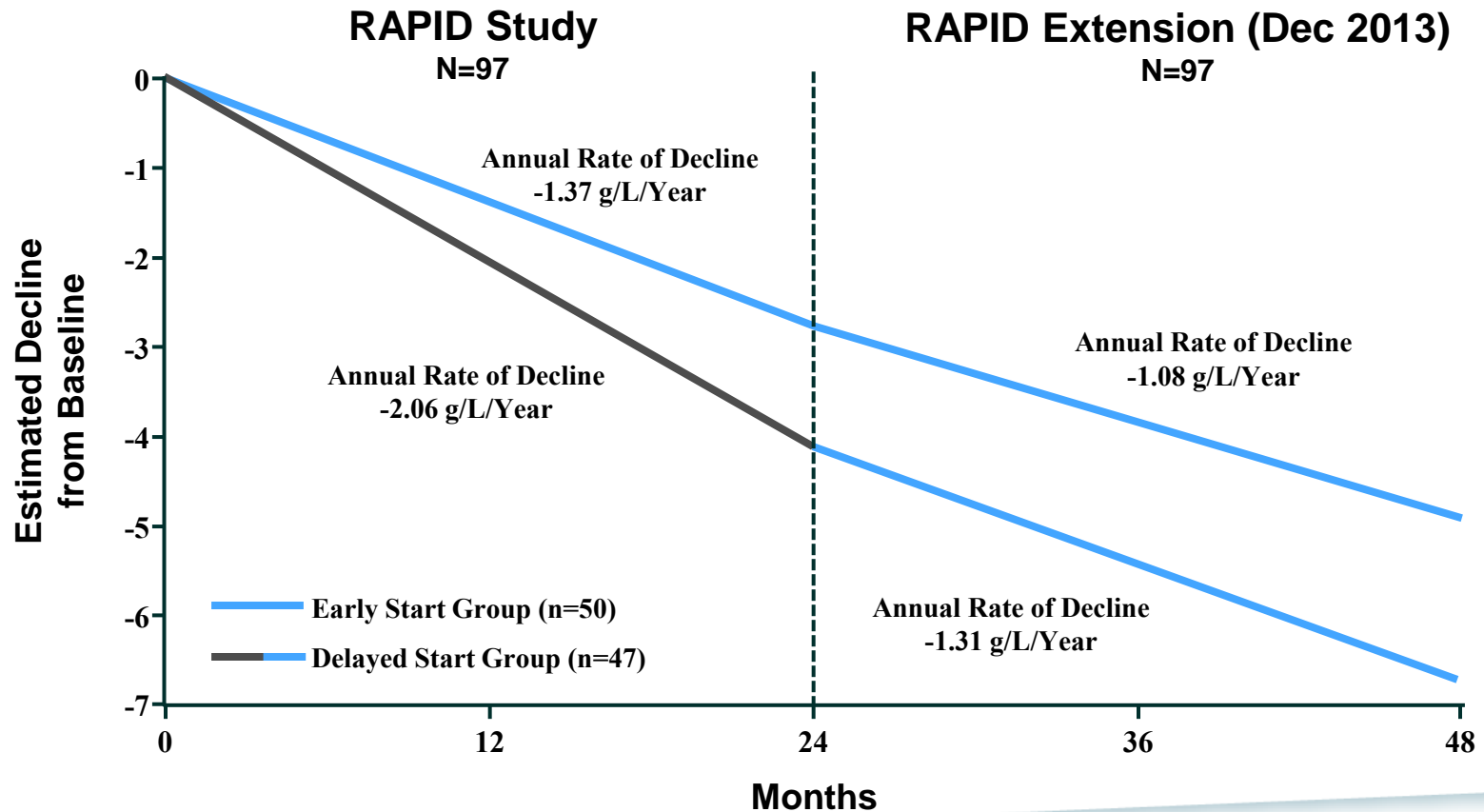


RAPID Study



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

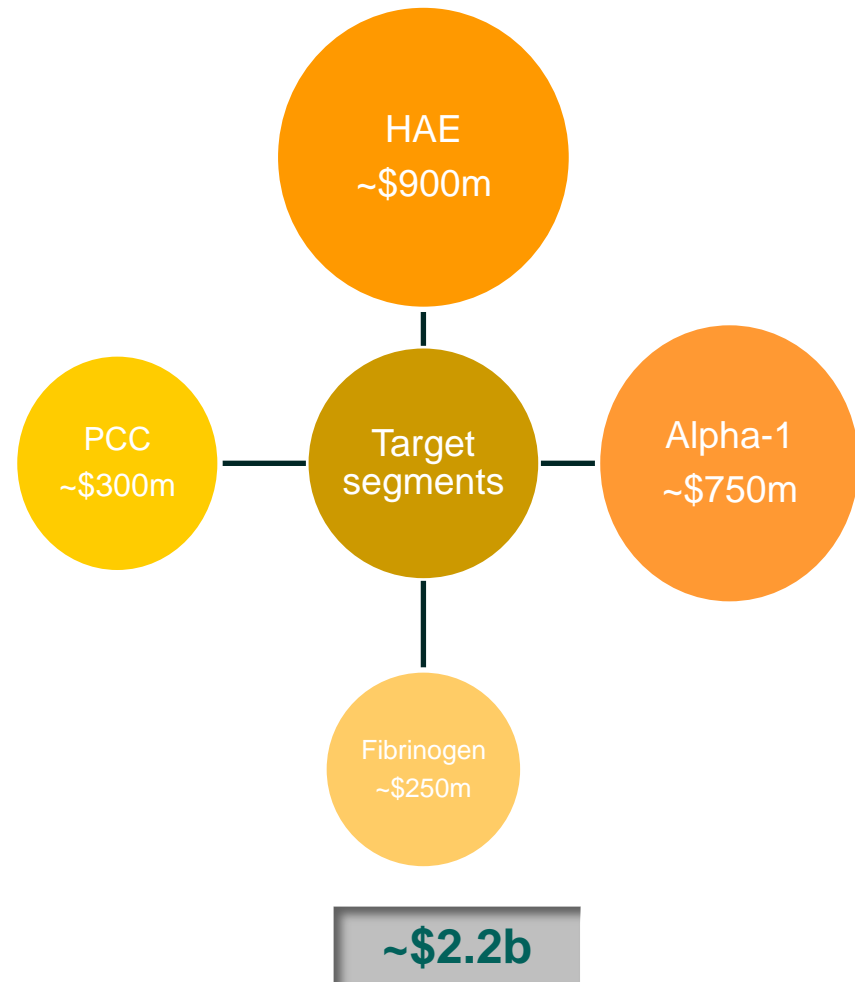
Estimated Rate of Decline in Physiologically Adjusted P15 at TLC



Commercial Opportunities and Activities

Select Specialty Products – Global Markets

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



CSL's Specialty Products Portfolio

2013/14 Sales (USD)

Other Specialty
Products

BERINERT[®]

Zemaira[®]
alpha₁-proteinase inhibitor (Human)

Beriplex[®] P/N
Prothrombin Complex Concentrate

Kcentra[™]
Prothrombin Complex
Concentrate (Human)

RIASTAP[®]
Fibrinogen Concentrate

HAEMOCOMPLETTAN[®] P
Fibrinogen Concentrate

Peri-Operative
Bleeding

- Increase demand
- Geographical expansion
- Education and diagnosis

\$848m



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 expansion¹

- Eastern Europe
- Japan

Life cycle management

- Improved virus filtration
- New 1000IU vial

Berinert treats the fundamental cause of HAE symptoms by providing C1-Inhibitor deficient patients with the missing human protein¹

Berinert has demonstrated that it provides fast relief of pain and swelling within 30 minutes²

Geographical expansion

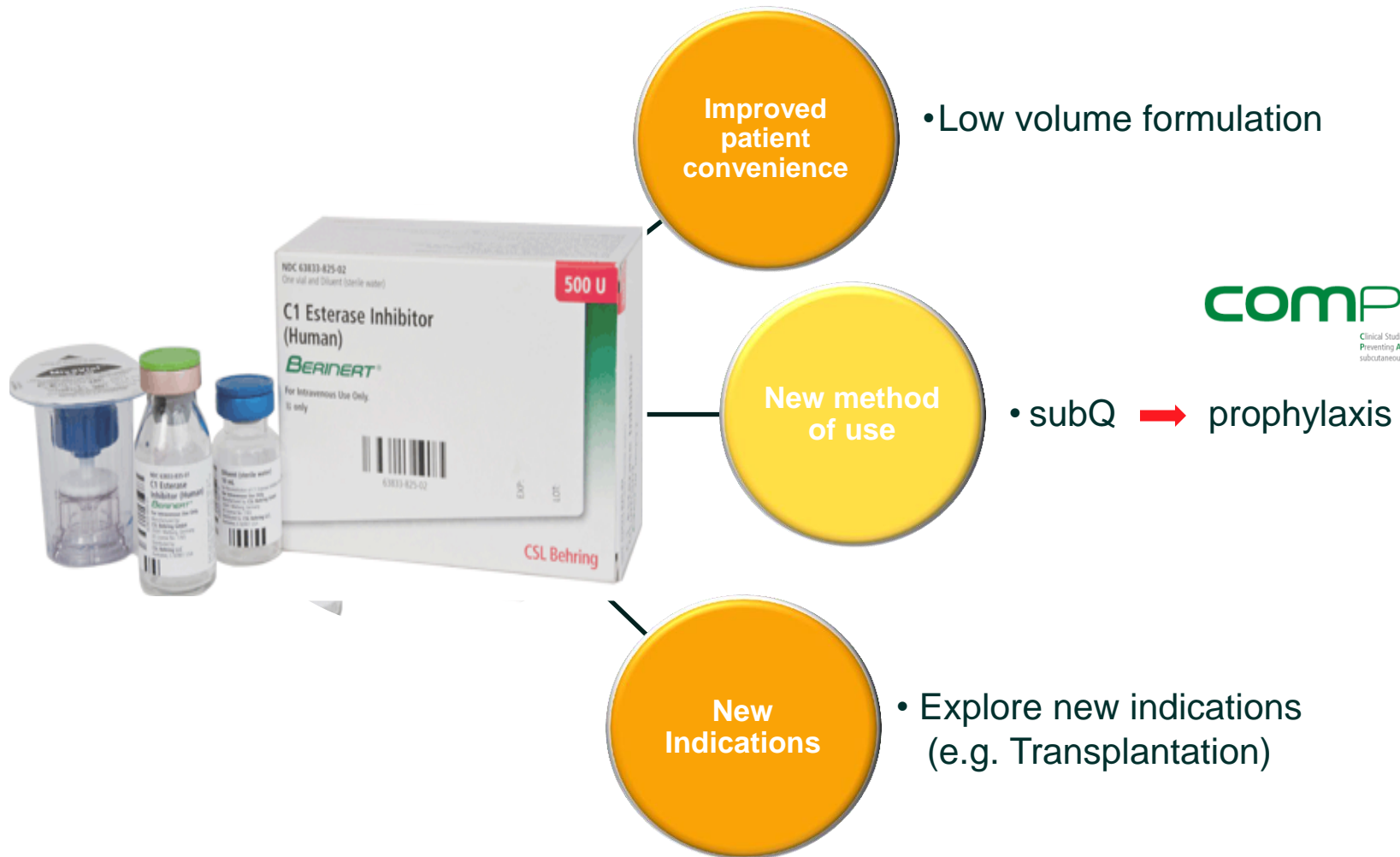
- Asia
- Latin America
- Russia

Patient care and convenience

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

Berinert® Key Features

BERINERT®



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

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

DNA₁ 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 DNA₁ test

Continued investment

- Expand US sales force
- Explore new formulations

Geographical expansion

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

RAPID data

- Publish in high impact journal
- Medical Affairs education

Q&A

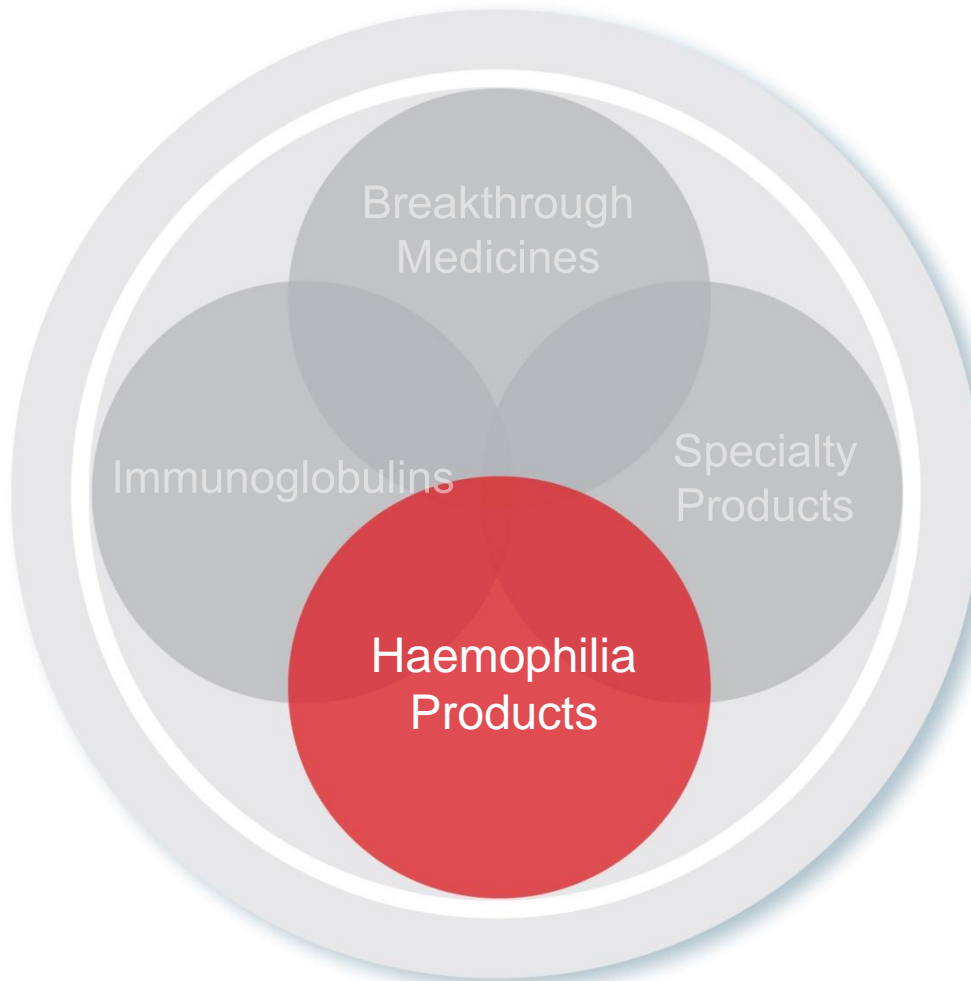
Break

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

Scientific Edge

Improved
half life,
extended
dosing
interval

rAlbumin
as fusion
platform

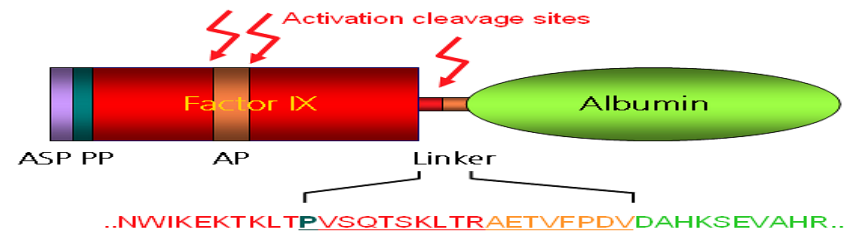
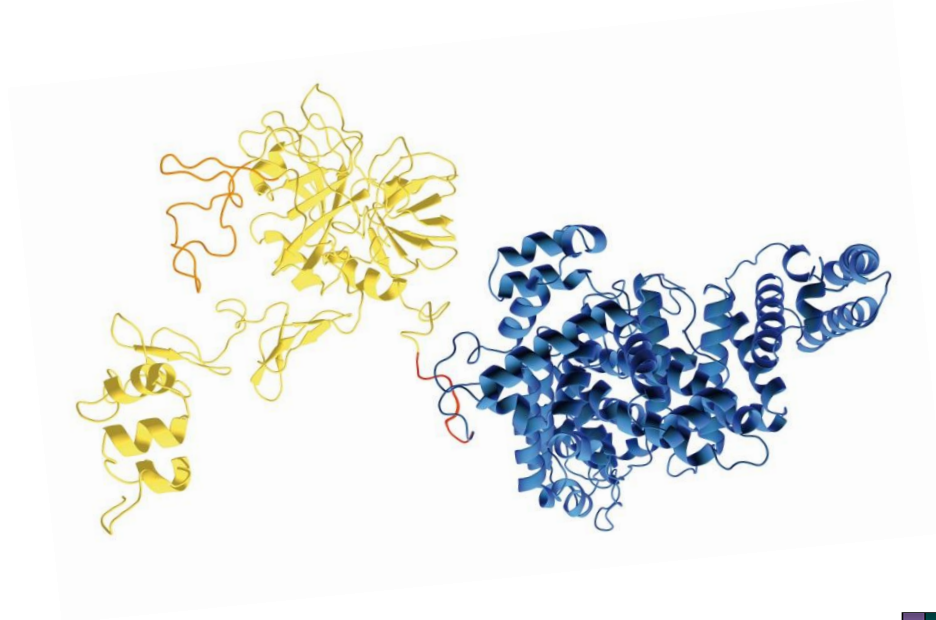
Precise
engineering
of
specially
designed
linker

Strong vWF binding

Greater molecular integrity and
stability

Opportunity for Extended
Dosing Interval

PROLONG-9FP Clinical Development Program: rIX-FP



PROLONG **9** FP

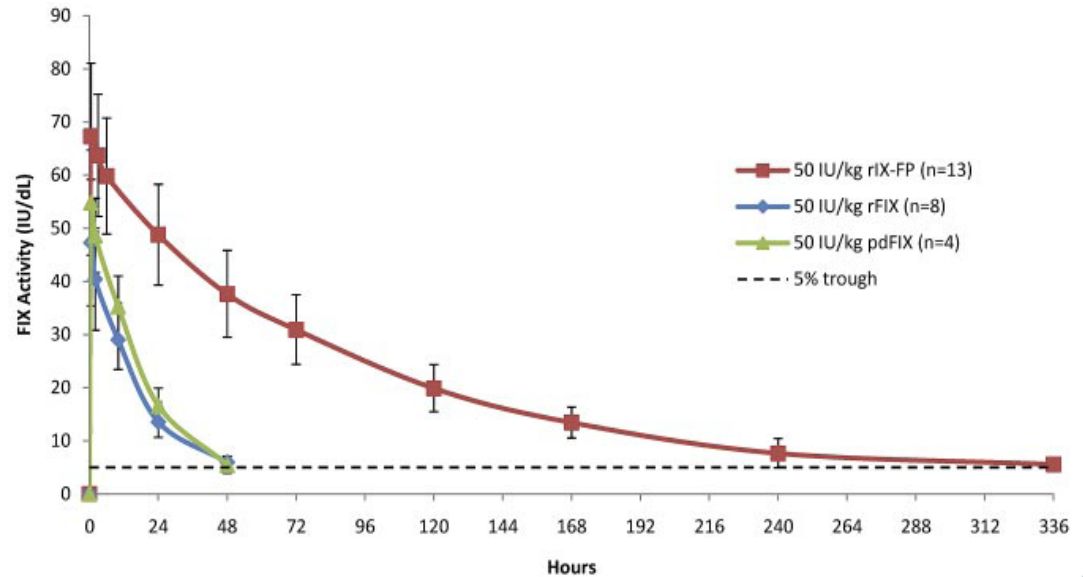
www.clinicaltrials.gov

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

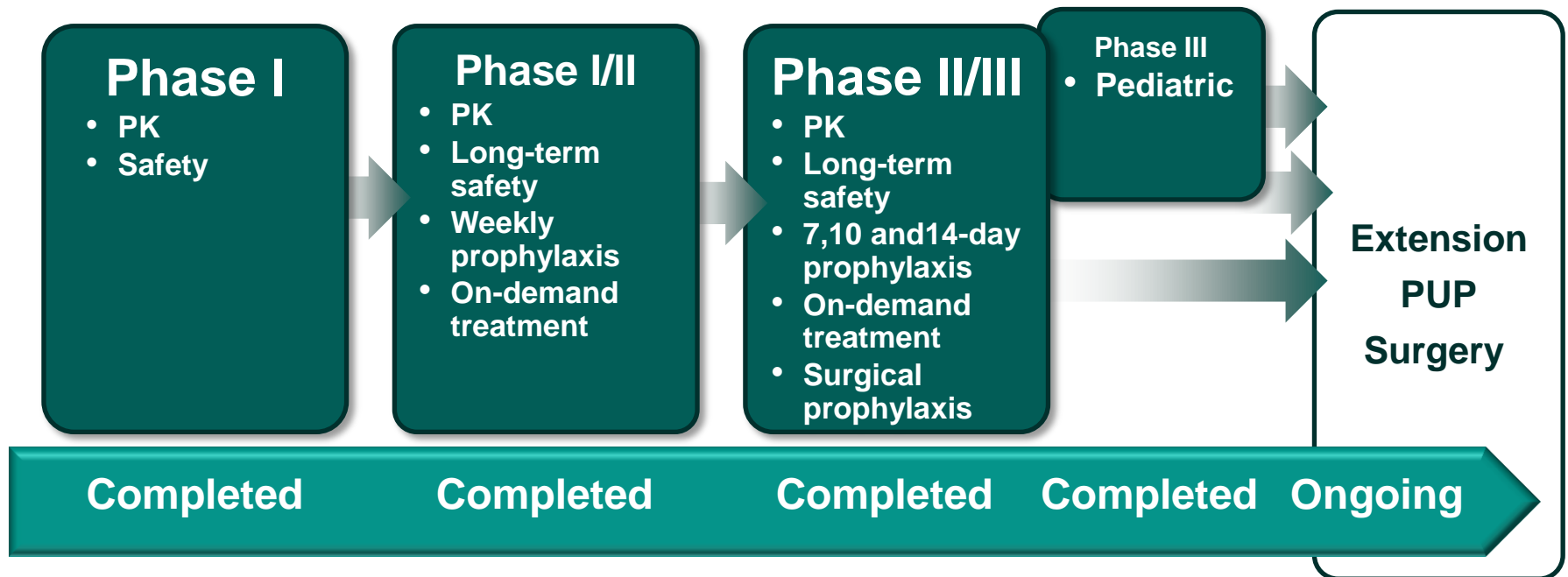
Elena Santagostino, Claude Negrier, Robert Klamroth, Andreas Tiede, Ingrid Pabinger-Fasching, Christine Voigt, Iris Jacobs and Massimo Morfini

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-9FP Clinical Development Program: rIX-FP



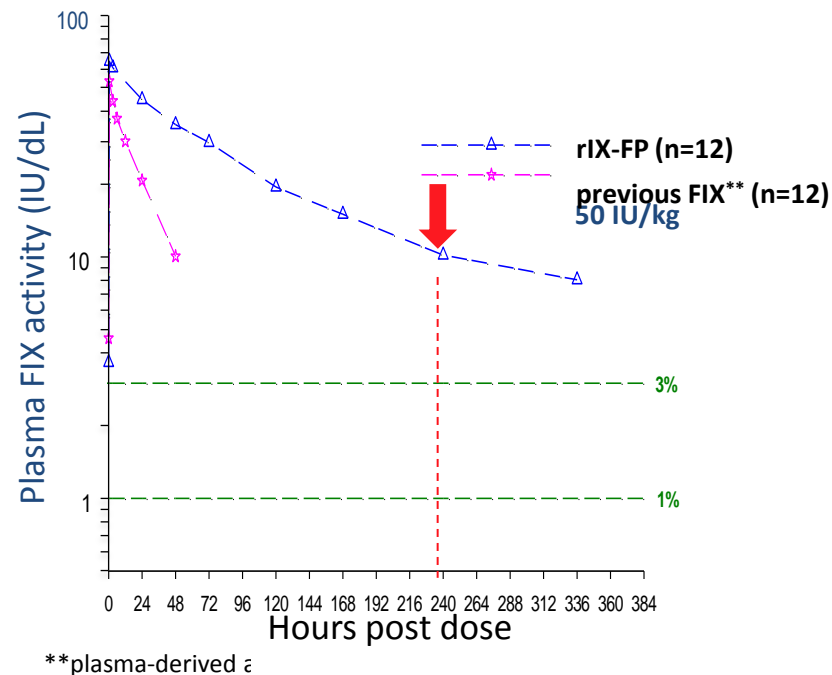
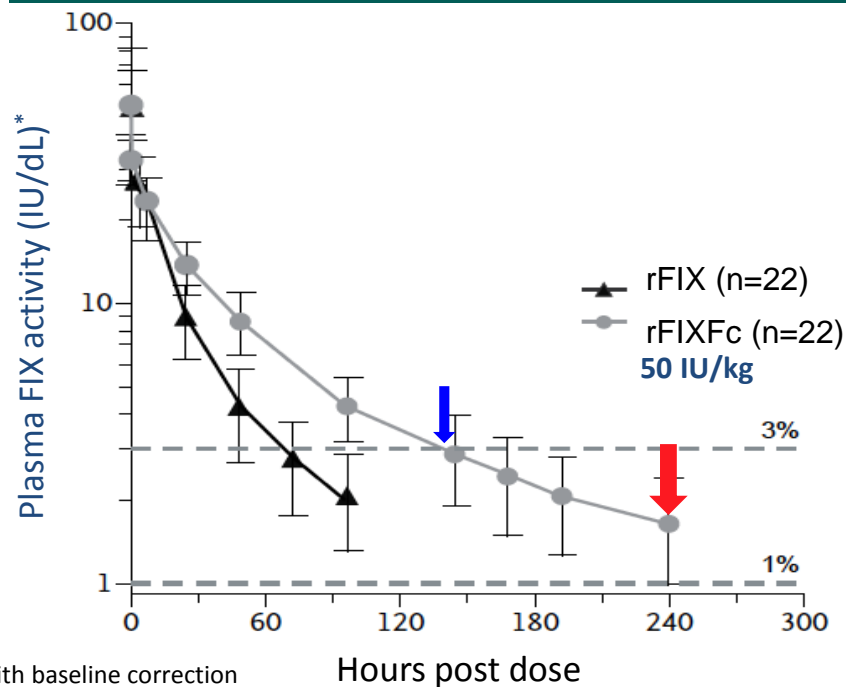
PROLONG-9FP Clinical Results Summary



- 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



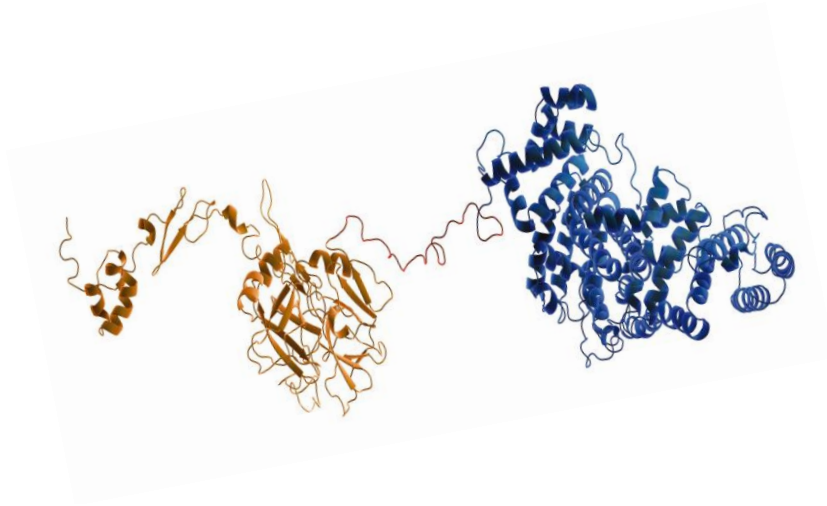
Plasma FIX activity-time profiles in ≥ 12 -year olds

rIX-FP (CSL654) Clinical Development

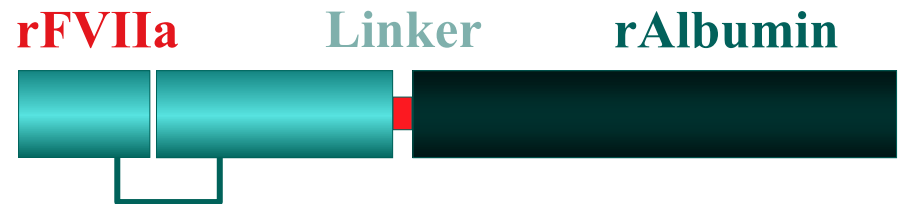
- All patients now in extension study
- Dossier submission for adult and paediatric indications
 - FDA Dec 2014
 - EMA Q2 2015



rVIIa-FP (CSL689)



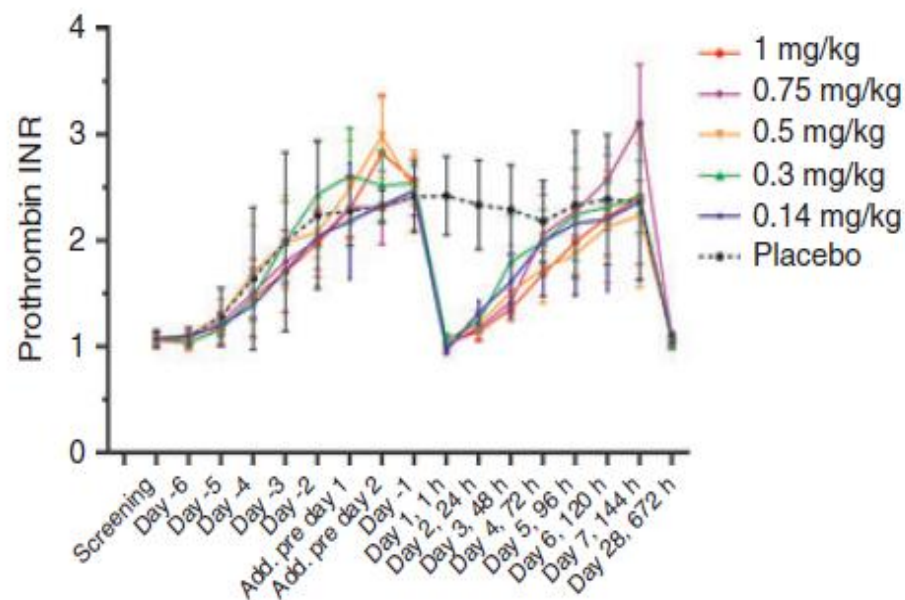
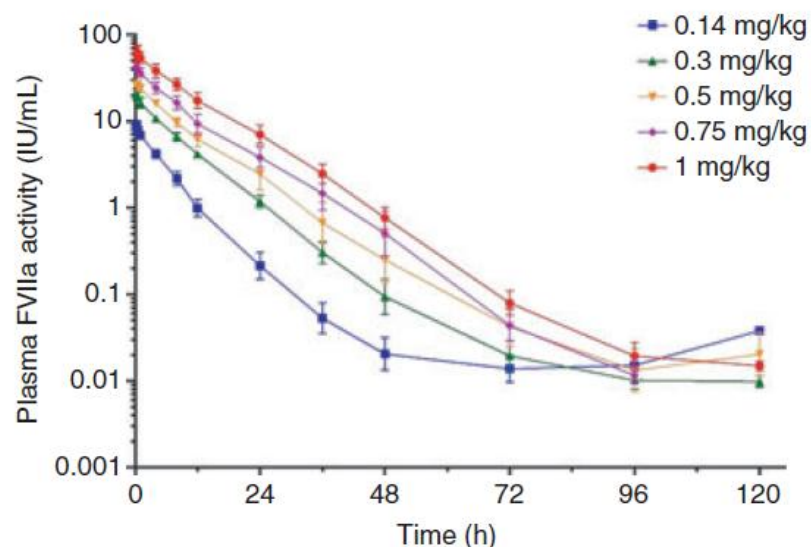
PROLONG **7** FP



ORIGINAL ARTICLE

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

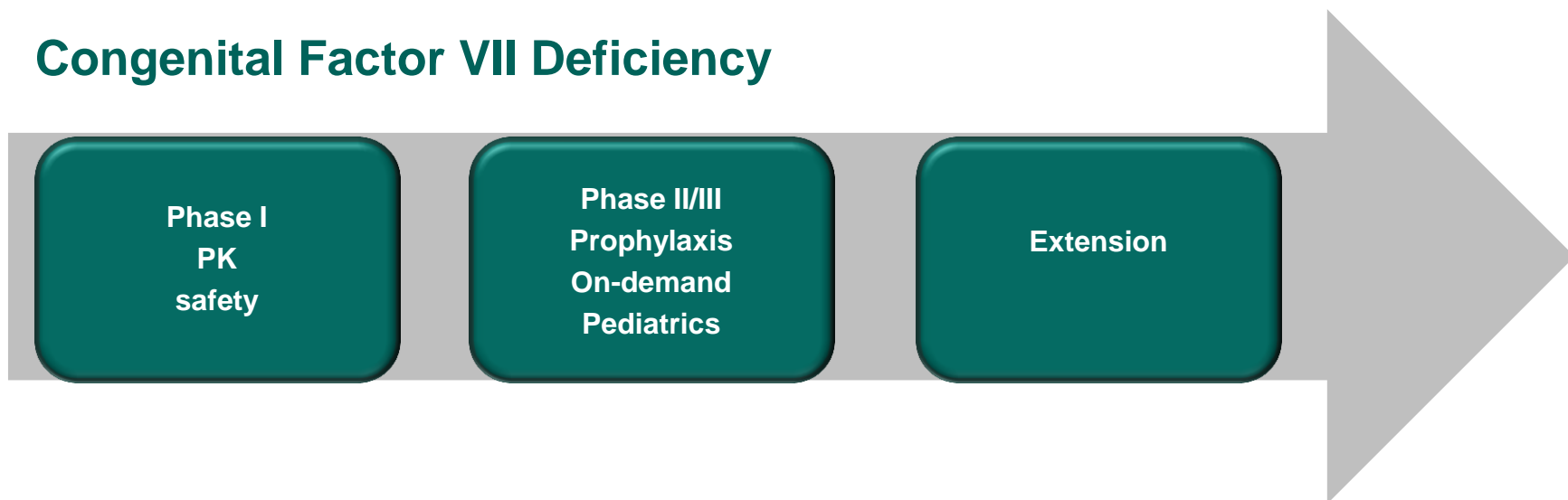
G. GOLOR,* D. BENSEN-KENNEDY,† S. HAFFNER,* R. EASTON,† K. JUNG,‡ T. MOISES,‡ J.-P. LAWO,‡ C. JOCH‡ and A. VELDMAN‡



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

rVIIa-FP Clinical Development Program

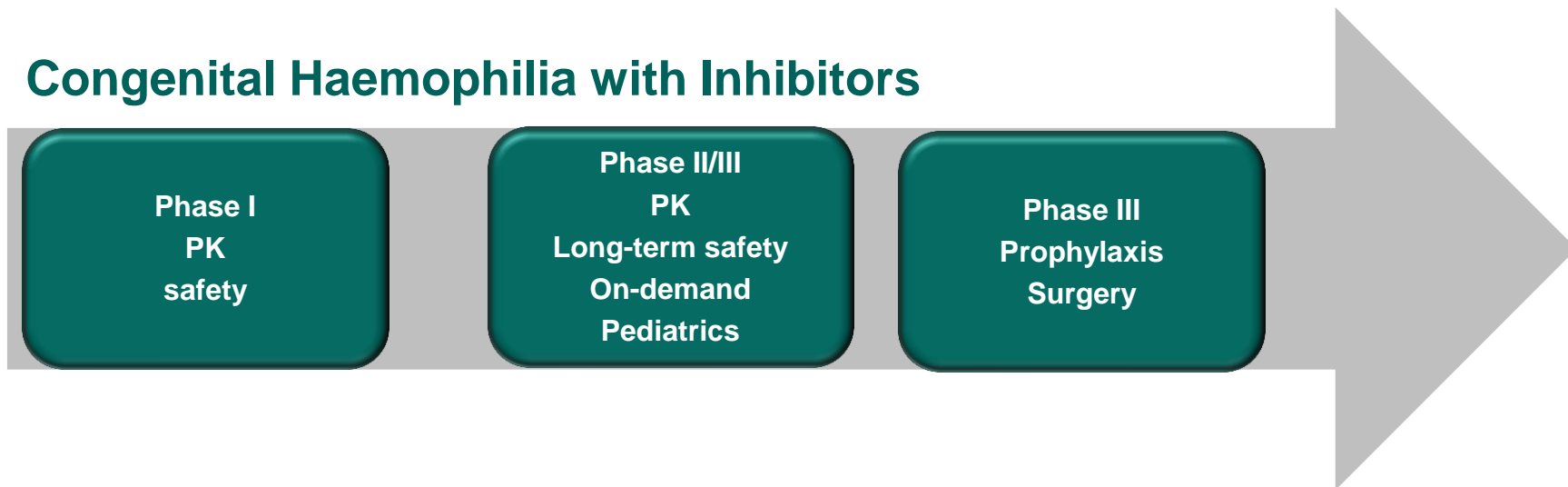
Congenital Factor VII Deficiency



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

rVIIa-FP Clinical Development Program

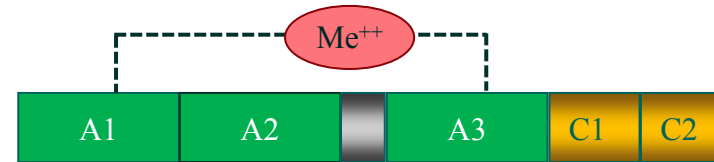
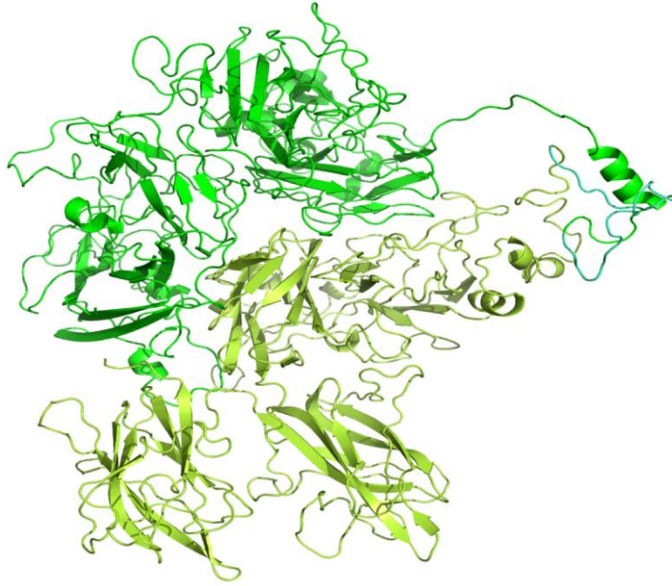
Congenital Haemophilia with Inhibitors



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

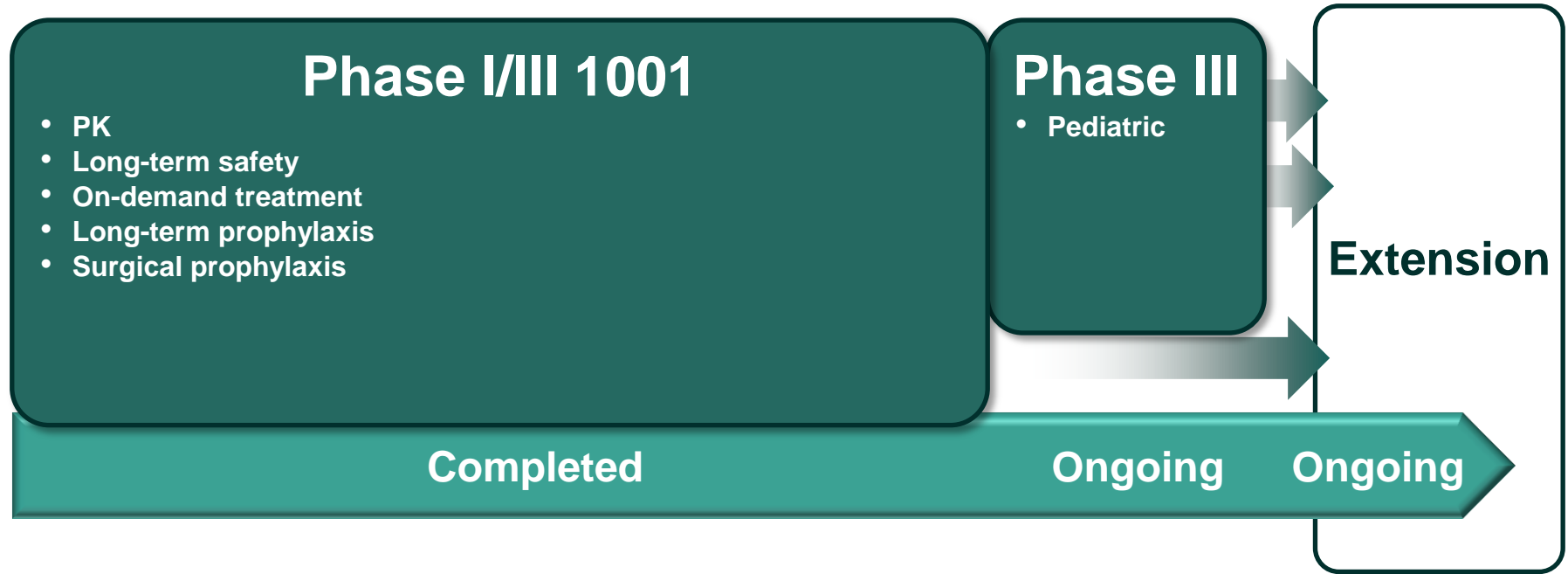
PROLONG **7** FP

rVIII-SingleChain (CSL627)

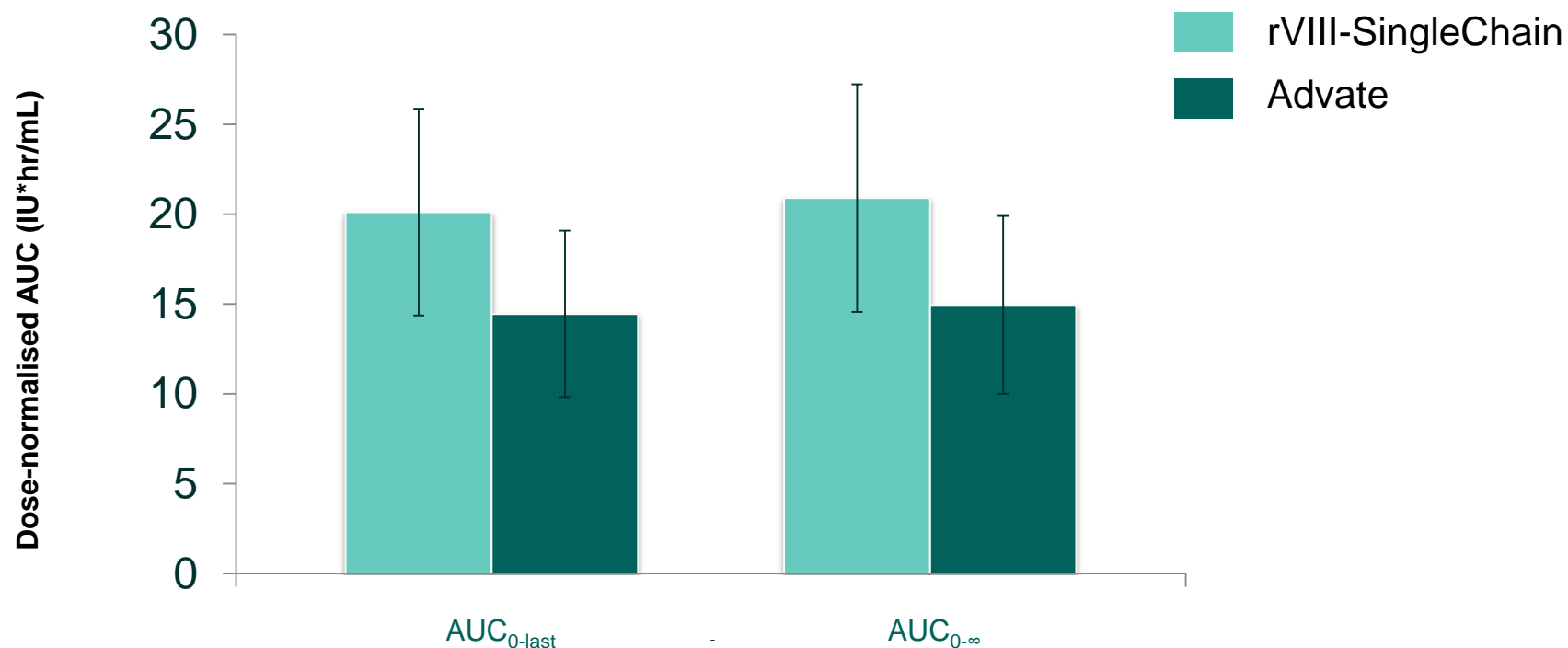


rVIII-SingleChain

AFFINITY Clinical Development Program: rVIII-SingleChain

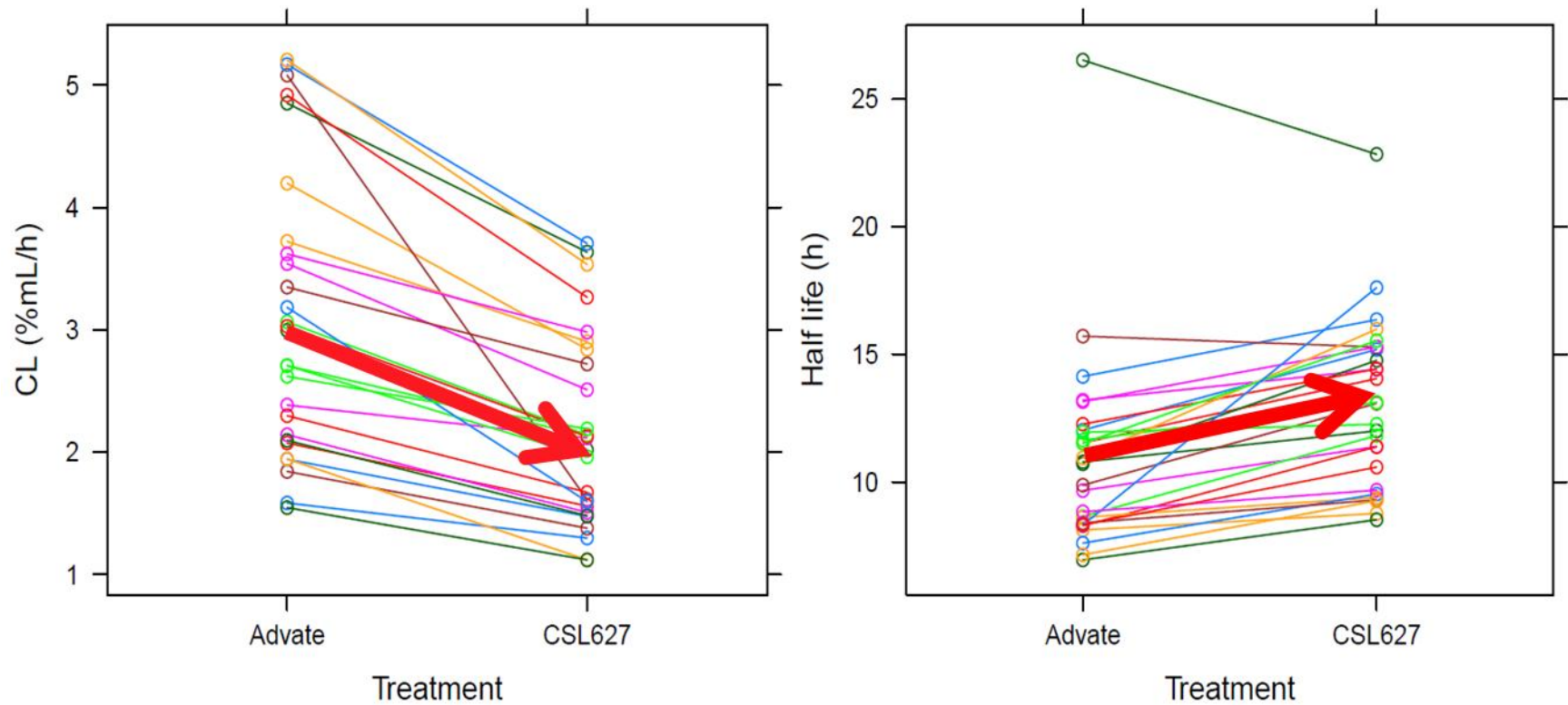


CSL627 PK Evaluation: Area Under the Curve



*Dose-normalised baseline-corrected FVIII activity AUC_{0-last} and $AUC_{0-\infty}$ 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 \pm SD n=27

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

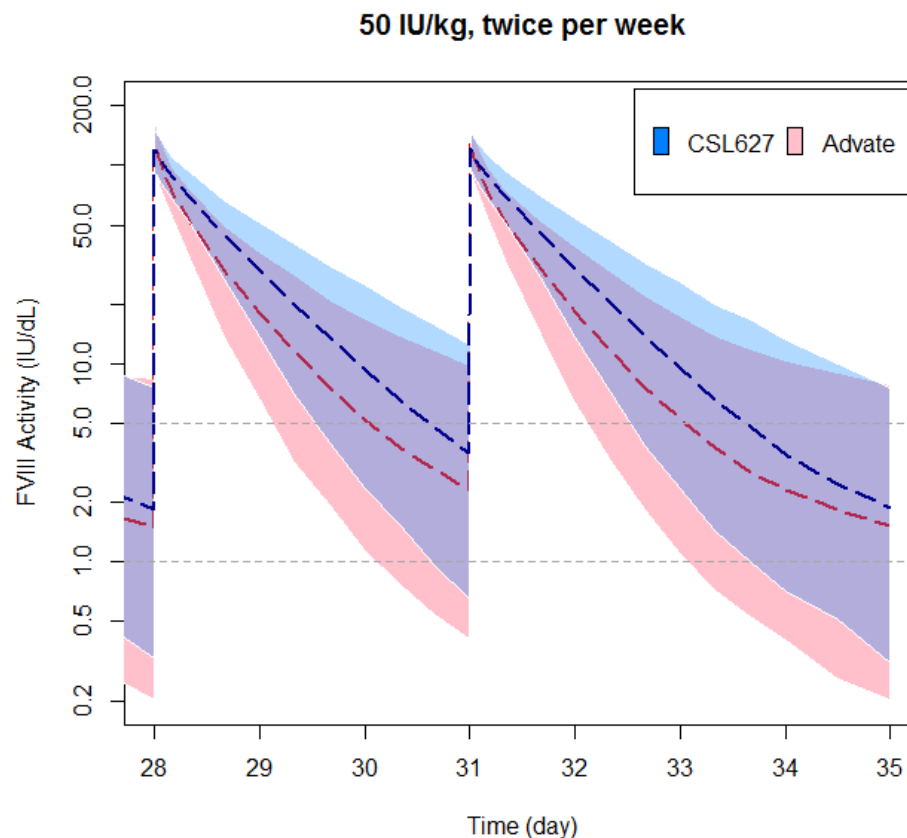


*Dose-normalised baseline-corrected FVIII activity Clearance and half-life in plasma following a single intravenous administration of rFVIII-SingleChain or Octocog alpha. FVIII activity determined by chromogenic assay and normalised by individual dose to 50 IU/kg. n=27

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

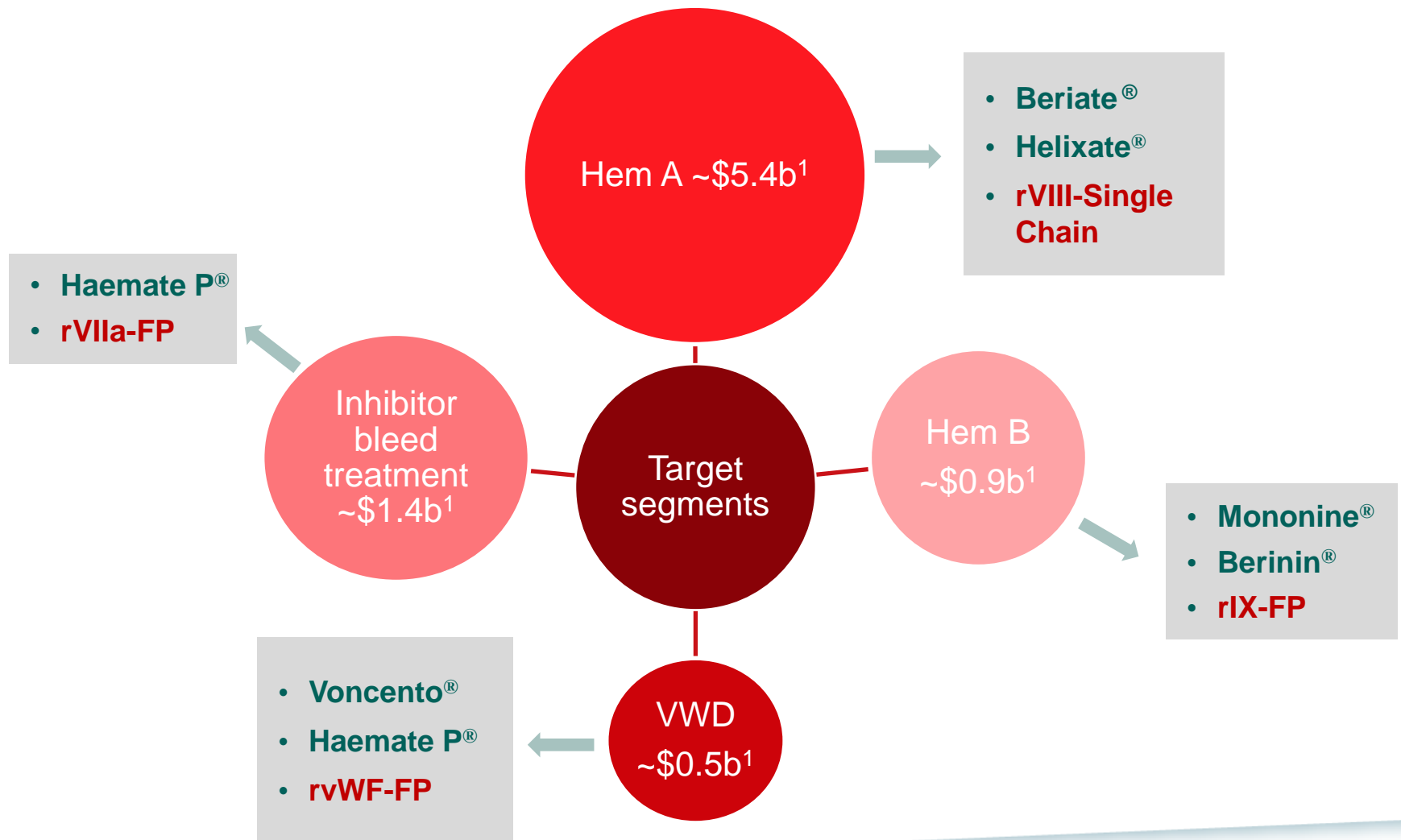


rVIII-SingleChain Phase I/III Study

- 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

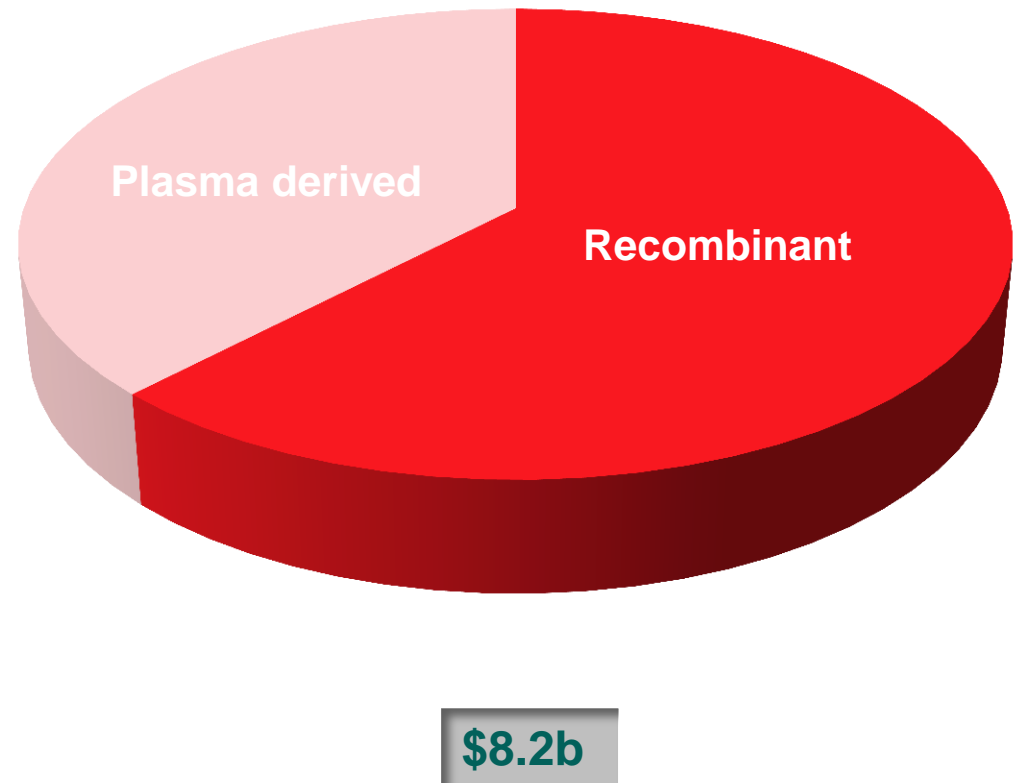
Commercial Opportunities and Activities

Coagulation: Key Market Segments (USD)



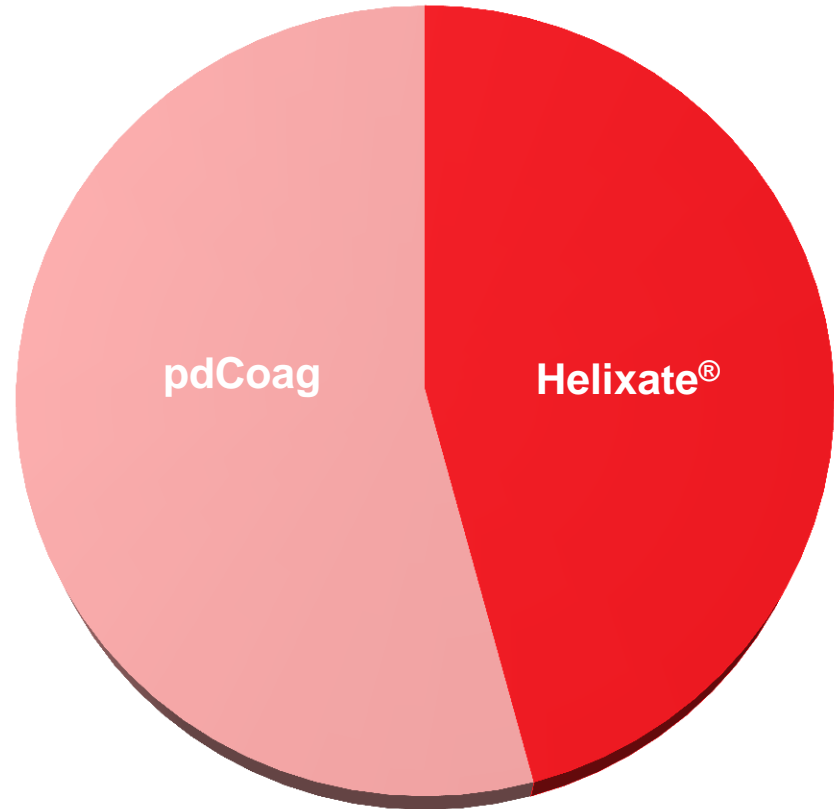
Global Haemophilia Market (USD)

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

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

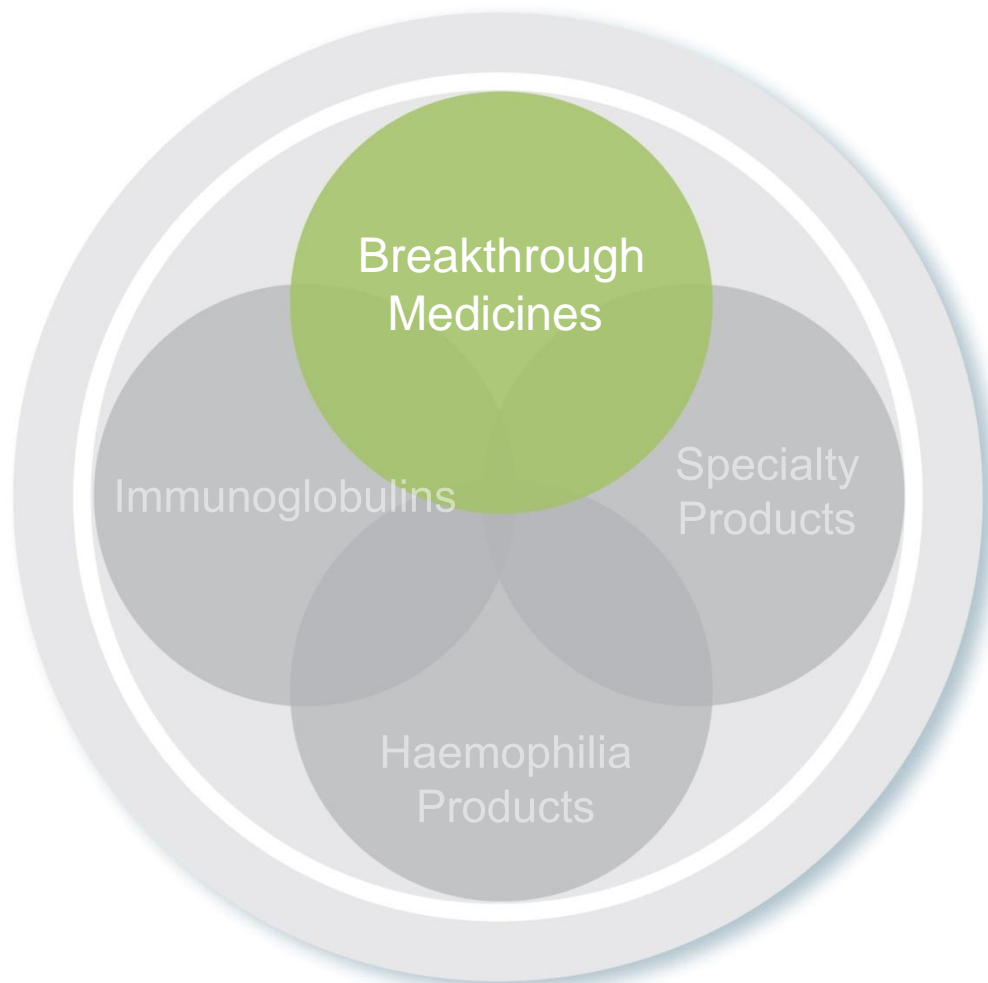
- Hemophilia B – long acting → rIX-FP
- Hemophilia A – longer acting → rVIII-SingleChain
- Inhibitors – long acting → rVIIa-FP

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

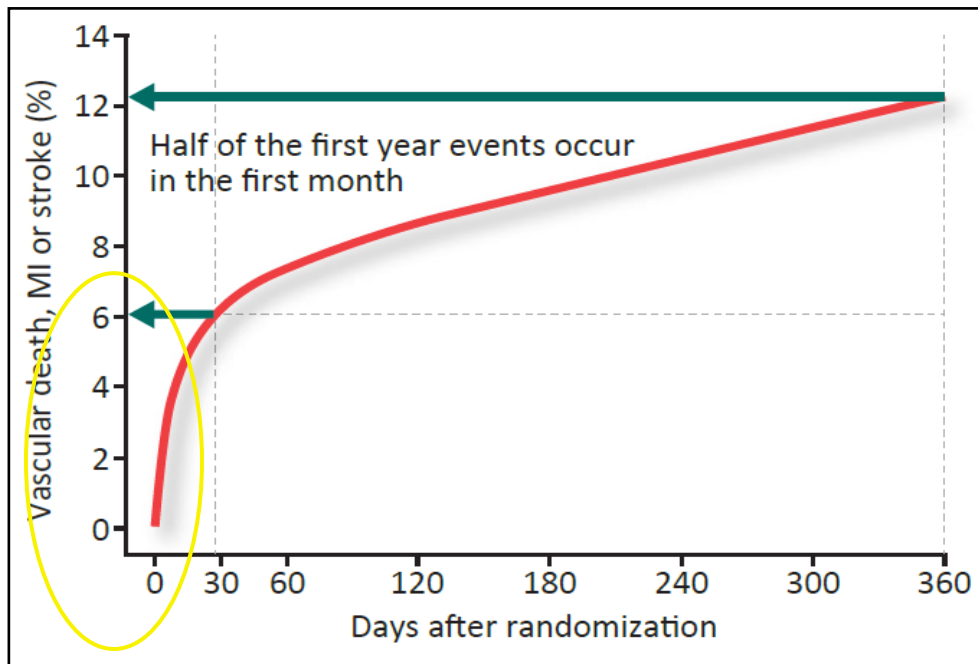
- Significant unmet need
- Multiple indications

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

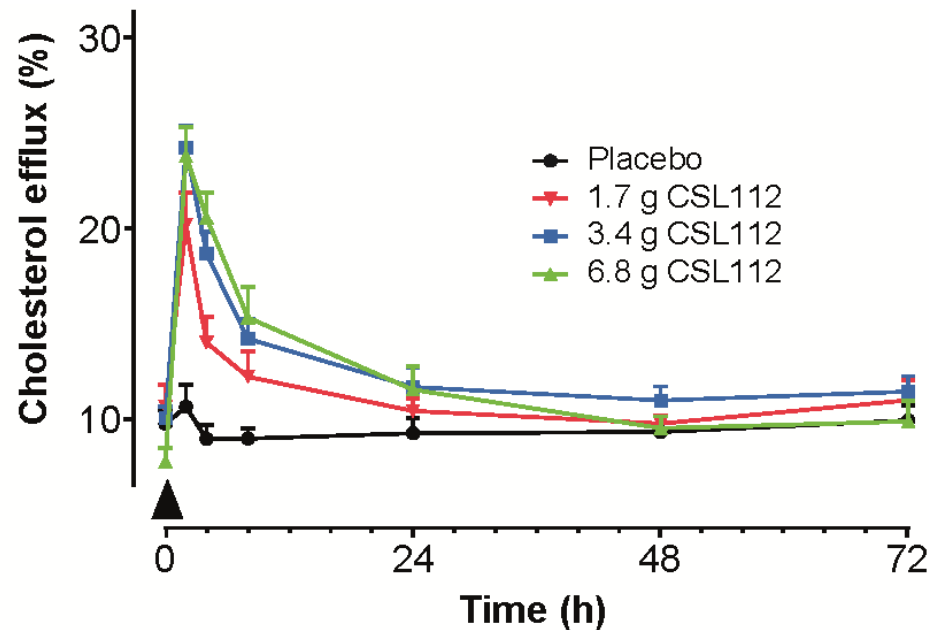


- Recurrent CV events occur early, are associated with high mortality and are inadequately addressed by available therapies

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 early recurrent cardiovascular events

CSL112 AHA Presentations

Nov 18, 2014

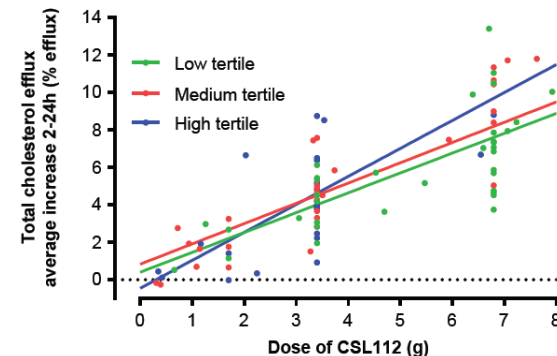
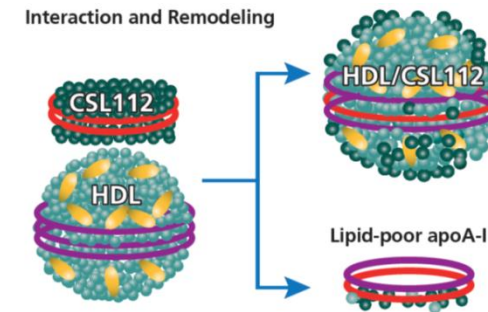
Further elucidation of mechanisms by which CSL112 may rapidly stabilise plaque at risk of rupture

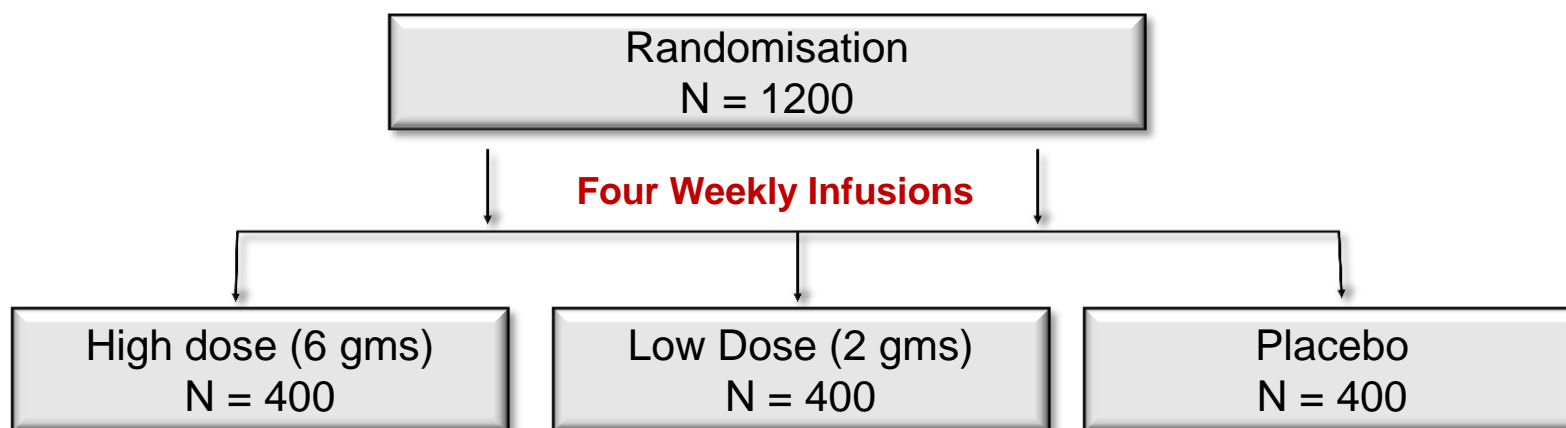
Mechanism of HDL Remodeling Induced by CSL112

- 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





Administered in acute MI setting

Primary endpoint: liver and renal safety

To be followed by Phase 3 morbidity/mortality trial

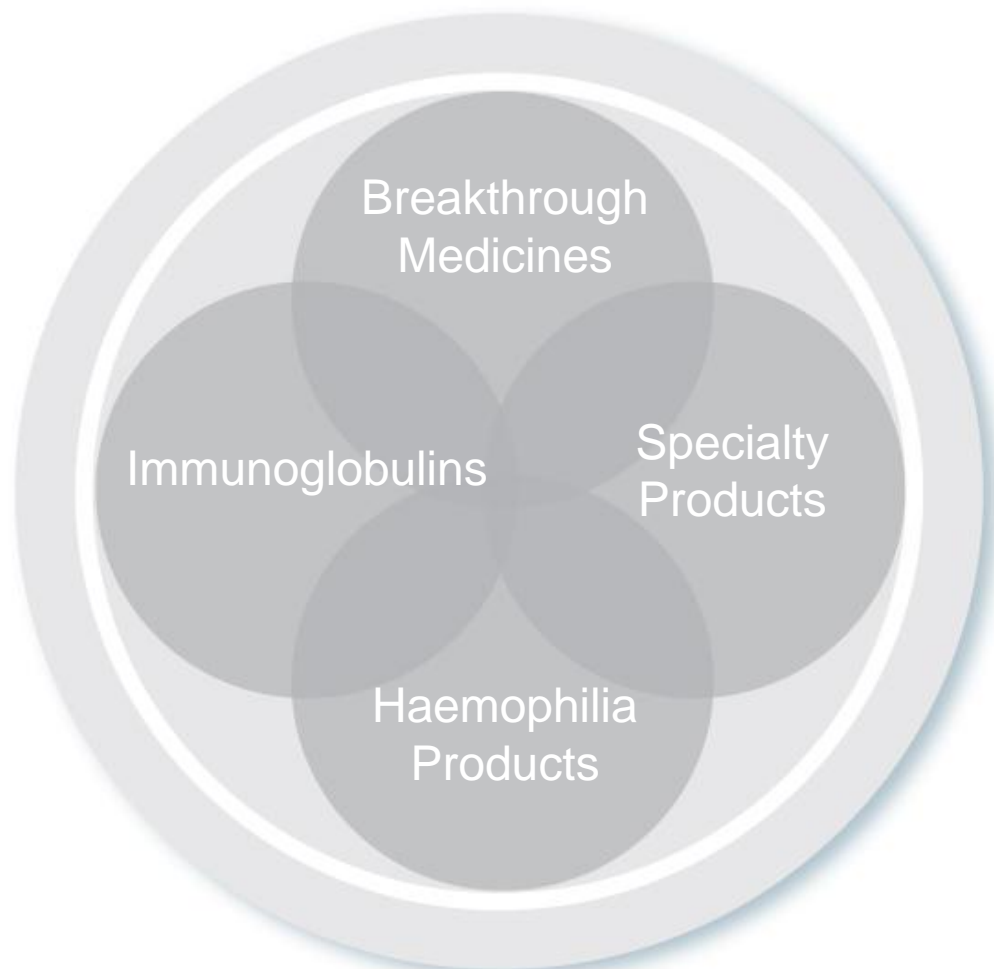
Target indication

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-CSFR α - Medi/AZ)
 - Periodontal disease (Sanofi)
 - CSL362 (Janssen)
 - CSL334 (ASLAN)
- ISCOMATRIX[®] adjuvant

- 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

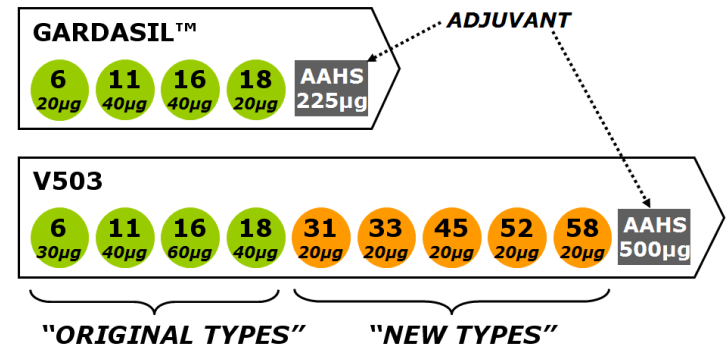
- Current Australian cervical screening program data show that rates of high grade cervical disease are declining in both the <20 year old age group and in women aged 20–24 years

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®

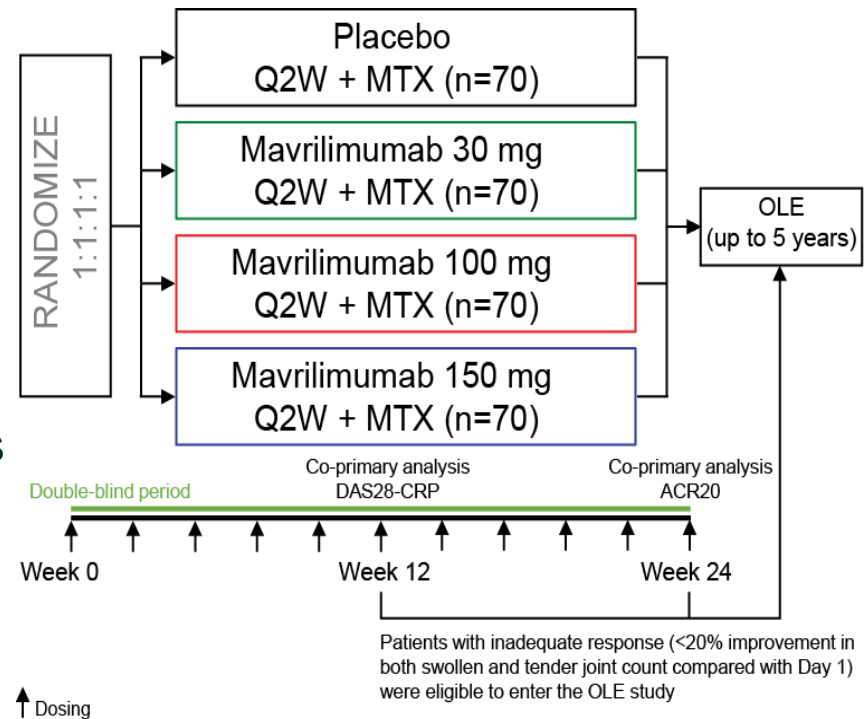
- Long term protection
 - Follow up studies up to 8 years demonstrate no break through disease
- V503: 9-Valent HPV Vaccine
 - Merck's 2nd generation HPV vaccine
 - Phase III data: prevented 97% cervical, vaginal and vulvar pre-cancers caused by additional 5 types
 - US - BLA Dec 2013 for 2015 launch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



Mavrilimumab (GM-CSFR α mAb)

Phase IIb (EARTH EXPLORER 1) study:

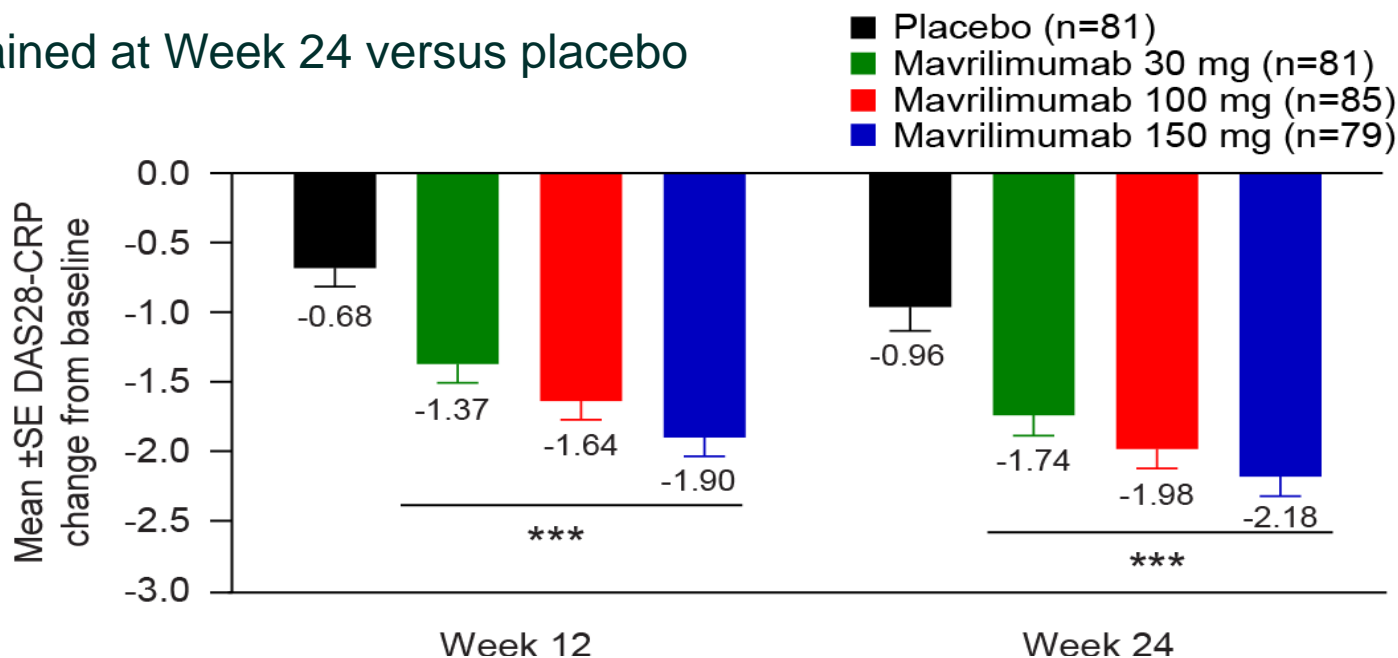
- 326 patients with moderate-to-severe RA and an inadequate response to at least one disease-modifying anti-rheumatic drug
- Dosing (30, 100, 150mg) every 2 weeks for 24 weeks
- Co-primary endpoints
 - Mean change from baseline in DAS28-CRP at Week 12
 - ACR20 response rate at Week 24
- Other endpoints
 - 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

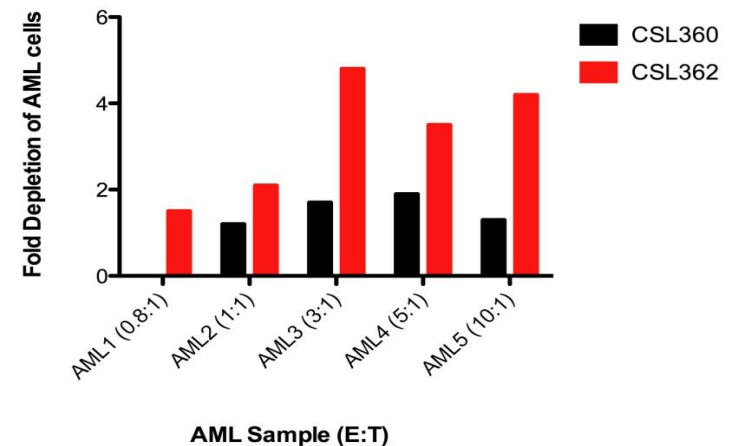
Mavrilimumab

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-3R α 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

	Research	Pre-clinical	Phase I	Phase II	Phase III	Registration	Commercial/ Phase IV
Life Cycle Management[#]							Immunoglobulins Haemophilia Specialty Products Influenza Vaccine
Market Development		Fibrinogen New Indications PCC New Indications		Beriplex [®] NOACs Daiichi*	Hizentra [®] CIDP Beriplex [®] Japan CSL830 C1-INH subcut Fibrinogen Aortic EU	Zemaira [®] EU	Hizentra [®] Japan Privigen [®] CIDP Hizentra [®] biweekly Voncento [®] EU Kcentra [™] US Bleeding /Surgery
New Product Development	Novel Plasma Proteins Rec Coagulation Factors Partnered Vaccine Programs* P. gingivalis/POD OH-CRC/Sanofi* Discovery Projects	CSL650 rVWF-FP Partnered Vaccine Programs* FXIIa Antagonist CSL324 G-CSFR CSL346 VEGFB CSL334 IL-13R	CSL689 rVlla-FP Congen Def Partnered Vaccine Programs* CSL362 IL-3R* Janssen	CSL689 rVlla-FP Inhibitors CSL112 reconstituted HDL CAM3001 GM-CSFR –AZ*	CSL627 rVIII-SC Quadrivalent Flu Vaccine	CSL654 rIX-FP	

Core Capabilities:

Immunoglobulins

Haemophilia

Specialty Products

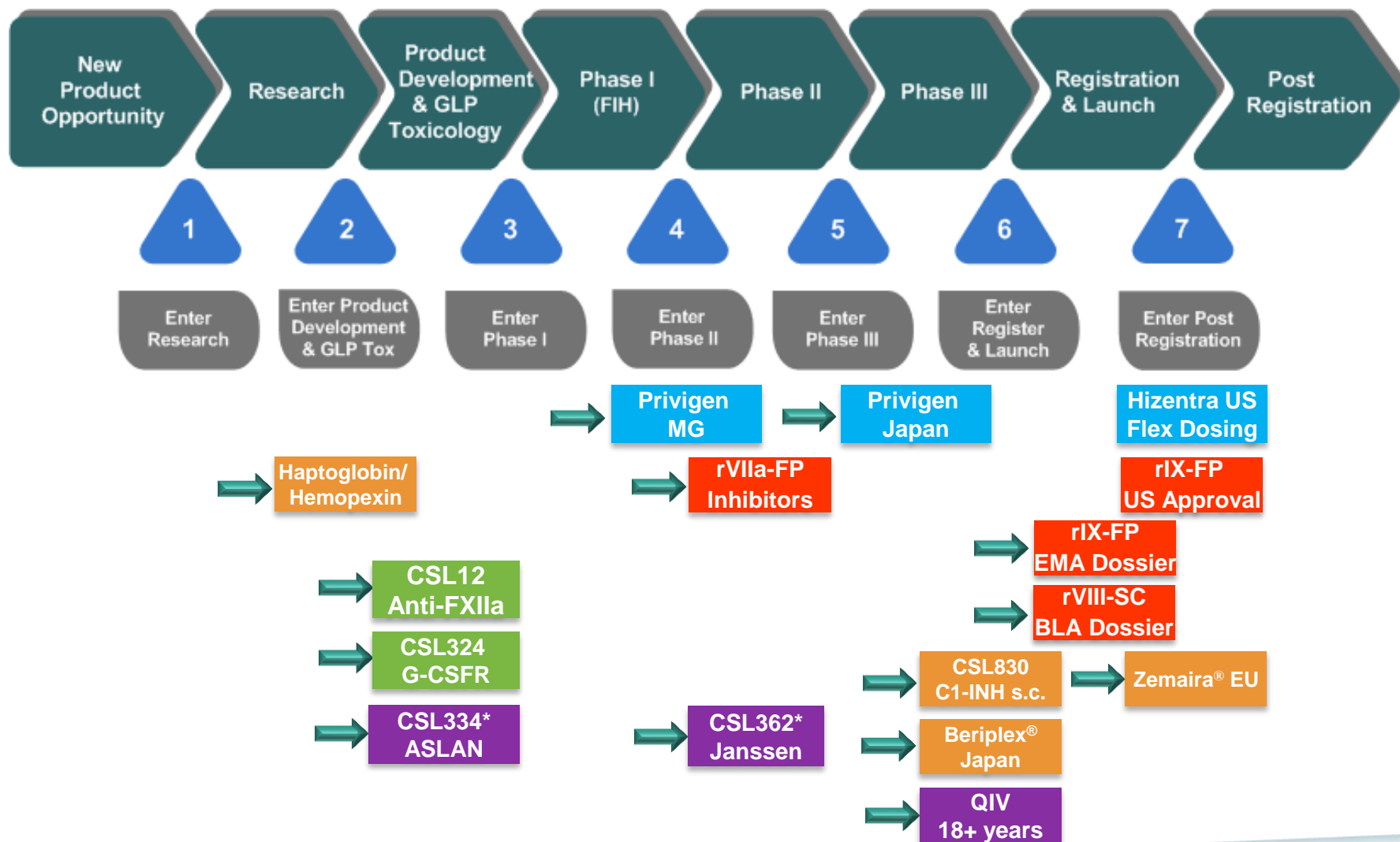
Breakthrough Medicines

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

2014	2015	2016	2017	2018	2019
Voncento™ Haem A EU	Voncento™ V WD EU	CSL654 rIX-FP US CSL654 rIX-FP EU CSL627 rFVIII-SC US	CSL654 rIX-FP Japan CSL627 rFVIII EU/Japan		CSL689 rVIIa-FP Congen Def
Kcentra™ Surgical	Zemaira® EU		CSL830 C1-INH SubCut Beriplex® Japan Fibrinogen EU Aortic Surgery		
Hizentra® Japan		Quadrivalent Flu Vaccine 18+		Hizentra® CIDP Privigen® Japan PID/SID	

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.

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