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ASX Announcement

For immediate release

4 December 2019

ANNUAL RESEARCH AND DEVELOPMENT INVESTOR BRIEFING

Melbourne, Australia – CSL (ASX:CSL; USOTC:CSLLY)

Please find attached the presentation and an accompanying media release ahead of CSL's Annual Research and Development Investor Briefing being held today at 9am ADST.

The briefing will be webcast and can be accessed in the "Investor" section of CSL's website (www.CSL.com).

Fiona Mead
Company Secretary

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R&D Investor Briefing

December 4, 2019

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Introduction

William Mezzanotte, M.D.

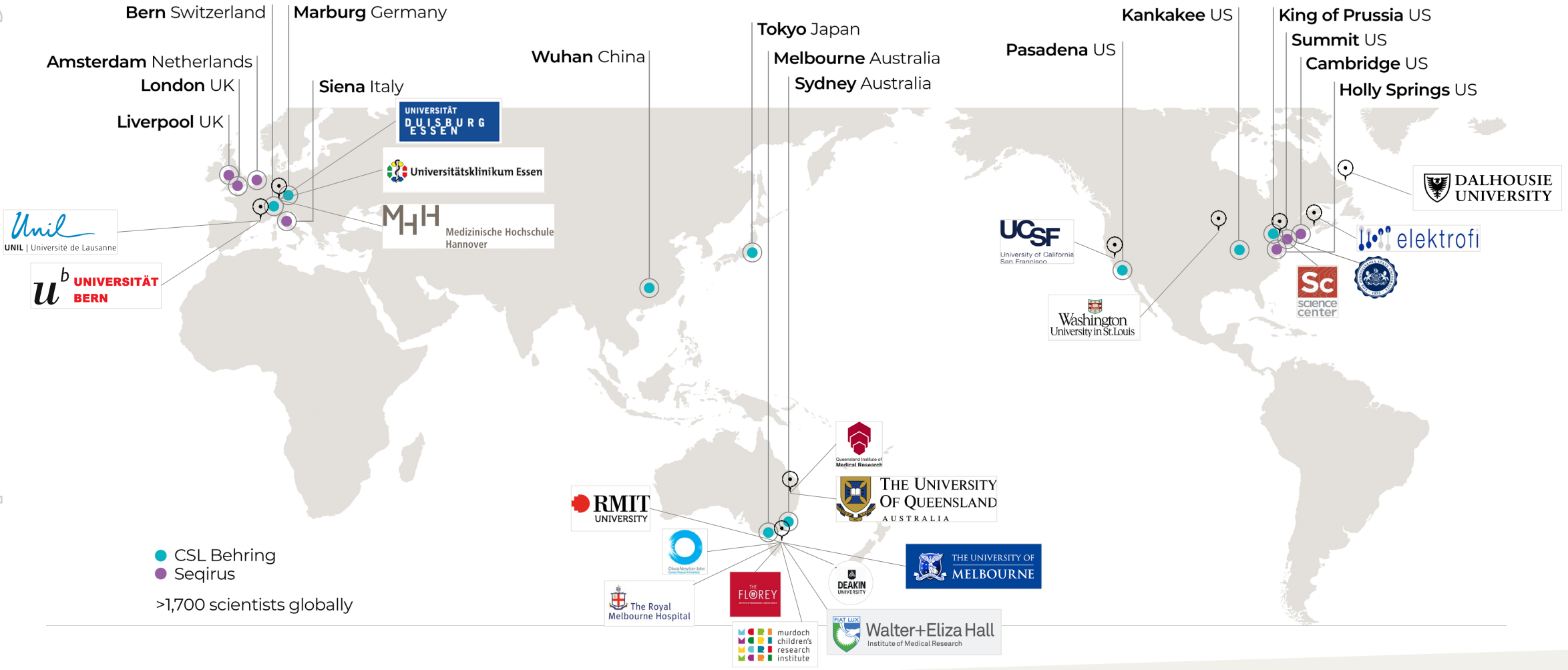
Executive Vice President, Head of Research and Development
CSL Behring

Agenda

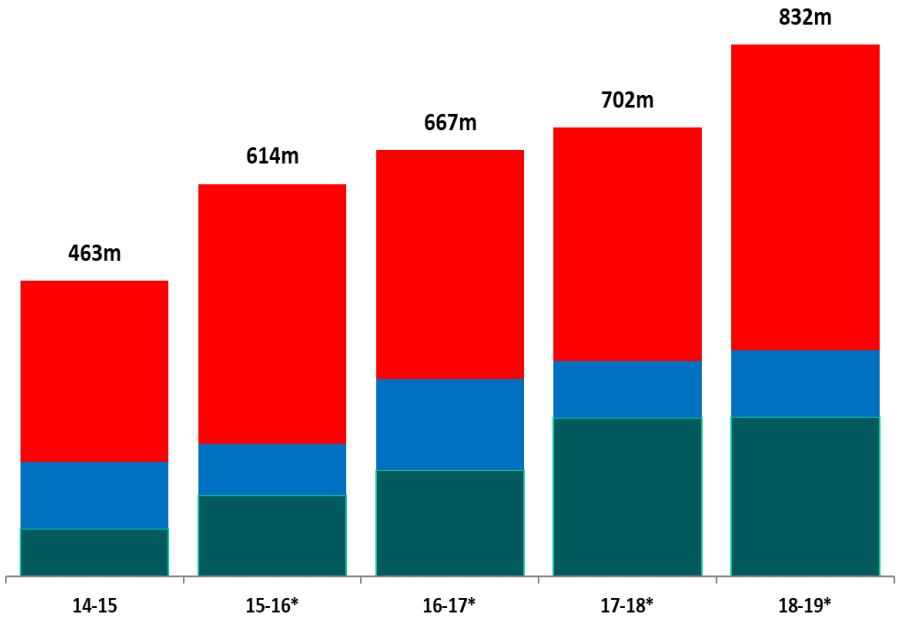
Welcome	*Mark Dehring*
Introduction	*Bill Mezzanotte*
Research, Gene and Cell Therapy	*Andrew Nash*
Clinical Development Part 1	*Diana Lanchoney*
Commercial Part 1	*Bill Campbell*
Panel Q&A Session	
Break	
Commercial Part 2	*Bill Campbell*
Seqirus	*Russell Basser*
Clinical Development Part 2 and Summary	*Bill Mezzanotte*
Panel Q&A Session	

Global Research and Development Footprint

Global Collaborations for Innovation Access



Commitment to Research and Development



New Product Development
activities focus on innovative new therapies for life-threatening diseases

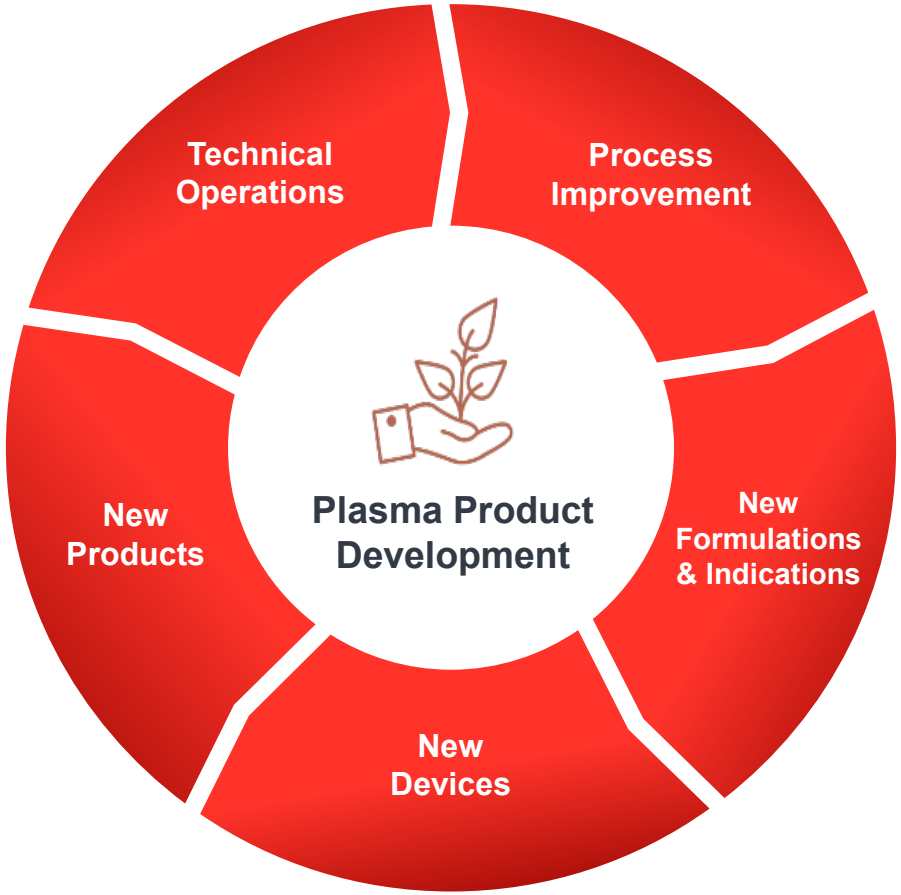
Market Development
strategies seek to bring therapies to new markets and new indications

Life Cycle Management
ensures continuous improvement of existing products

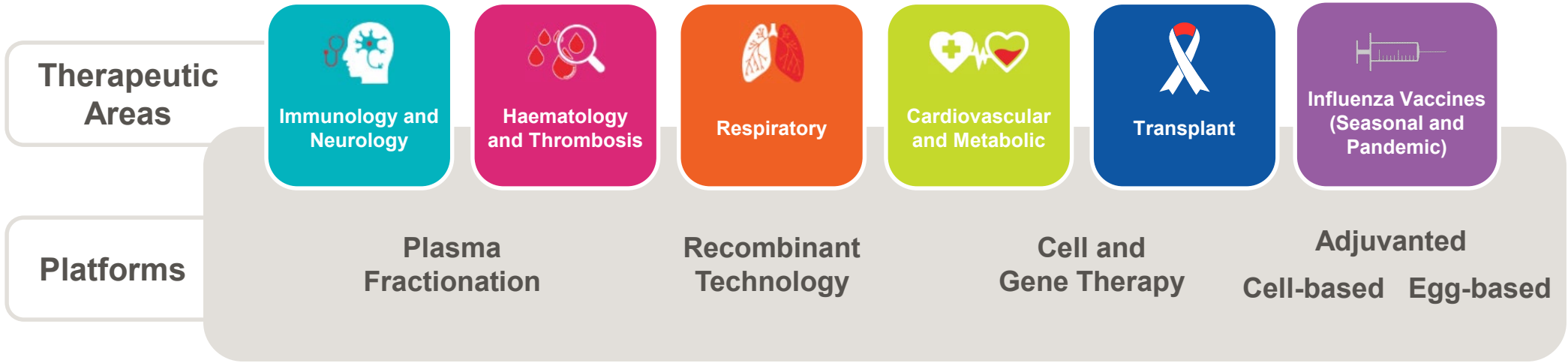
* Includes R&D for CSL Behring and Seqirus.
m = US$ millions

R&D investment ~10-11% global revenue

Active R&D Support for Growth in Plasma Business



Focus Through Our Therapeutic Areas and Platforms



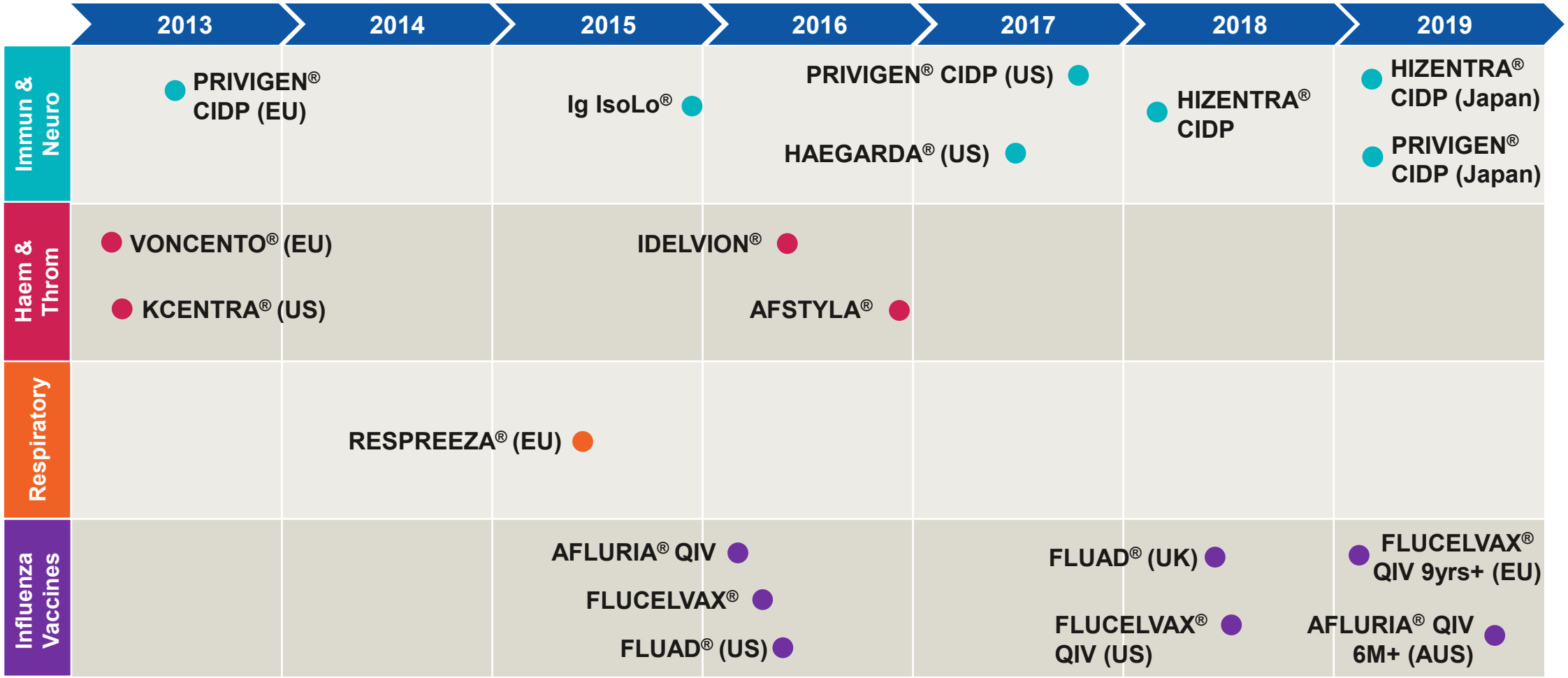
R&D Portfolio – December 2018

PRE-CLINICAL	PHASE I	PHASE II	PHASE III	REGISTRATION	POST-REGISTRATION
CSL200 (CAL-H)SCD	CSL730 rFc Multimer	CSL312 Anti-FXIIa HAE	PRIVIGEN® PID Japan	PRIVIGEN® CIDP Japan	CSL830 C1-INH Subcut EU
CSL889 Hemopexin SCD	CSL324 Anti-G-CSFR	Mavrilimumab GM-CSFR	HIZENTRA® IIM	HIZENTRA® CIDP Japan	PRIVIGEN® CIDP US
CSL787 Nebulised Ig	CSL346 Anti-VEGF-B		CSL630 pdFVIII Ruide	FLUCELVAX® QIV 9yrs+ EU	HIZENTRA® CIDP
CSL311 Anti-Beta Common	CSL334 IL-13R		CSL112 ApoA-I	AFLURIA® QIV 6M-4yrs AUS	HAEGARDA® US
P. gingivalis/POD			Clazakizumab		IDELVION®
			CSL842 C1-INH rAMR		AFSTYLA®
			CSL964 GvHD Prevention		KCENTRA® Japan
			FLUAD® QIV 65yrs+		FLUAD® aTIV 65yrs+
			Pre-Pandemic Vaccine (aH5N1c)		FLUCELVAX® QIV 4yrs+ US
					AFLURIA® QIV 6M+ US

Partnered Projects

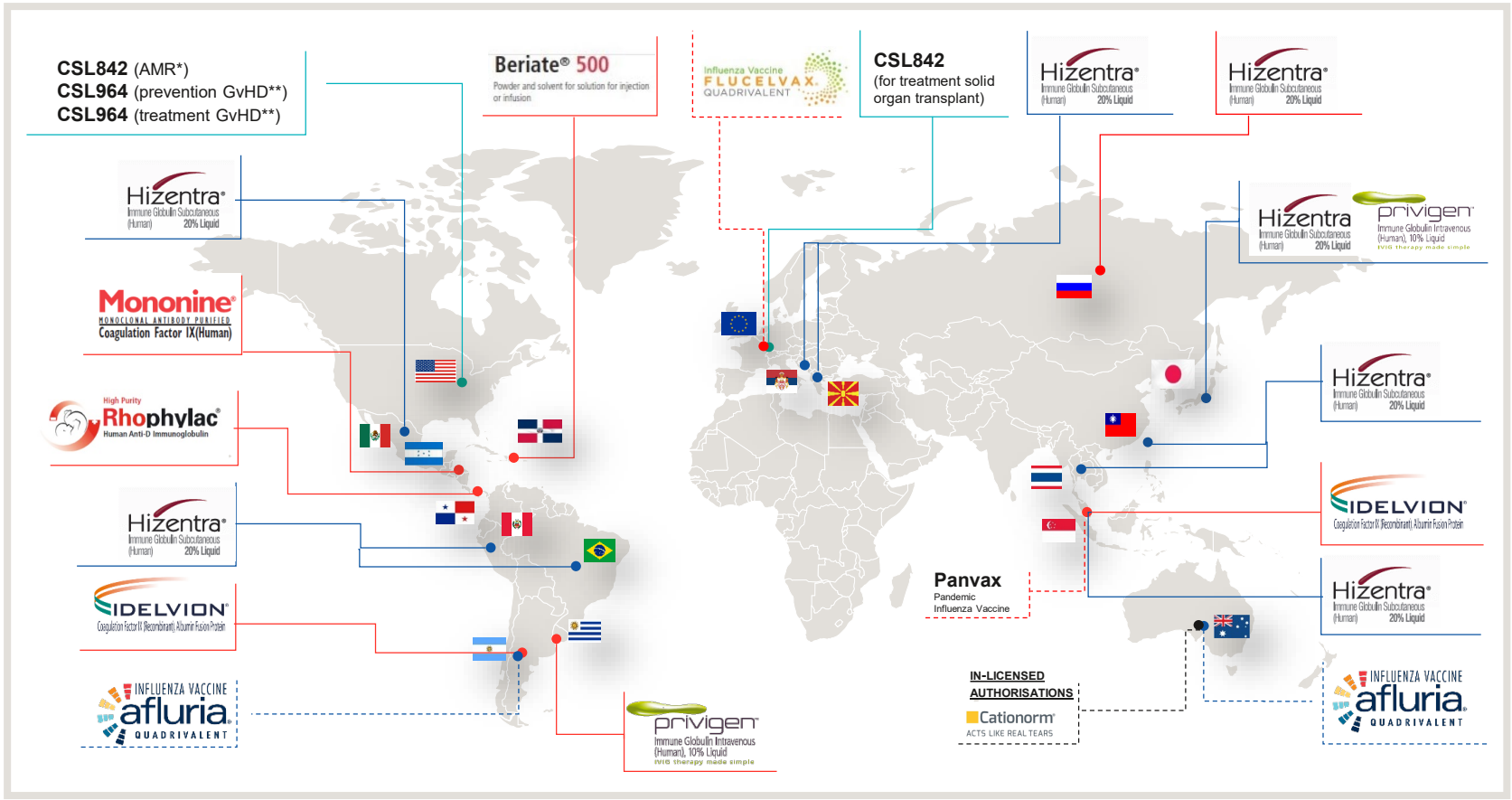
Immunology and Neurology | Haematology and Thrombosis | Respiratory | Cardiovascular and Metabolic | Transplant | Influenza Vaccines

Key Past Launches from R&D Portfolio



Notable Regional Regulatory Approvals

1 Dec 2018 – 20 Nov 2019



Ongoing Activities

CSL Behring

- Hizentra — Expanded Label for Enhanced Administration Parameters
- IDELVION — Expanded Label for Dosing Every 21 days in Patients ≥12yrs of Age

Seqirus

- FLUCELVAX QUADRIVALENT — Geographic Expansion
- afluria QUADRIVALENT — Geographic Expansion
- FLUAD QUADRIVALENT influenza vaccine, adjuvanted — Special Population Label Expansion
- **aH5N1c** — New Registration in US

CSL Behring
Seqirus

New Initial Marketing Authorization Approvals

New Line Extensions/ Indications Approvals
CSL Behring: CIDP Indication
Seqirus: paediatrics

Orphan Drug Designation

*AMR - Antibody-Mediated Rejection
**GvHD - Graft vs Host Disease

Clinical Portfolio Progression in 2019

PRE-CLINICAL/PHASE I	PHASE II	PHASE III	REGISTRATION	POST-REGISTRATION
CSL200 (CAL-H) SCD	PRIVIGEN® SSc	HIZENTRA® DM	PRIVIGEN® PID Japan	PRIVIGEN® CIDP Japan
CSL312 Anti-FXIIa Thrombosis	HIZENTRA® SSc	CSL964 GvHD Treatment	AFLURIA® QIV 6M-4yrs AUS	HIZENTRA® CIDP Japan
CSL889 Hemopexin SCD			FLUCELVAX® QIV 9yrs+ EU, AUS	
CSL311 Anti-Beta Common			FLUAD® QIV 65yrs+ EU, AUS	
aQIVc (MF59 plus FLUCELVAX® antigen)			Pre-Pandemic aH5N1c	

Immunology and Neurology | Haematology and Thrombosis | Respiratory | Cardiovascular and Metabolic | Transplant | Influenza Vaccines

Key Partnerships and Collaborations

PRE-CLINICAL	PHASE I	PHASE II	PHASE III
P. gingivalis/POD Denteric	CSL730 rFc Multimer MOMENTA	Mavrilimumab GM-CSFR KINIKSA	Clazakizumab Anti-IL-6 Vitaeris
	CSL334 / ASLAN004 IL-13R ASLAN PHARMACEUTICALS		CSL964 GvHD Treatment BLOOD AND MARROW TRANSPLANT CLINICAL TRIALS NETWORK

R&D Portfolio – December 2019

RESEARCH	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	REGISTRATION	POST-REGISTRATION
Discovery Projects	Improved Fibrinogen	CSL730 rFc Multimer	CSL312 Anti-FXIIa HAE	HIZENTRA® DM	PRIVIGEN® PID Japan	CSL830 C1-INH Subcut EU
Discovery Projects	CSL787 Nebulised Ig	CSL324 Anti-G-CSFR	HIZENTRA® SSc	CSL112 ApoA-I	FLUAD® QIV 65yrs+ US/EU/Canada	PRIVIGEN® CIDP US, Japan
Discovery Projects	aQIVc (MF59 plus FLUCELVAX® antigen)	CSL200 (CAL-H) SCD	PRIVIGEN® SSc	Clazakizumab AMR	Pre-Pandemic aH5N1c	HIZENTRA® CIDP US, Japan
Discovery Projects	P. gingivalis/POD	CSL889 Hemopexin SCD	HAEGARDA® Japan	CSL842 C1-INH rAMR		HAEGARDA® US
Discovery Projects		CSL312 Anti-FXIIa Thrombosis	CSL630 pdFVIII Ruide	CSL964 GvHD Prevention		IDELVION®
		CSL311 Anti-Beta Common	Mavrilimumab GM-CSFR	CSL964 GvHD Treatment		AFSTYLA®
		CSL346 Anti-VEGF-B		FLUCELVAX® 6M+		KCENTRA® Japan
		CSL334 / ASLAN004 IL-13R				ZEMAIRA® / RESPREEZA® AAT
						AFLURIA® QIV 6M+ US, AUS

◤ Partnered Projects

Immunology and Neurology | Haematology and Thrombosis | Respiratory | Cardiovascular and Metabolic | Transplant | Influenza Vaccines

Research, Gene and Cell Therapy

Dr. Andrew Nash

Senior Vice President, Research
CSL Behring

CSL™

CSL Research

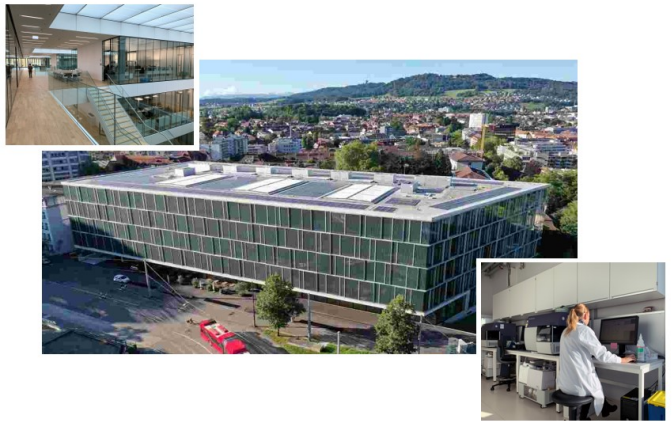
- **Capabilities and facilities**

- **New product opportunities**
  - **Plasma** – Haptoglobin for the treatment of Subarachnoid Haemorrhage (SAH)
    - Innosuisse grant awarded to the University Hospital Zürich and CSL Behring in 2017
  - **Recombinant** – CSL311 for the treatment of inflammatory disease
  - **Gene therapy** – Sickle Cell Disease (CSL200) and immune deficiencies

CSL Research
New Facilities

Bio21 Institute, Melbourne

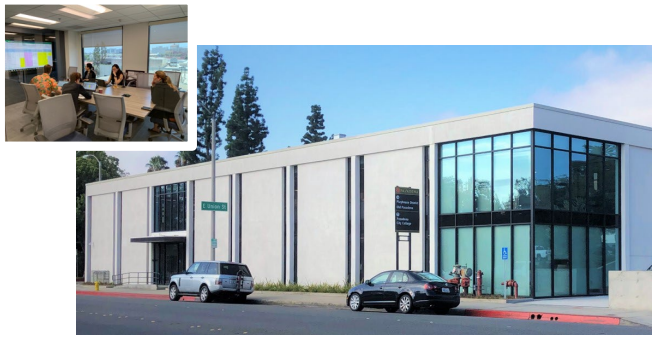
- ~ 4100m^2 of lab and office space
- Parkville precinct
- Melbourne University, MRI's
- 4 major teaching hospitals



SITEM*, Bern

- 2000m^2 of lab and office space
- Bern University and Hospital campus

*SITEM – Swiss Institute for Translational and Entrepreneurial Medicine

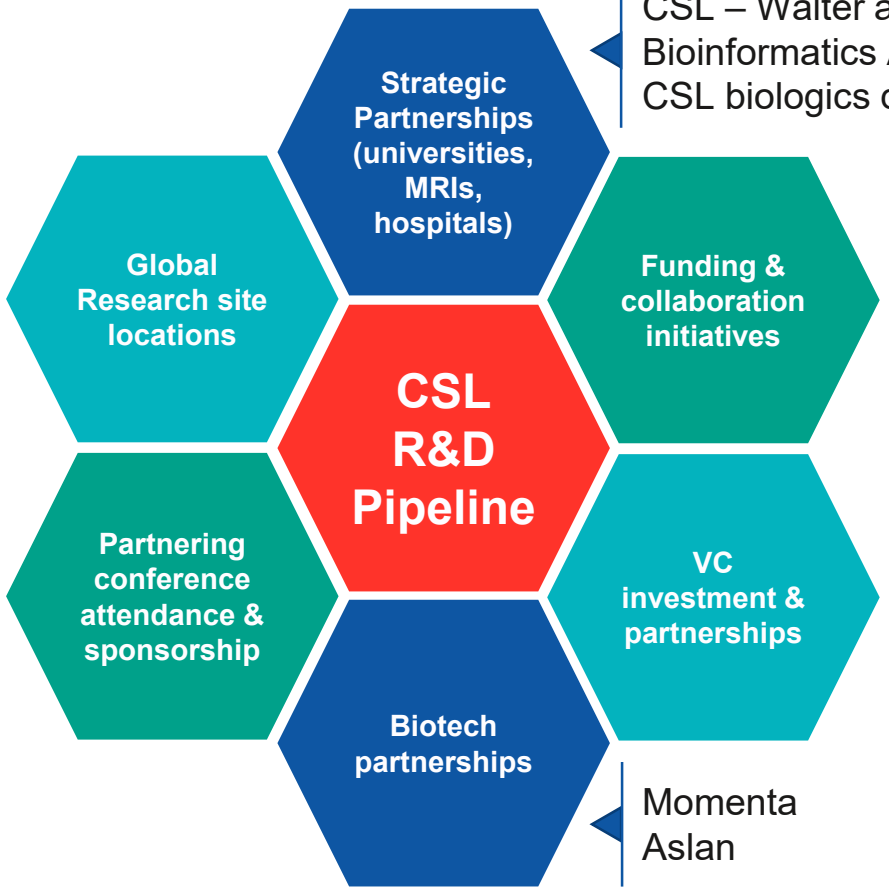


Gene therapy, Pasadena

- Expanding gene therapy expertise
  - Research, QA, cell processing and manufacture
  - Wet-lab space (non-GMP) tripled from 132 to 480 m^2
  - GMP space (330 m^2) to engineering qualification level

CSL Research

External Innovation Strategy



CSL – Walter and Eliza Hall Institute (WEHI)
Bioinformatics Alliance
CSL biologics discovery platform

Research Acceleration Initiatives
AUS, EU and US
Innosuisse grant
University Hospital Zürich

Active partner in ~$700m of venture funding (Brandon Capital Partners)

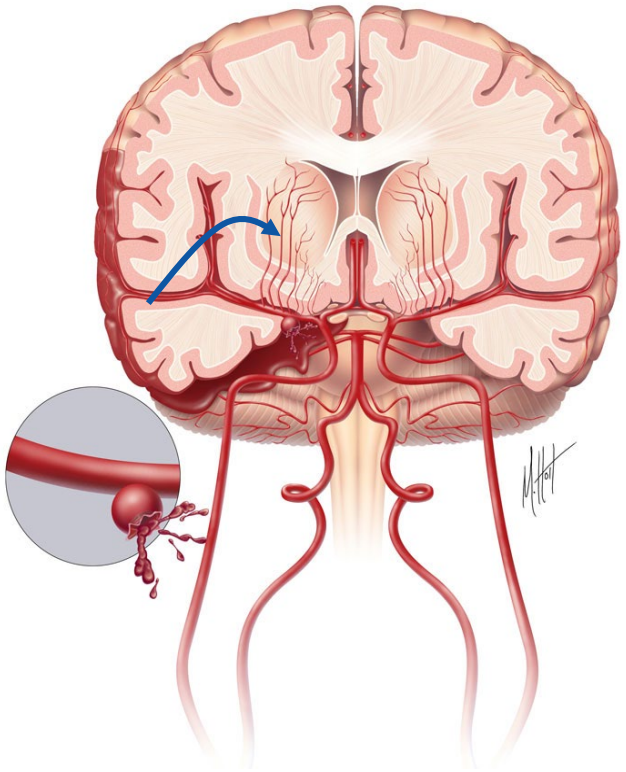
Momenta
Aslan

m = AU$ millions

Haptoglobin for the Treatment of Subarachnoid Haemorrhage (SAH)

Pathophysiology of SAH

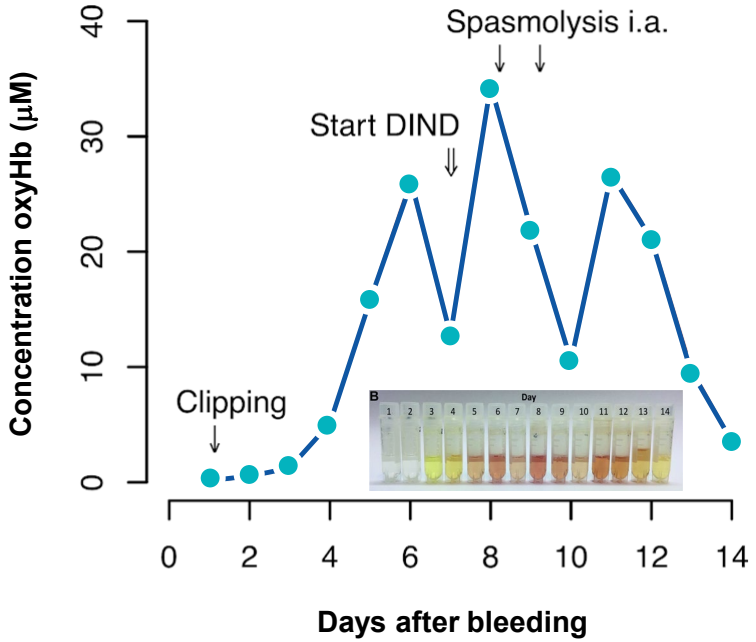
- Acute indication – rupture of an aneurysm in the brain, followed by bleeding and haemolyis within the subarachnoid space
- Survivors of initial bleeding are at risk for Delayed Ischemic Neurological Deficits (DIND)
- High mortality and morbidity
  - 5% of all strokes; high fatality rate
  - Very limited treatment options
- Haemoglobin (Hb) concentrations in cerebral spinal fluid (CSF) correlate with DIND in SAH patients



Source: www.strokecenter.org

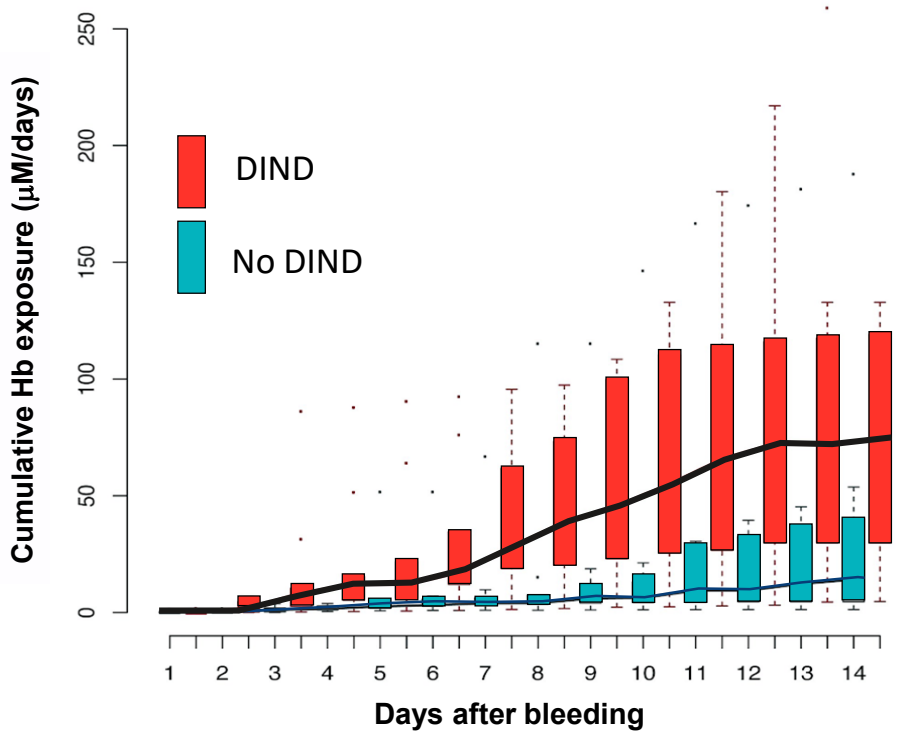
Haptoglobin and SAH

Link Between CSF Hb Levels and DIND



Hb levels in CSF correlate with DIND

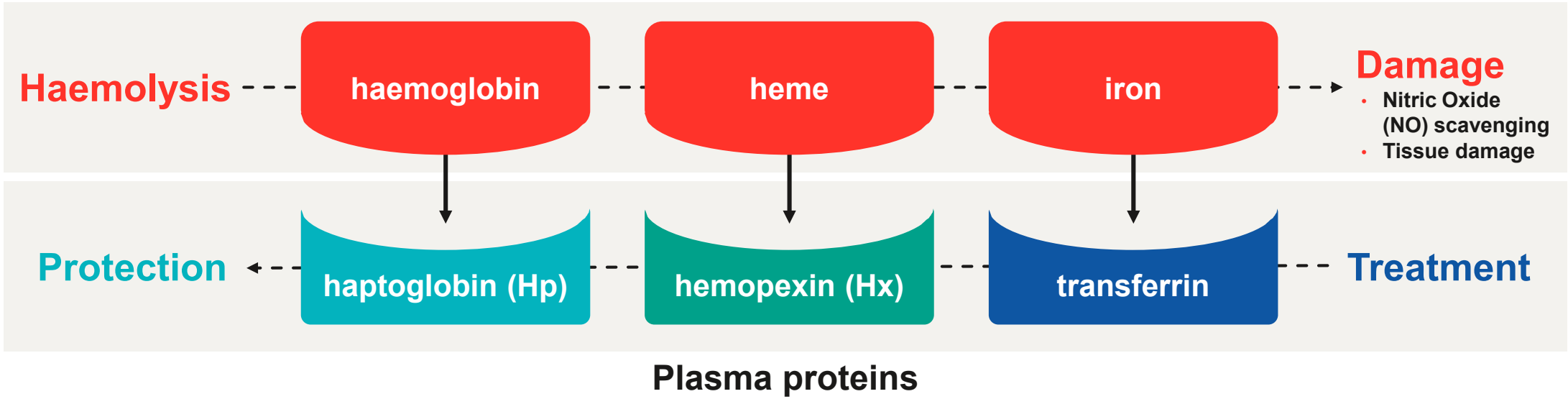
39 year old, right-handed female with thunderclap headache, vomiting and loss of consciousness



SAH patients (n=18) developing DIND have higher cumulative Hb exposure

Source: Hugelshofer et al. World Neurosurgery 2018

How the Body Deals with Toxic Free Haemoglobin (Hb) and Heme

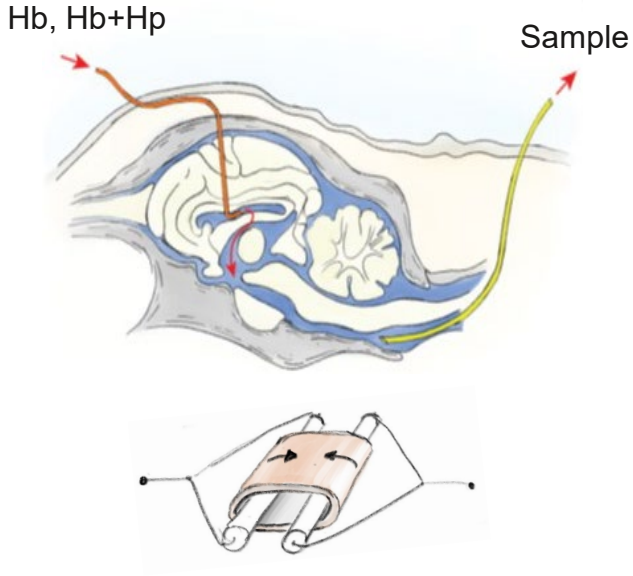


- Opportunities to treat chronic and acute haemolytic disease
- Replacement and/or augmentation therapy

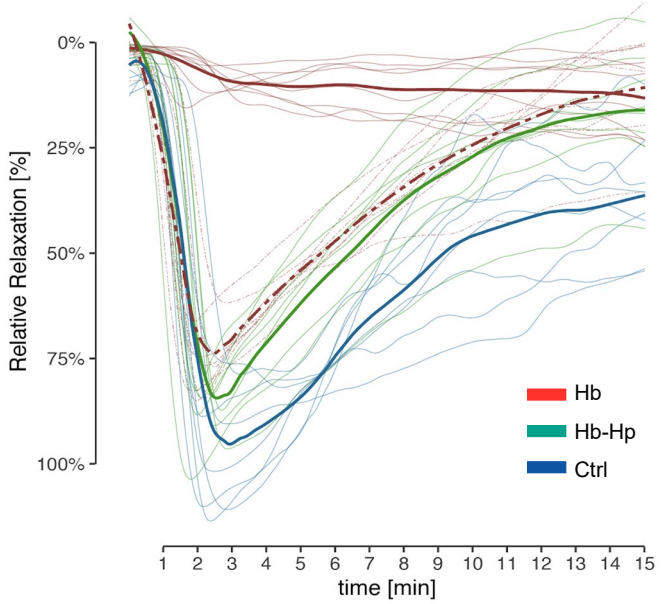
Haptoglobin for the Treatment of SAH

Haptoglobin Prevents Vasospasms Induced by Haemorrhagic CSF – *ex vivo* Functional Assay

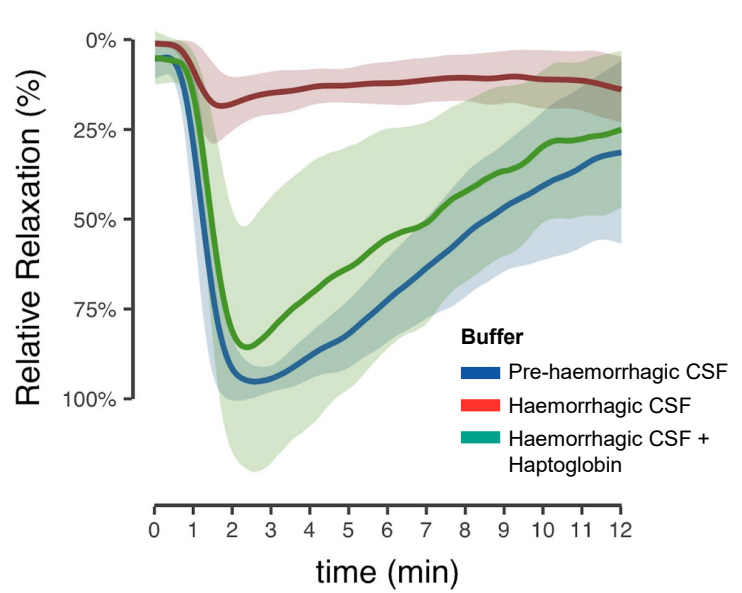
Sheep Model of SAH



CSF From Sheep SAH Model



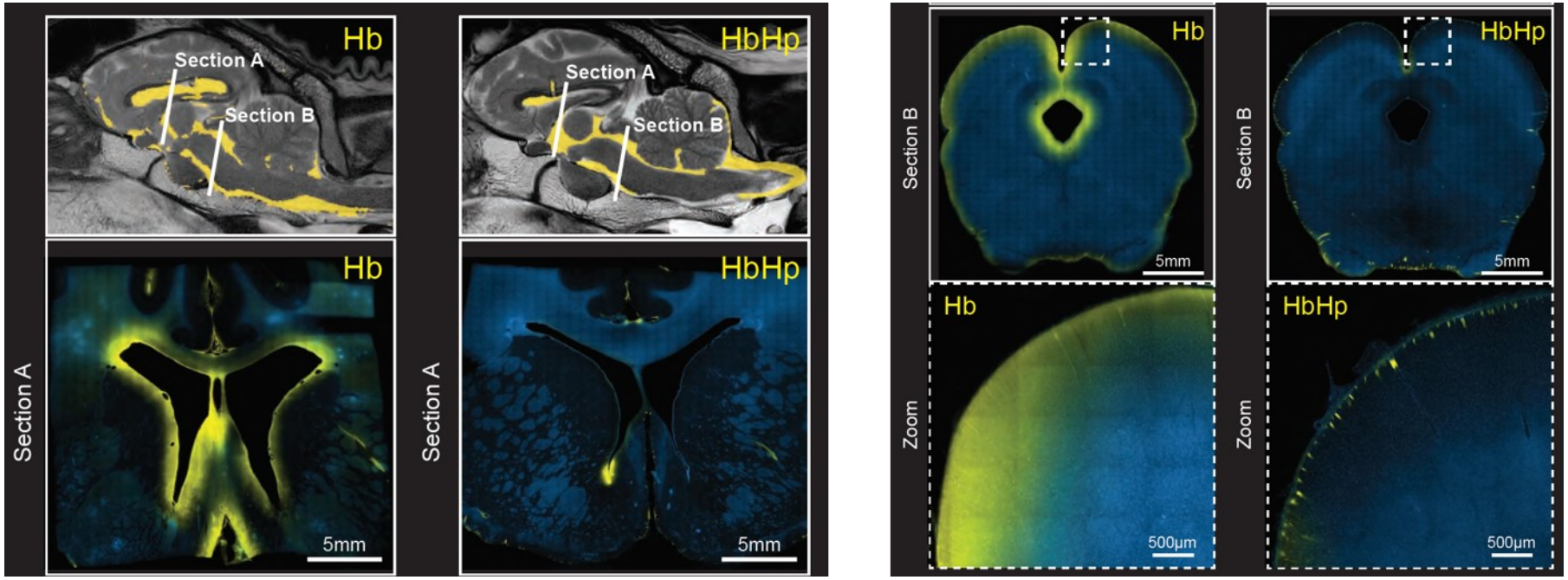
CSF Samples From SAH Patients



Source: J Clin Invest. 2019. https://doi.org/10.1172/JCI130630

Haptoglobin for the Treatment of SAH

Haptoglobin Prevents Penetration of Hb into Brain Tissue



Labeled Hb ± haptoglobin was injected into CSF 2 hours before analysis

Source: J Clin Invest. 2019. https://doi.org/10.1172/JCI130630

Haptoglobin for the Treatment of SAH

Summary

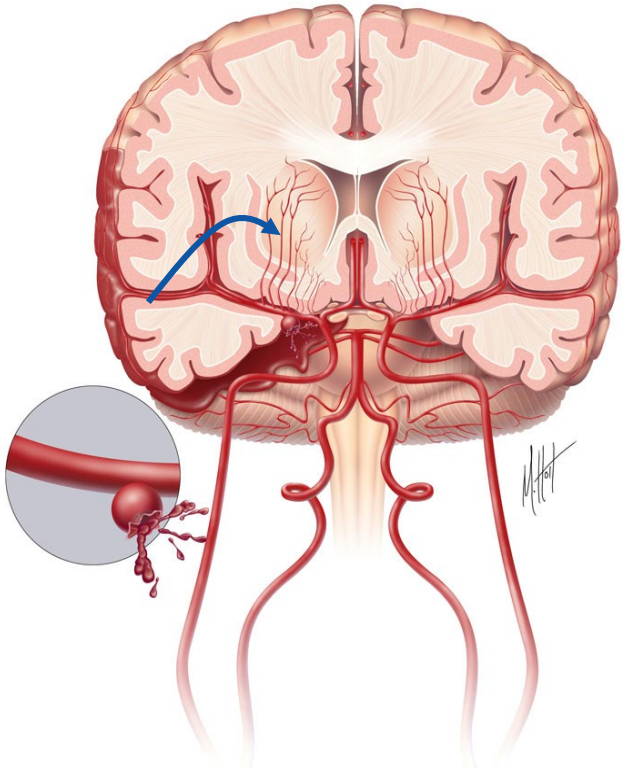
Haemoglobin

- Concentrations in CSF correlate with DIND in SAH patients
- Rapidly penetrates from CSF into the brain parenchyma
- Induces angiographic vasospasms in 100% of animals

Haptoglobin

- Blocks tissue penetration of cell-free Hb
- Prevents Hb induced vasospasms in *ex vivo* assay
- Prevents Hb induced segmental vasospasm *in vivo*

Current Status - enter development H2 2020

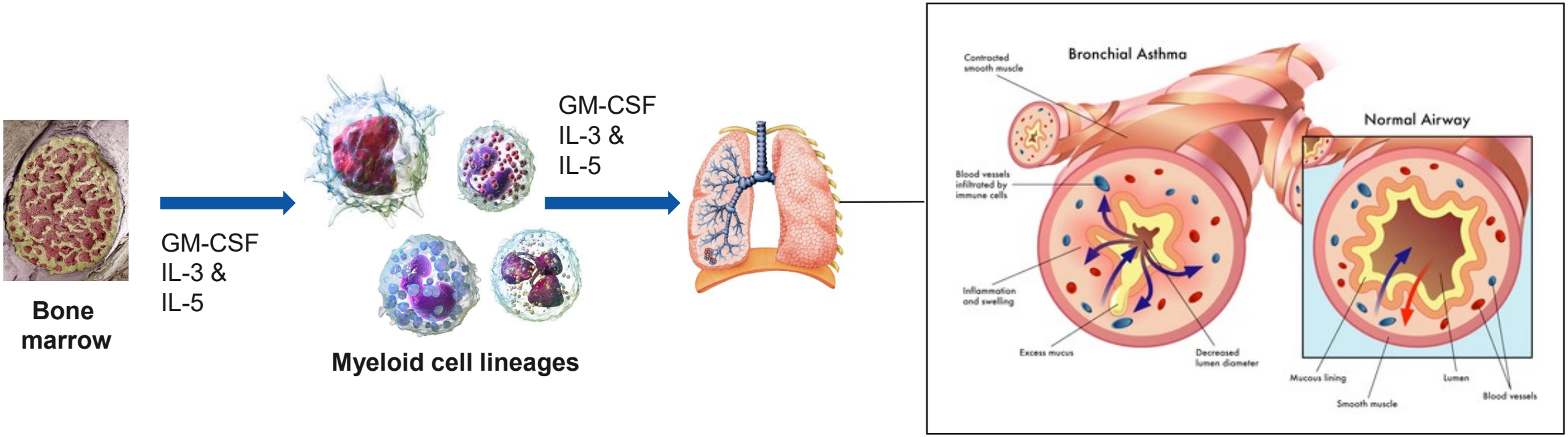


Source: www.strokecenter.org

CSL311 for the Treatment of Airways Inflammation

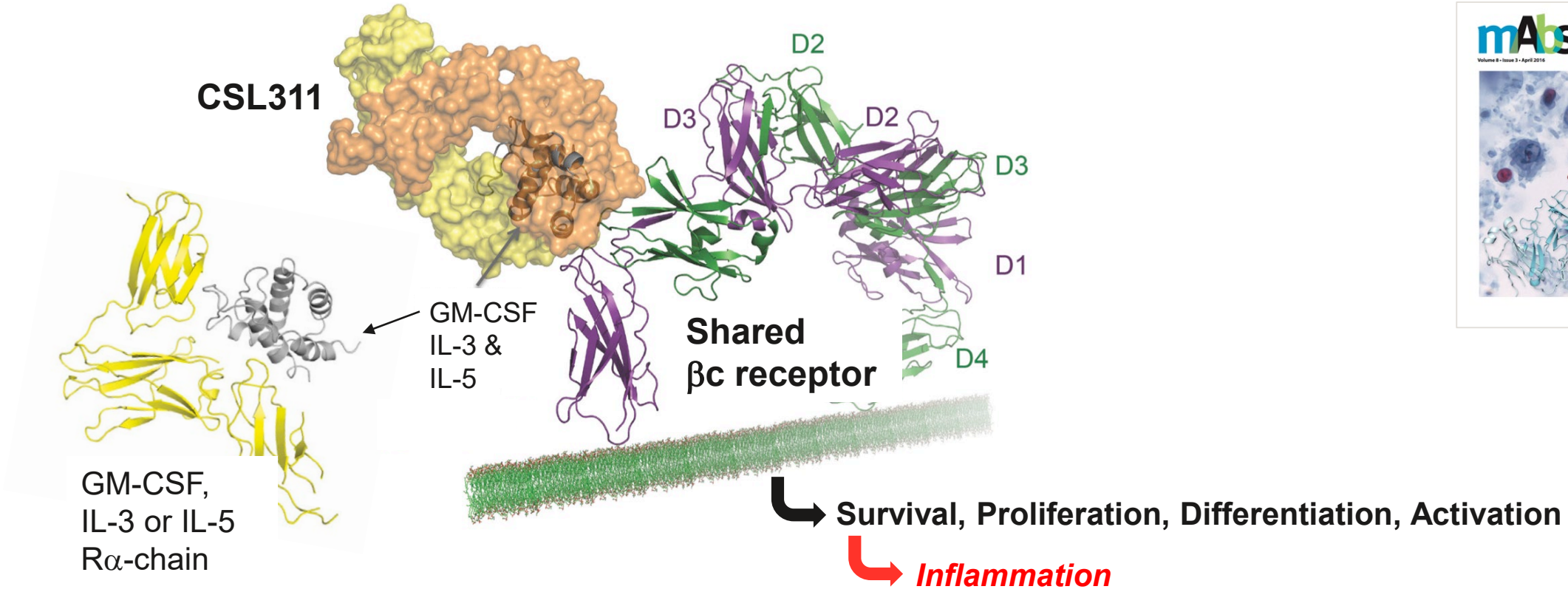
Airways Inflammation

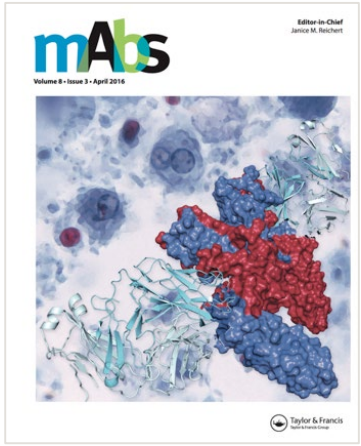
Targeting multiple inflammatory mediators with a single therapeutic



CSL311 for the Treatment of Airways Inflammation

CSL311 Targets Multiple Cytokines via a Shared Receptor



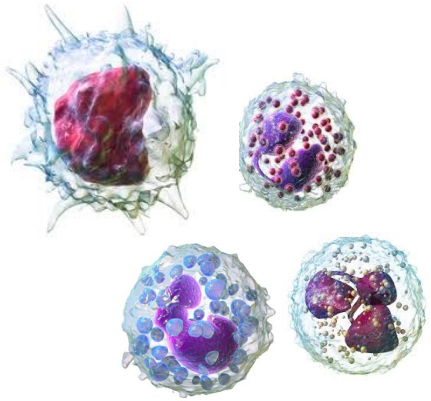


Source: Panousis et al., Mabs 8:436, 20126

CSL311 for the Treatment of Airways Inflammation

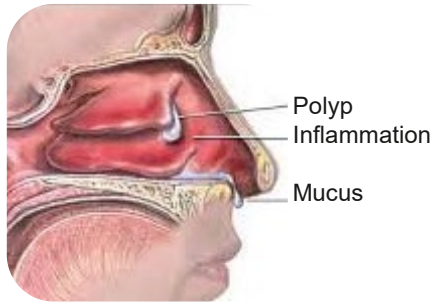
In Vivo Efficacy in a Mouse Model of Human Airways Inflammation

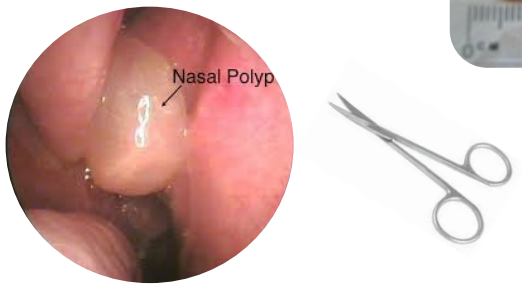
Xenografting human nasal polyps into immunodeficient mice

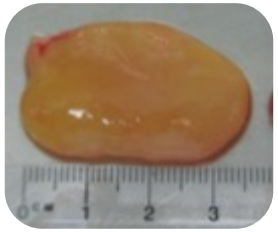


Myeloid cell lineages

GM-CSF
IL-3
or
IL-5







Xenograft

CSL311
1 x / week for 4 weeks, 5 mg/kg

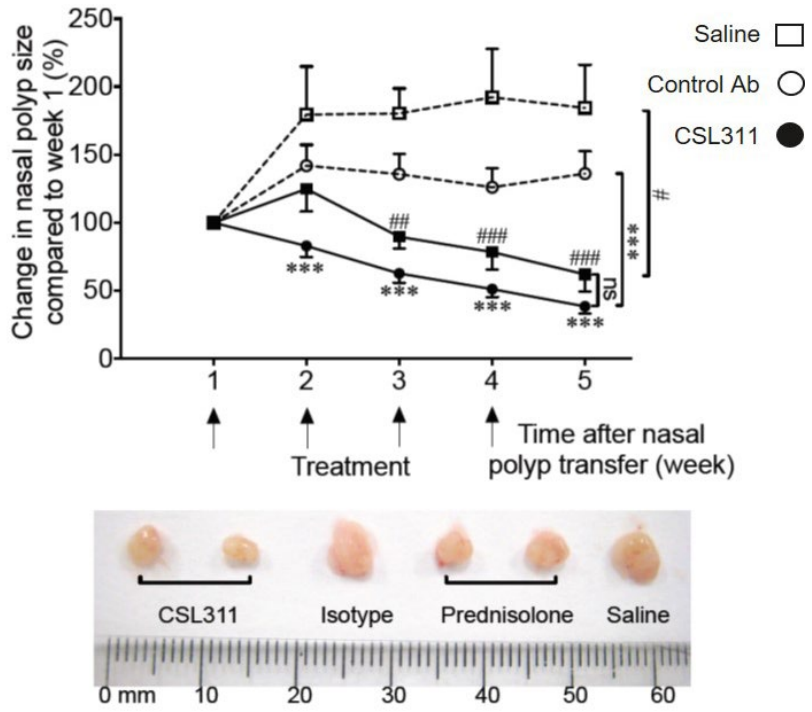
Graft size, cellular composition, mucus production, transcriptomics

Source: Yip et al., Allergy 2019 Sep 10. doi: 10.1111/all.14041

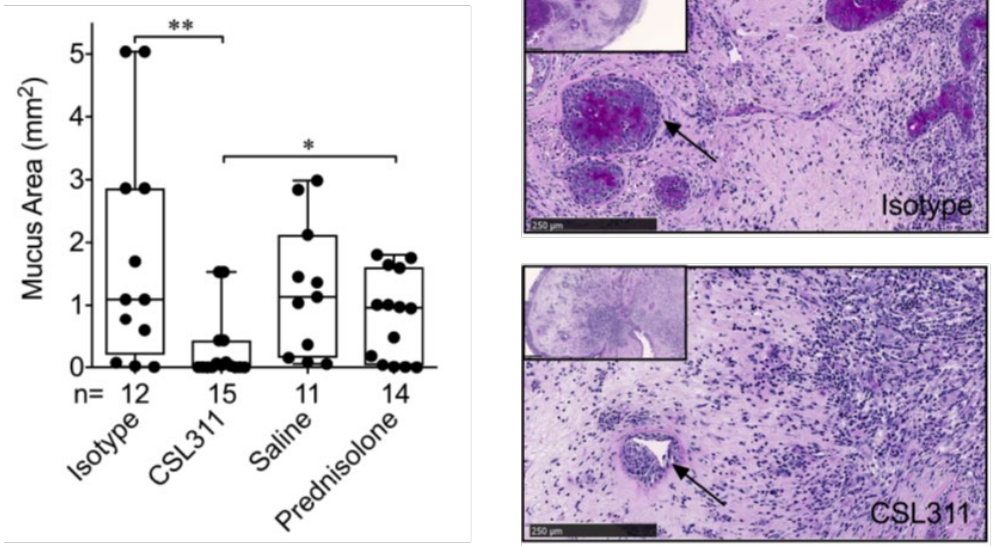
CSL311 for the Treatment of Airways Inflammation

In Vivo Efficacy – Mouse Model of Human Airways Inflammation

CSL311 restrains human nasal polyp xenograft progression *in vivo*



CSL311 treatment reduces mucous glad numbers and mucus production in nasal polyps *in vivo*

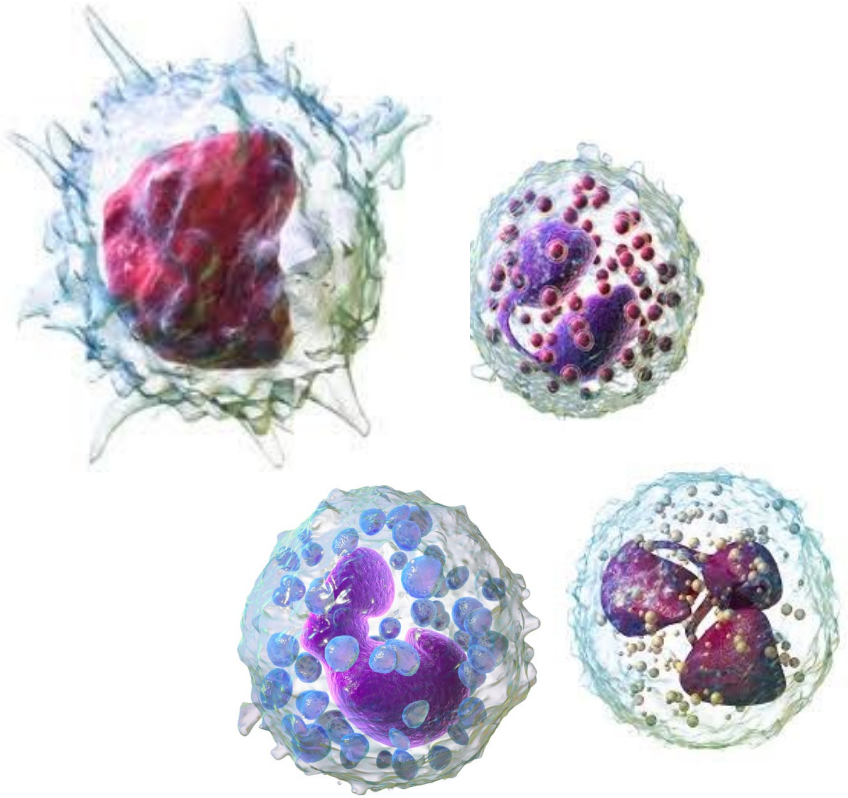


Source: Yip et al., Allergy 2019 Sep 10. doi: 10.1111/all.14041

CSL311 for the Treatment of Airways Inflammation

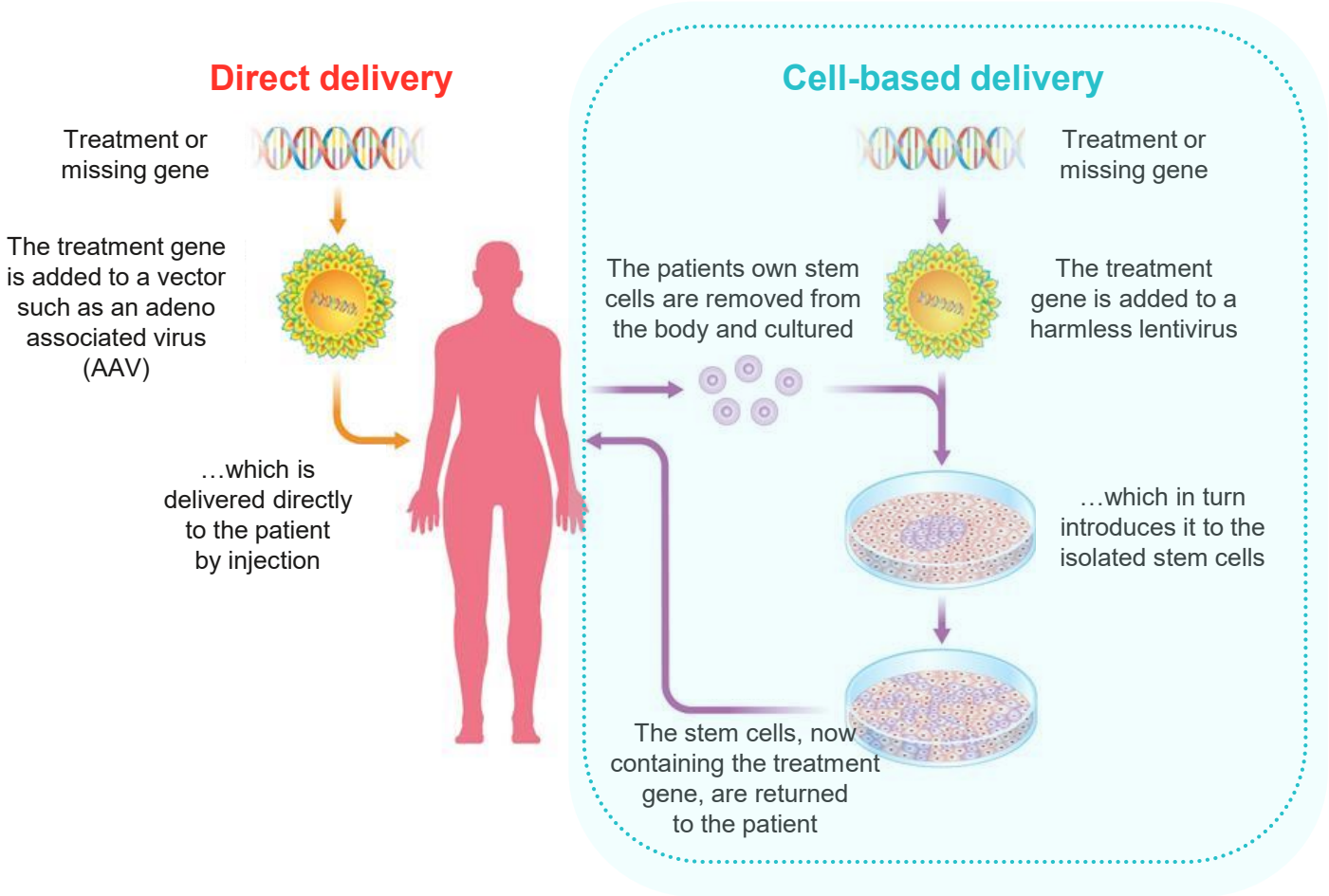
Summary

- CSL311 is a potent antagonist of IL-3, IL-5 and GM-CSF *in vitro*
- CSL311 inhibits the activity of multiple cell types involved in inflammation
- CSL311 demonstrates efficacy in an *in vivo* translational model of airways inflammation
- GLP Toxicology program successfully completed



CSL Gene Therapy

In Vivo vs *Ex Vivo* Gene Therapy



Cell and Gene Therapy Research and Product Development

- 2+ years post-acquisition of Calimmune
- Integration into CSL R&D complete
- First clinical program recruiting patients
- Pipeline of early stage gene therapy projects

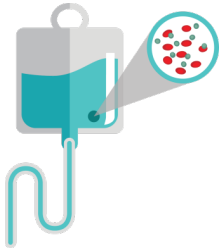
Expertise/Know-how
Vector Design

Ability to design and make extremely efficient therapeutic vectors

***In Vivo* Selection Tool**
Select+™

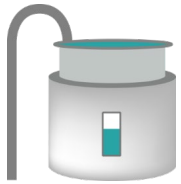
Genetic cassette to render stem cells protected against well-known drug to drive *in vivo* selection

Cell Processing
Proprietary Methods



Novel SOPs to achieve high cell yields and standardization of cell product

Lenti Manufacturing
Cytegrity™

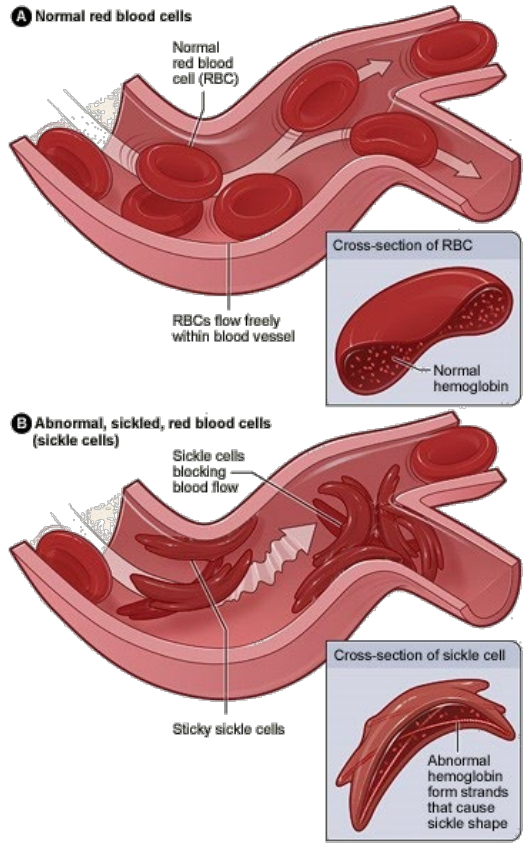


Only large-scale, stable vector production system used clinically

CSL200 for the Treatment of Sickle Cell Disease (SCD)

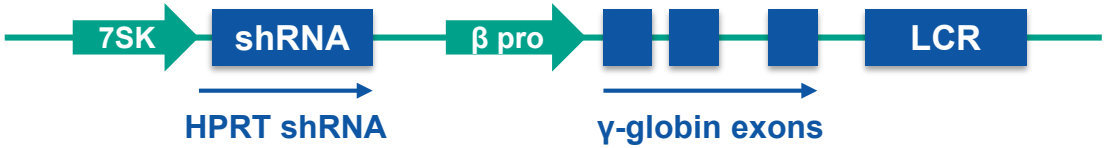
Sickle Cell Disease

- Group of disorders caused by abnormal beta-globin gene resulting in sickled red cells
- High unmet need



CSL200

Cytegrity™ lenti-backbone + **Select+™ technology** + **SIN-LV γ-globin construct (sGbG^{M})**

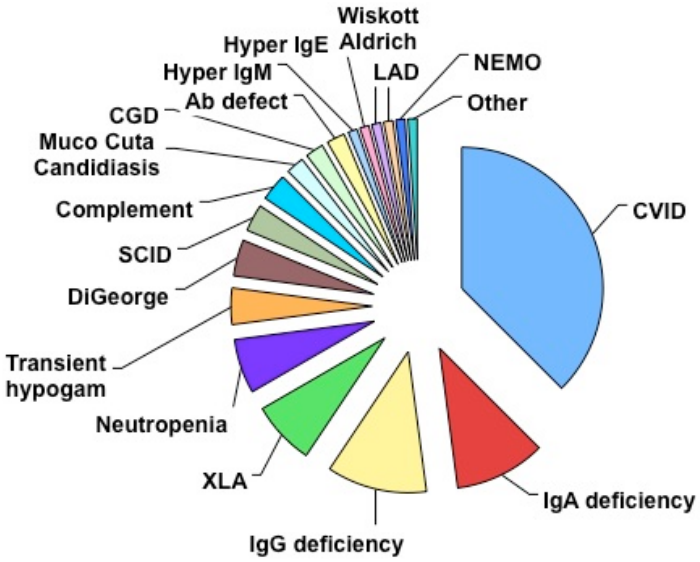


- CSL200 program aims to provide sufficient functional globin gene to prevent sickling

Gene Therapy for Wiskott-Aldrich Syndrome (WAS)

- WAS is a rare X-linked PID (~ 1:100,000 live births)
  - Mutations in the gene that encodes the WAS protein (WASp)
- WAS is exclusively expressed in blood cells and plays a key role in organizing the actin cytoskeleton, signal transduction and terminal differentiation
- WAS is characterised by:
  - Recurrent infections, microthrombocytopenia and eczema
  - An increased risk of autoimmune disorders and malignancy
  - Currently treated with IVIG
- Allogeneic Hematopoietic Stem Cell transplantation (HSCT) is the only available curative treatment

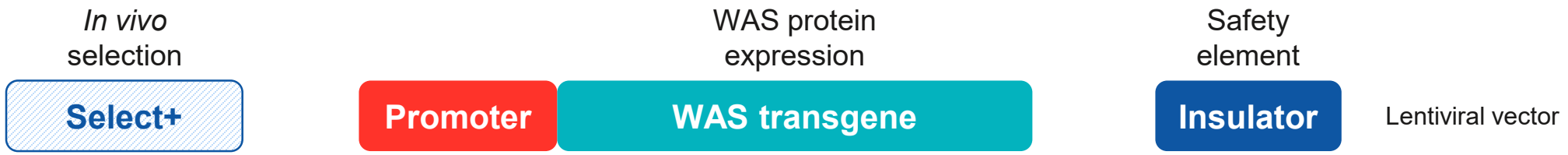
Primary Immune Deficiencies*



* **Source:** Icahn School of Medicine at Mt Sinai

Gene Therapy for Wiskott-Aldrich Syndrome (WAS)

Design and generation of lentiviral candidates based on our Cytegrity stable producer cell line backbone is in progress



Immunoglobulin Therapy

Mechanism of Action Summary

	Pathogen Neutralisation	Reduction of Pathologic Ig	Complement Scavenging	FcγR Expression Modulation	Immune Cells Modulation	Cytokine Modulation
Ig Therapy	✓	✓	✓	✓	✓	✓
IgG Fc Multimers	○	✓	✓	✓	✓	✓
FcRn Binding Agents	○	✓	○	✓	○	○

○ No Activity ✓ Possible Activity ✓ Activity

CSL Research

- Expanding capacity and capability across global research sites
- Continued investment in external innovation activities
- Leveraging our three strategic platforms across five therapeutic areas
- Continuing to innovate in areas of business strength
- Developing new opportunities in areas of unmet need
- Creating and progressing a sustainable portfolio of early stage opportunities
  - New gene therapy opportunities

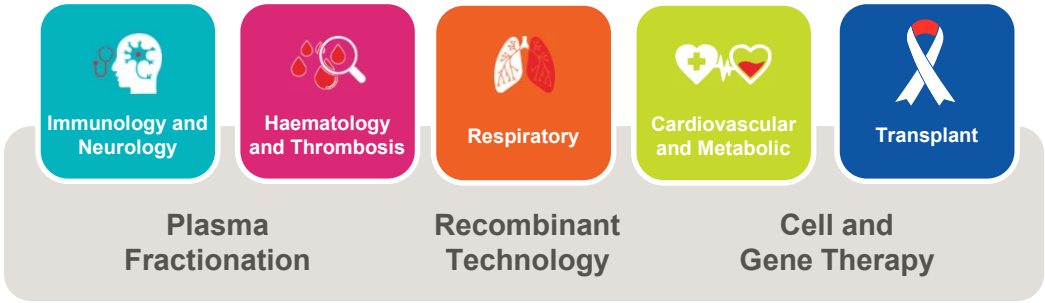
Clinical Development – Part 1

Dr. Diana Lanchoney

Vice President, Clinical Pharmacology and Translational Development
CSL Behring

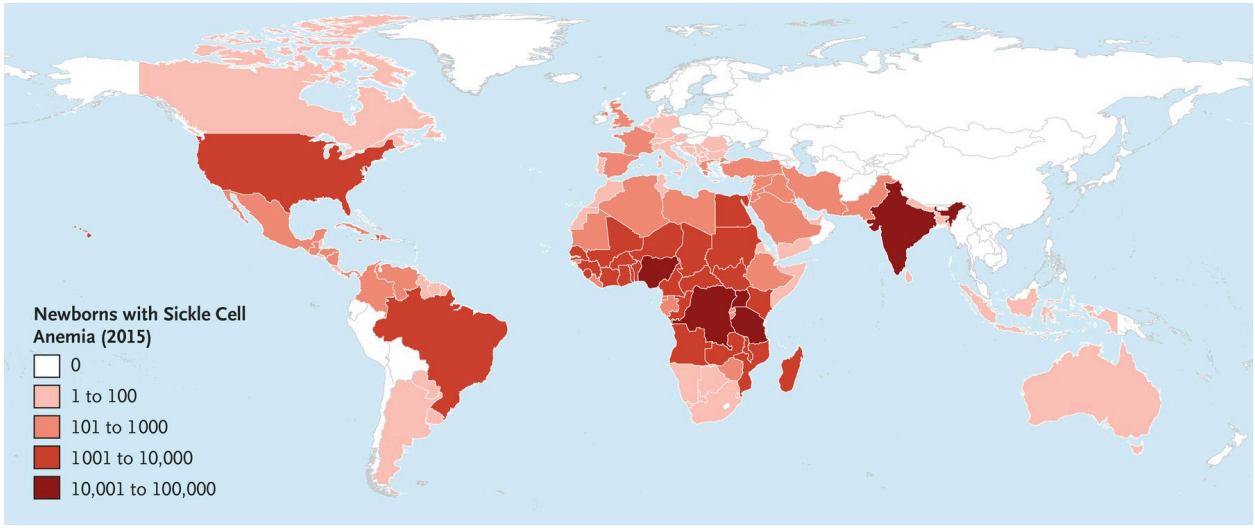
CSL Pipeline Progressing into Multiple New Disease Areas Using All Three Product Development Platforms

- **Sickle Cell Anemia** – CSL200 (lentiviral stem cell gene therapy), CSL889 (Hemopexin)
- **Contact Mediated Thrombosis** – Garadacimab (CSL312 Anti-Factor XIIa)
- **Respiratory Disease** – CSL311 (Anti-Beta Common)
- **Diabetic Nephropathy** – CSL346 (Anti-VEGF-B)
- **Neutrophilic Dermatoses** – CSL324 (Anti-GCSF)
- **Systemic Lupus Erythematosus** – CSL362 (Anti-IL-3Ra)
- **Scleroderma** – PRIVIGEN® and HIZENTRA®
- **Dermatomyositis** – HIZENTRA®
- **Hereditary Angioedema** – Garadacimab (Anti-Factor XIIa)



Overview of Sickle Cell Disease (SCD)

- Missense mutation of the β-globin gene
- Worldwide incidence ~300,000/year (US ~155,000)
- Sickle red blood cells are fragile, prone to endothelial adhesion
- Many downstream consequences
  - Avg. life expectancy 40 - 60yrs
- Vaso-occlusive crisis (VOC): commonly leads to hospitalization

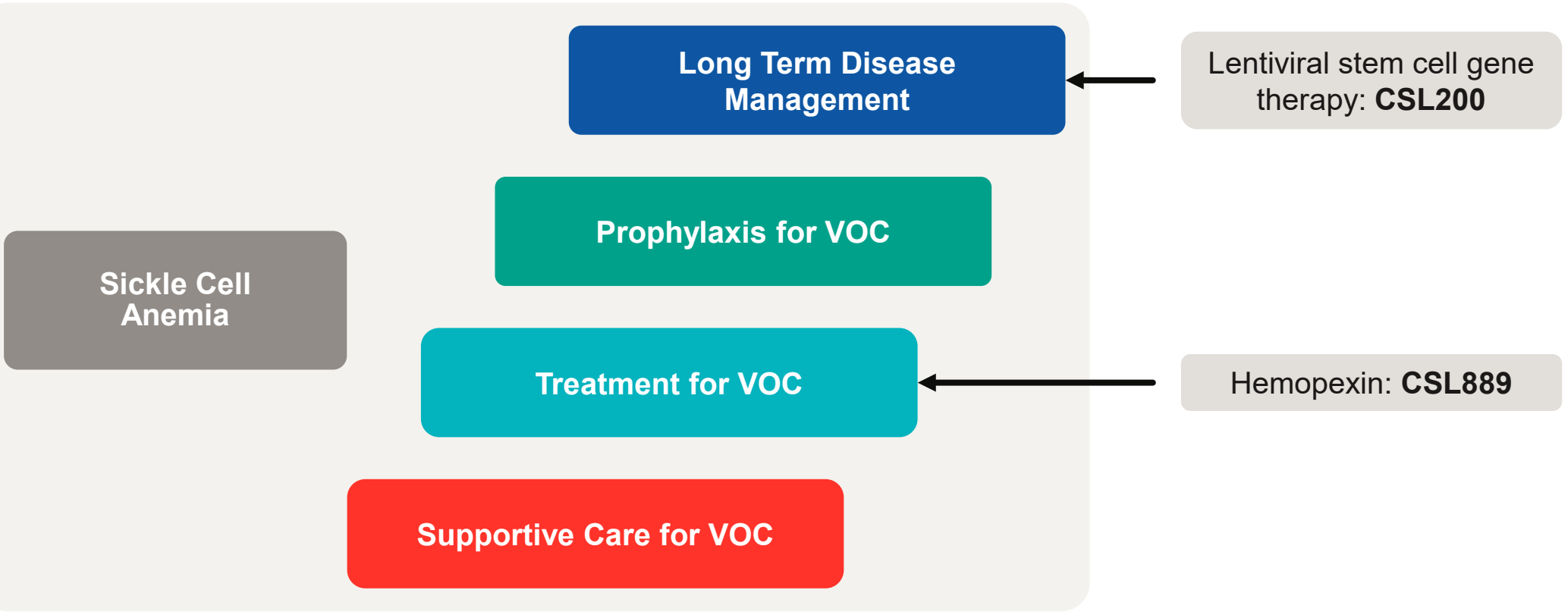


Global incidence of SSA in newborns, 2015

Source: https://www.nejm.org/doi/full/10.1056/NEJMra1510865

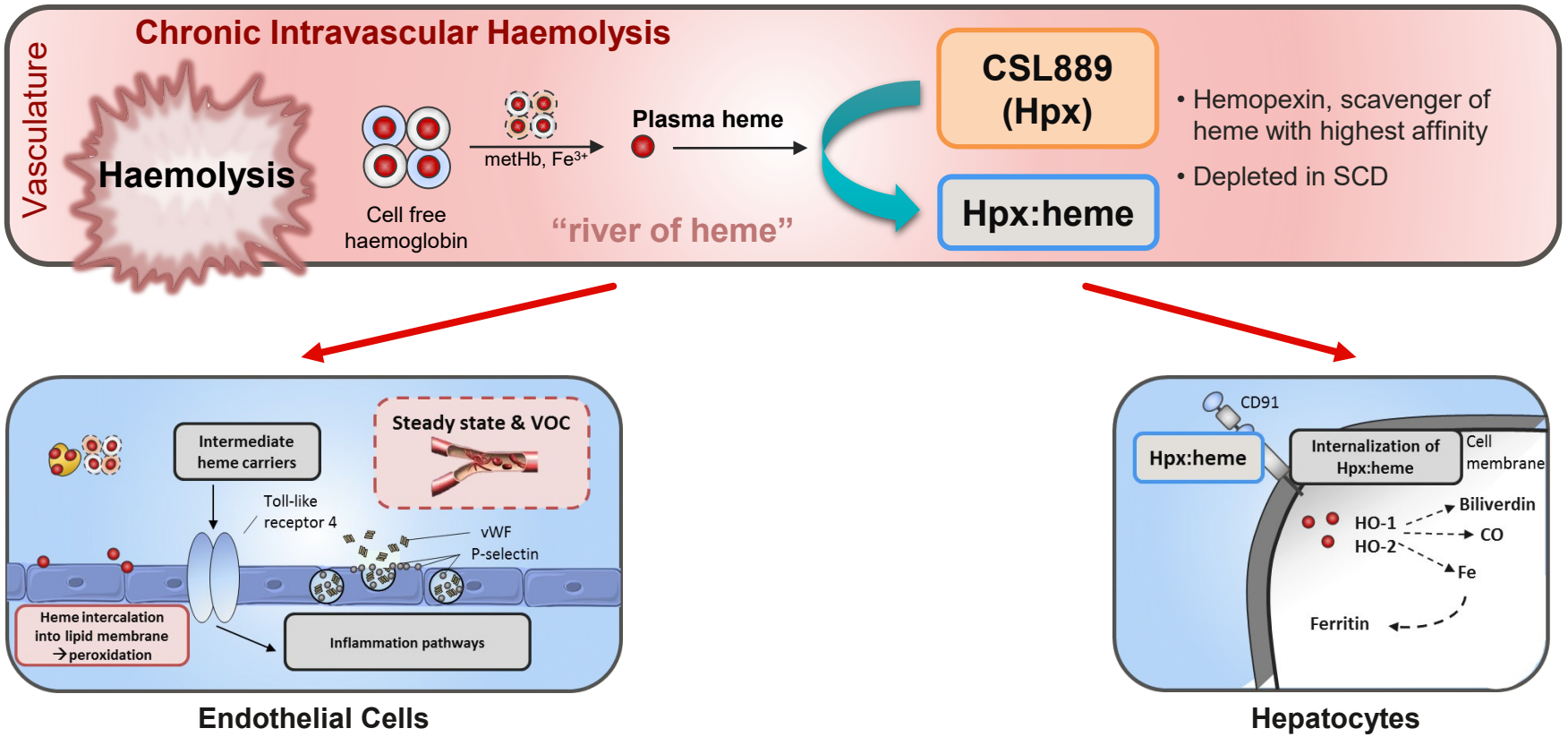
Sickle Cell Anemia

CSL Programs Poised to Evolve the Paradigm



CSL889 Hemopexin

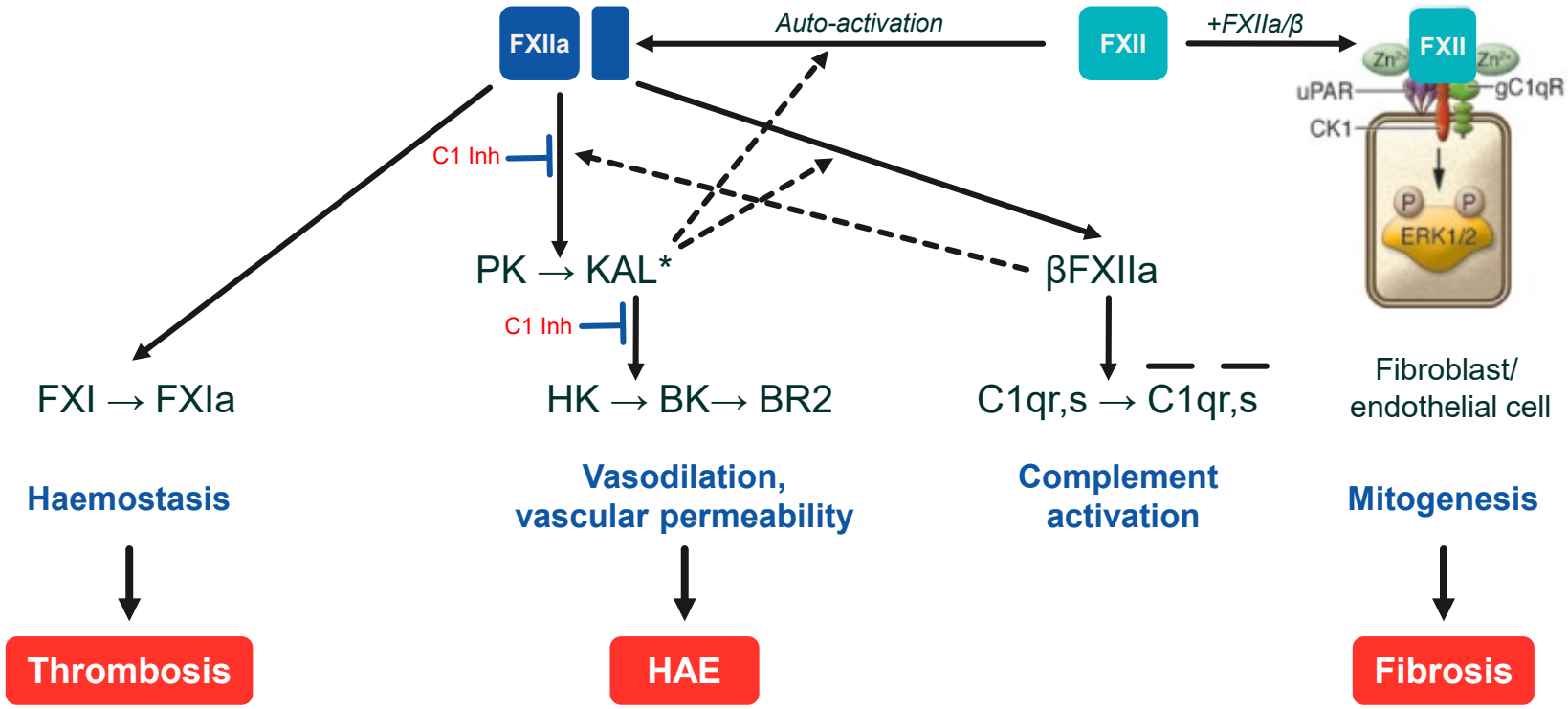
Addresses the Toxic Effects of Free Heme



Clearance of free heme, and reduced inflammation

Garadacimab (CSL312 Anti-Factor XIIa)

Multiple Potential Indications



Adapted from: Schmaier, AH., J Clin Invest. 2008 Sep 2; 118(9): 3006–3009.

Garadacimab (CSL312) Thrombosis Development Program Overview

Mechanism to Prevent Contact-Activated Thrombosis Without Bleeding Risk

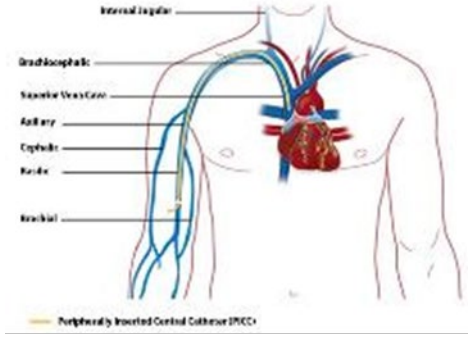
Phase I (FIH study)

SAD in healthy subjects

- Safety
- Pharmacokinetics (PK)
- Biomarkers

Contact Activation Associated Thrombosis

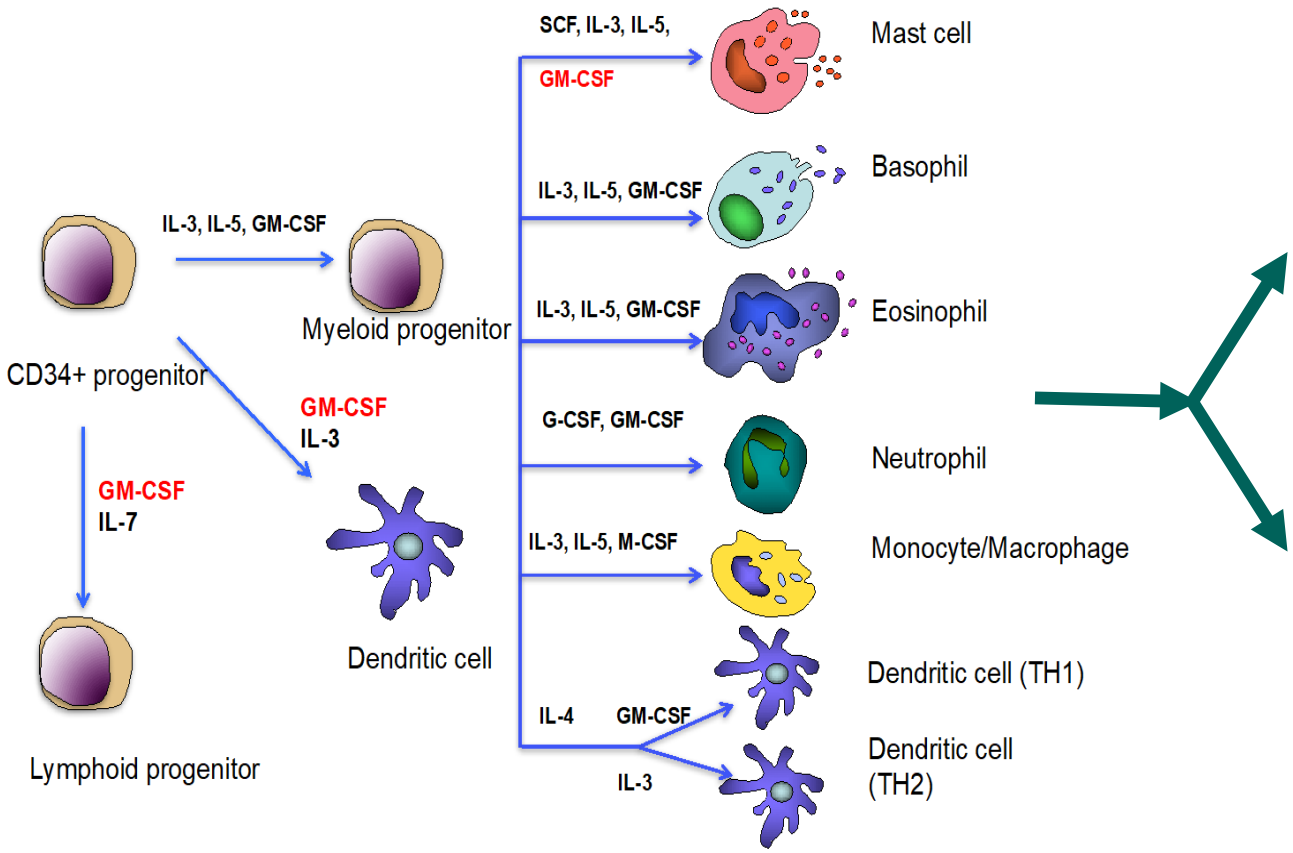
Commercial Indications

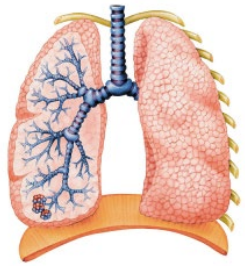


Peripherally Inserted Central Catheter (PICC) Thrombosis

CSL311 Anti-Beta Common

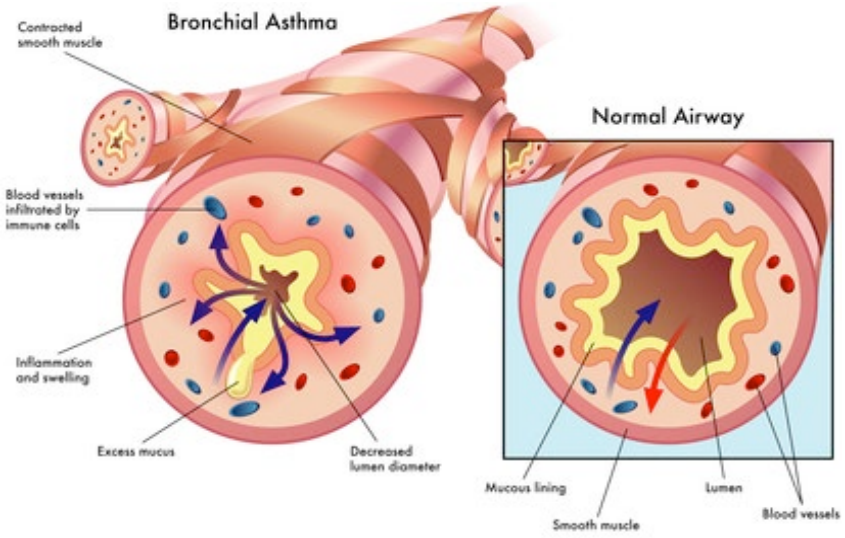
A Broad Mechanism of Action With Potential to Address the Entire Spectrum of Severe Asthma





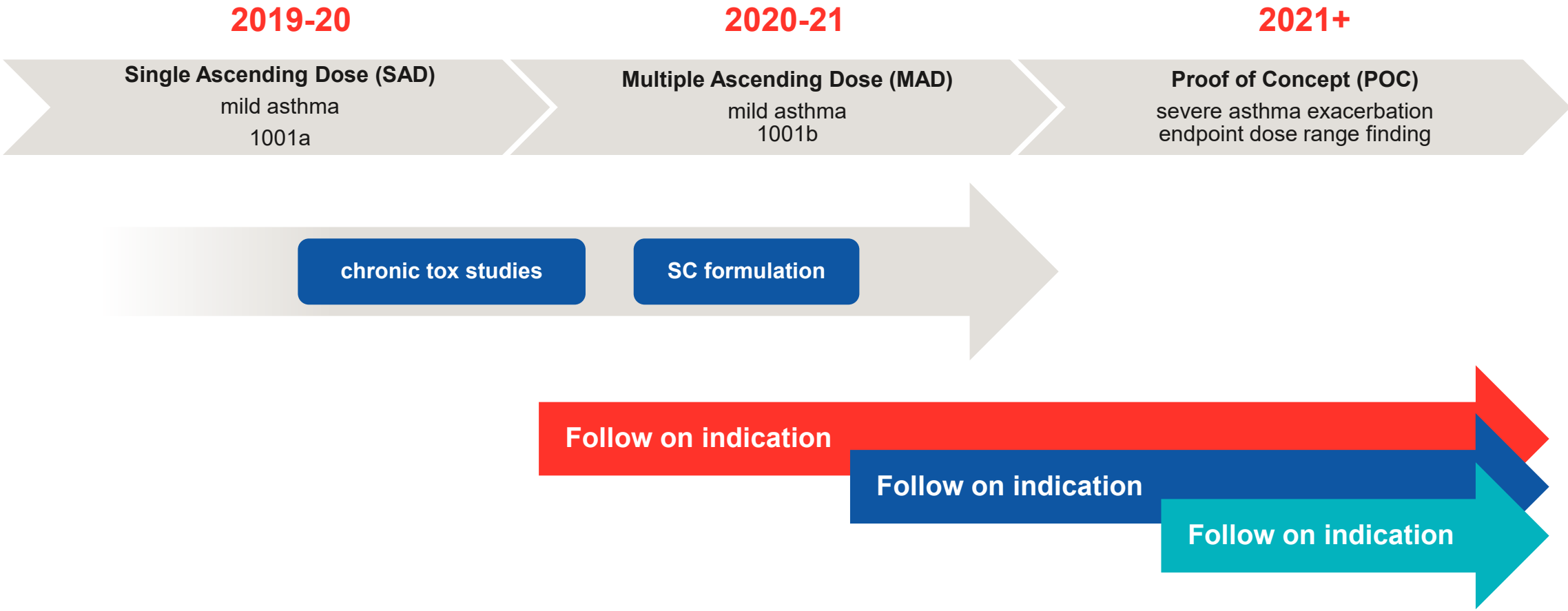
Asthma: ~300 million globally

Severe asthma: 2-10%



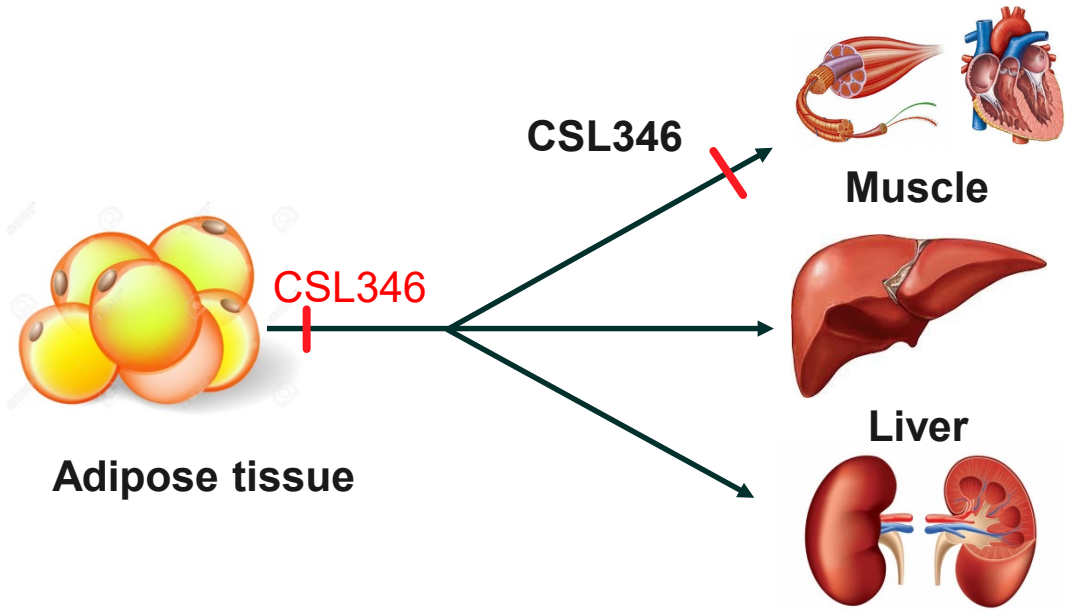
Source: https://www.atsjournals.org/doi/pdf/10.1513/AnnalsATS.201508-514MG

CSL311 Phase I Clinical Strategy Informs Early POC Expansion



CSL346 VEGF-B Antagonist

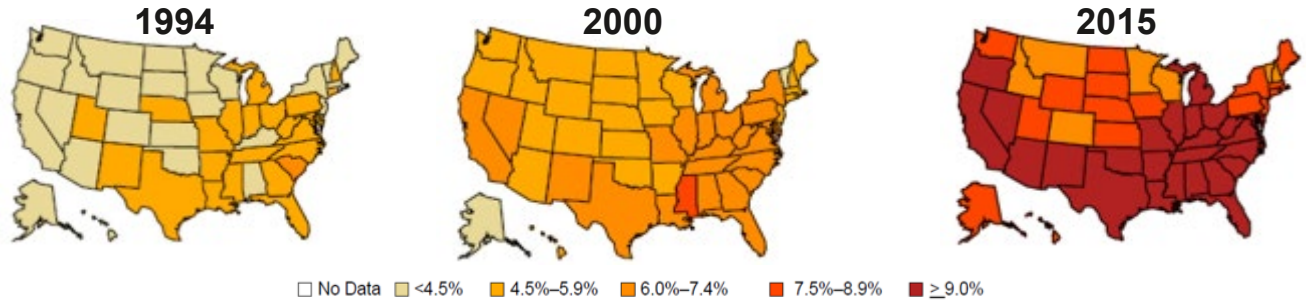
- CSL346 is a novel humanised monoclonal antibody (IgG4) that binds VEGF-B
- Strong renoprotective effects in diabetic kidney disease (DKD) animal models
- Phase II proof of concept study to start in early 2020



Source: http://dx.doi.org/10.1016/j.cmet.2017.01.004

Diabetes and Diabetic Kidney Disease

Increasing Prevalence



Diabetes accounts for 30-50% of all chronic kidney disease

1 in 3
diabetics develop DKD over time

70%
among them develop albuminuria
(ACR ≥30 mg/g; ie, incipient/overt nephropathy)

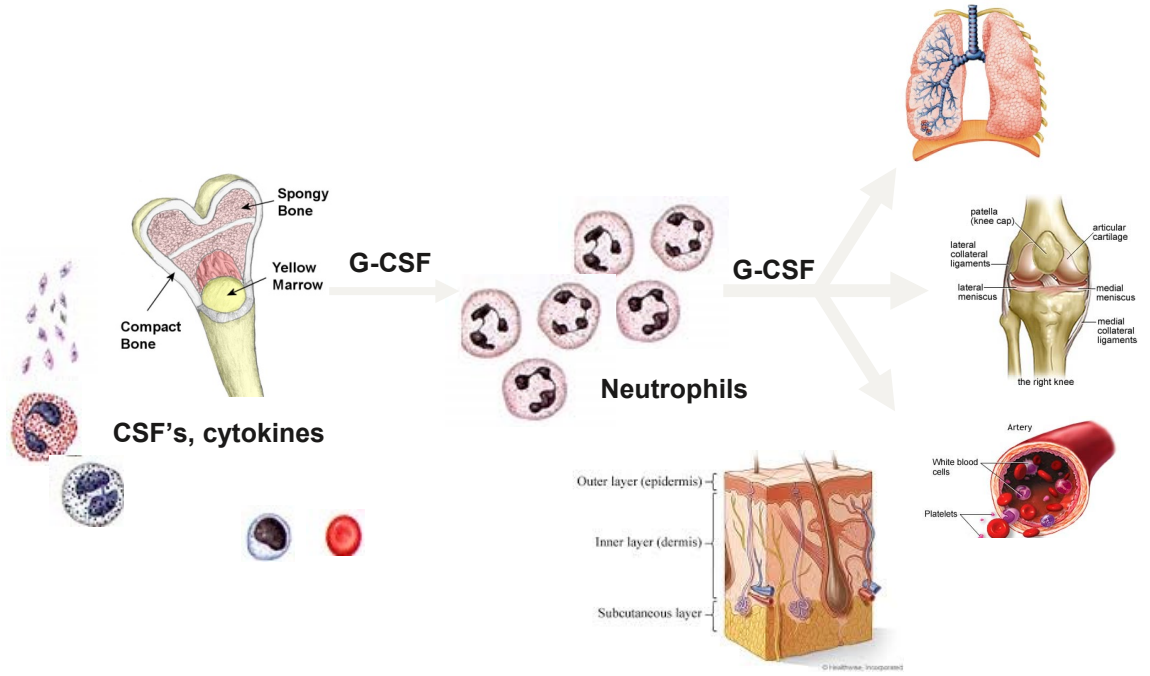
~300,000
People with DKD developed end stage renal disease (ESRD) in 2015

Sources: Map data: CDC Division of Diabetes Translation. US Diabetes Surveillance System (www.cdc.gov/diabetes/data) International Diabetes Federation 2015 Statistics; DN % - Calculated through consolidation of individual country sources. Top 7 markets: US, Japan, German, Italy, Spain, France, UK.
Mayo Clinic; The National Institute of Diabetes and Digestive and Kidney Diseases.
American Diabetes Association; Vecihi Batuman, Diabetic Nephropathy Workup, Medscape; International Diabetes Federation 2015 Statistics.

CSL324 G-CSF Receptor Antagonist

G-CSF, neutrophils and inflammatory disease

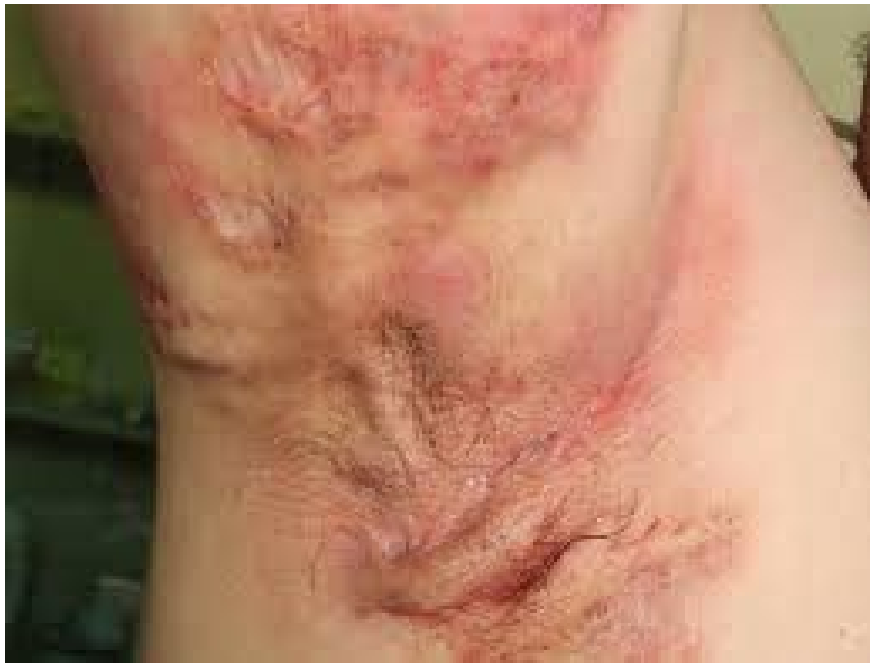
- Neutrophils are the most abundant white blood cells (WBC), ~10^9 cells / kg body weight leave the bone marrow daily
- Excessive neutrophil production and persistence within tissues leads to chronic inflammation and tissue destruction
- G-CSF plays a key role in neutrophil production, migration, lifespan and activation
- No competitors known to pursue G-CSF inhibition: First-in-Class



CSL324 G-CSF Receptor Antagonist

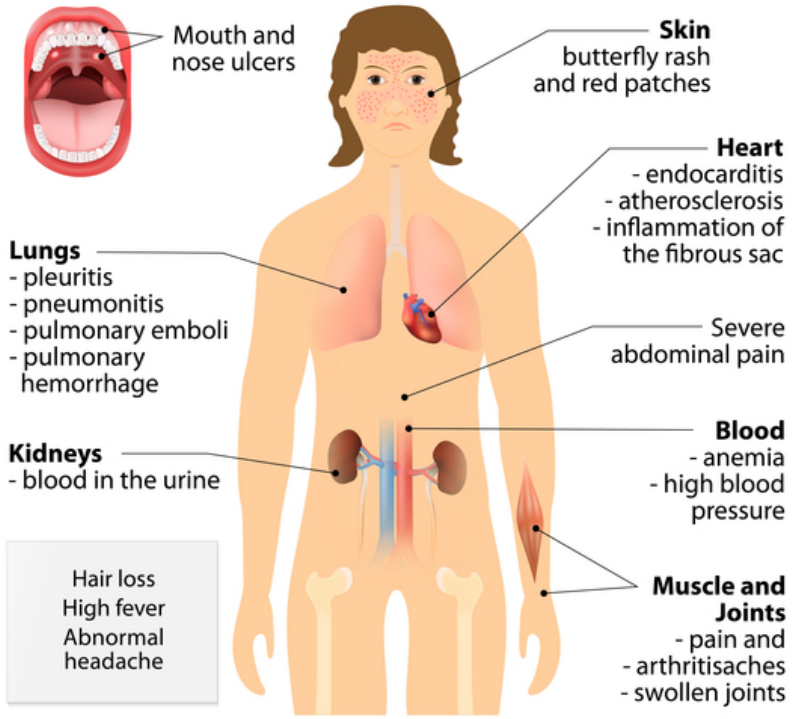
Begins Phase Ib Study in Neutrophilic Dermatoses

- Hidradenitis Suppurativa (HS) and Other Neutrophilic Dermatoses (ND)
  - Hidradenitis Suppurativa – 1% prevalence
    - A disease of hair follicles, immune dysregulation
    - Chronic inflammation, discharge, scarring
    - Growing in prevalence, limited treatments
    - High impact on quality of life
  - Phase I FIH trial complete
  - Initiation of Phase Ib in HS / ND patients
  - Safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and response



Source: https://rd.springer.com/article/10.1007/s13671-013-0064-8

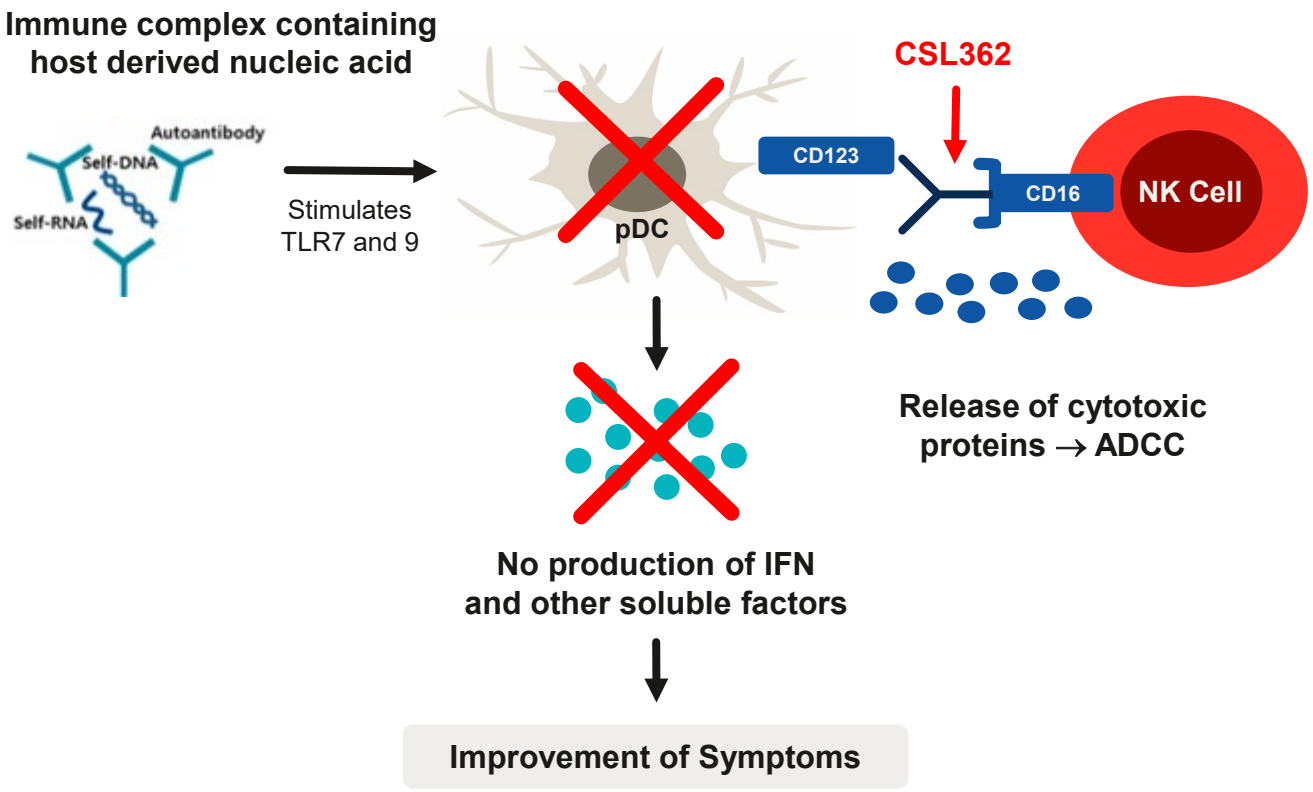
Systemic Lupus Erythematosus (SLE)



Disease Features	• Characterised by immunologic abnormalities, complex pathophysiology • Heterogeneous disease
Symptoms Diagnosis	• Nearly every organ system may be affected • Diagnosis based on clinical symptoms and laboratory testing
Risk Factors	• Women in childbearing years are most common • Prevalence is higher in non-Caucasian populations
Prognosis	• Survival rate is ~90% at 10 years, driven by organ damage • Quality of life may be significantly impacted

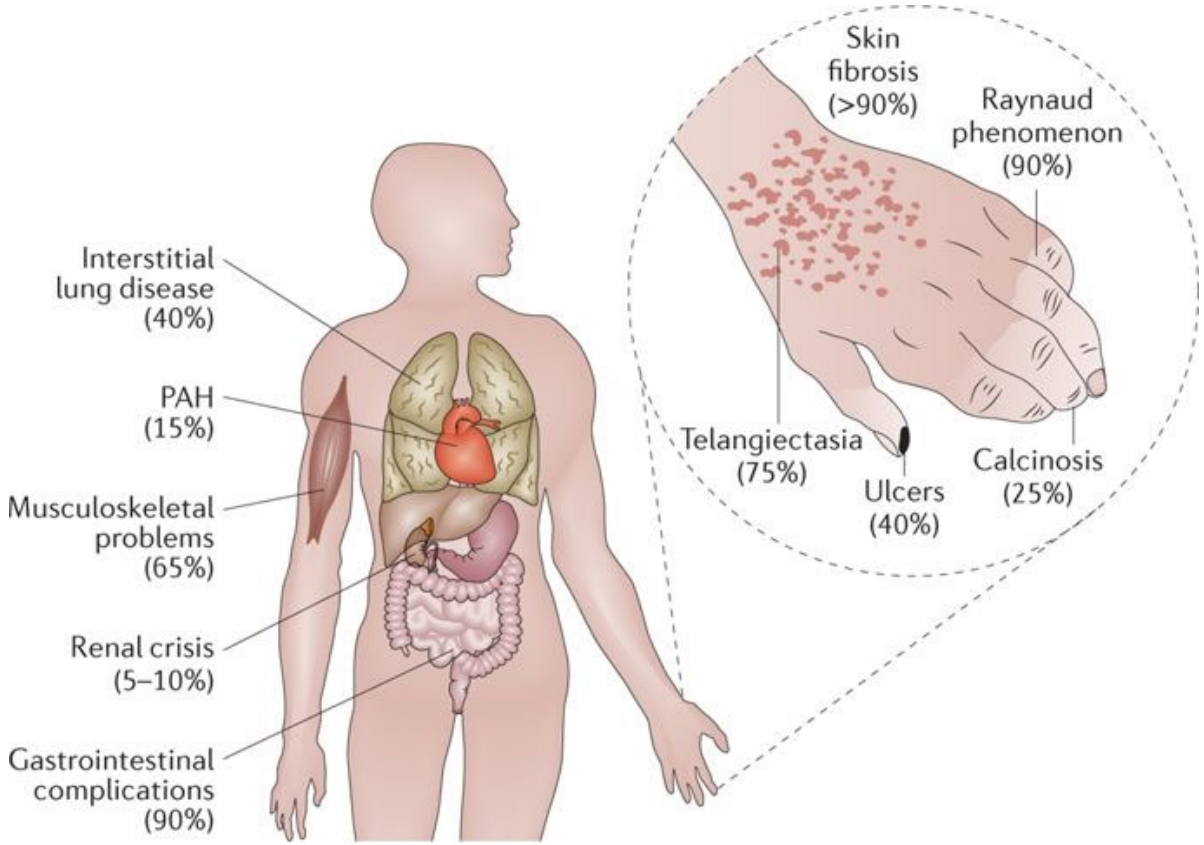
Strong Rationale for CSL362 Anti-IL-3Ra (CD123) in SLE

- Type 1 IFNs known to play a pivotal role in pathogenesis of SLE
- pDCs are the major producer of Type 1 IFNs
- CSL362 *ex vivo*
  - pDC depletion
  - Reduced interferon (IFN) gene signature
  - Basophil depletion
- Phase Ib in healthy volunteers and SLE patients to start in 1H2020



Systemic Sclerosis (SSc)

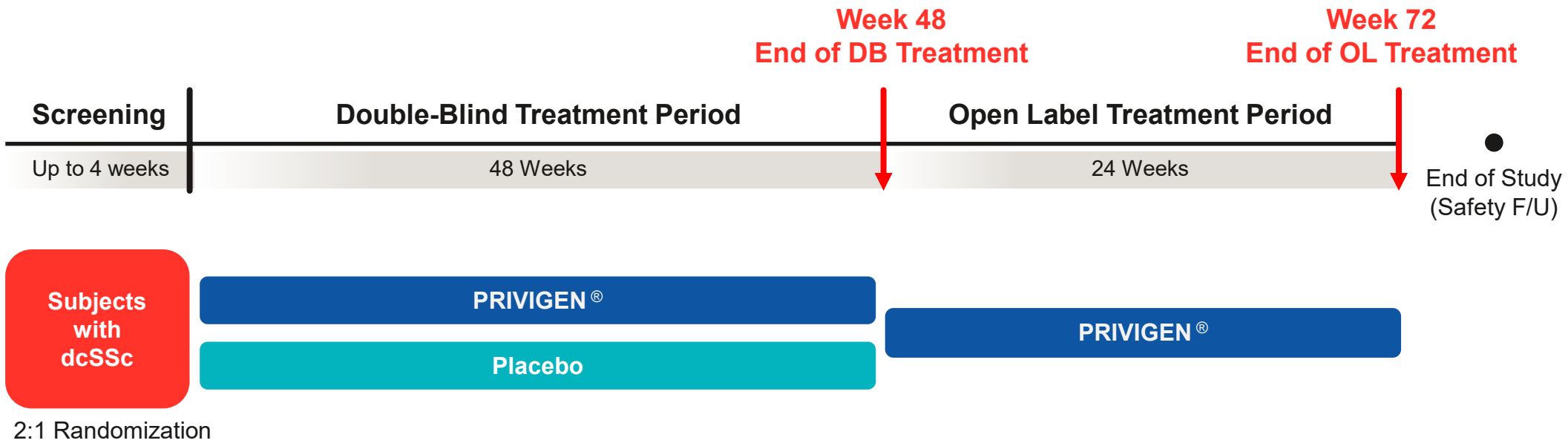
- Most life-threatening rheumatic disease: 10-year cumulative survival is 62.5%
- Limited approved disease modifying agents
- Most treatments aimed at improving symptoms and managing complications
- Prevalence 7 - 43/100,000 (US/EU)



Source: *Nature Reviews Disease Primers* **volume 1**, Article number: 15002 (2015) Clin Epidemiol. 2019; 11: 257–273

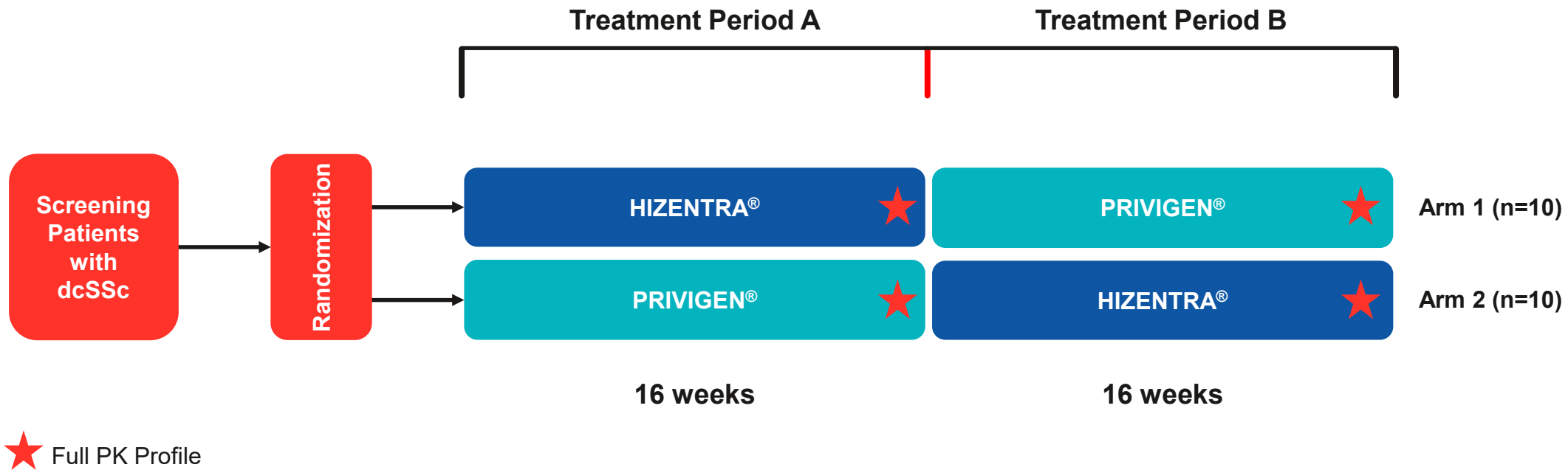
IMPRESS

PRIVIGEN® (IVIG) PhII, Efficacy and Safety Study



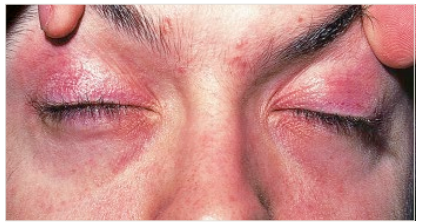
SURPASS

HIZENTRA® (SCIG) PhII, Safety and Bioavailability Study in Systemic Sclerosis

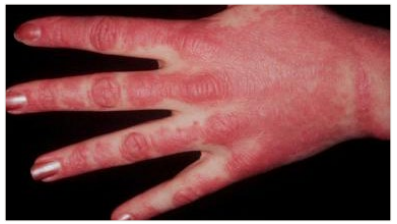


Dermatomyositis (DM)

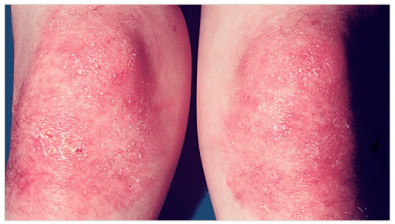
- Rare (2 - 9/100,000), serious, and life-threatening
  - 5-year mortality rate 10-30%
- Rash, muscle weakness, dysphagia, and systemic manifestations (heart, lung, gut, cancer) and specific autoantibodies
- Female predominant, typical onset in adults late 40’s – 60’s, in children 5 – 15yrs



Heliotrope Rash



Gottron’s Papules

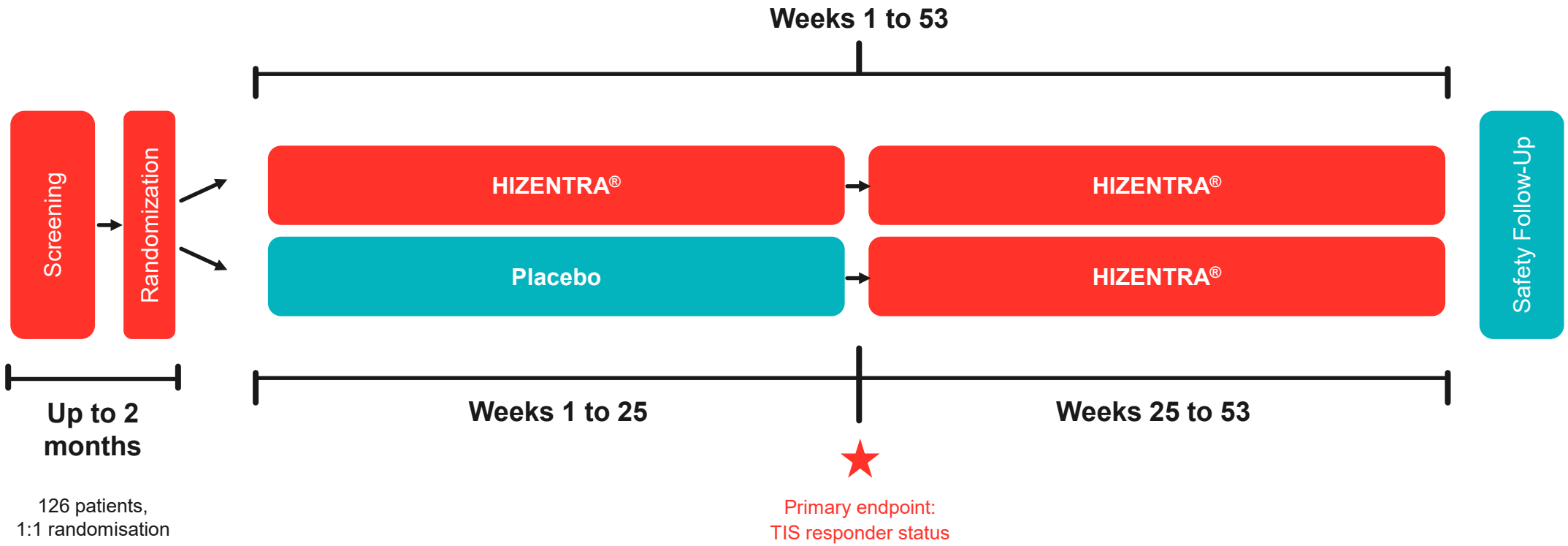


Skin Signs of DM

Sources: https://www.ncbi.nlm.nih.gov/books/NBK532860/; (2009) Epidemiology of Dermatomyositis. In: Dermatomyositis. Springer, Berlin, Heidelberg

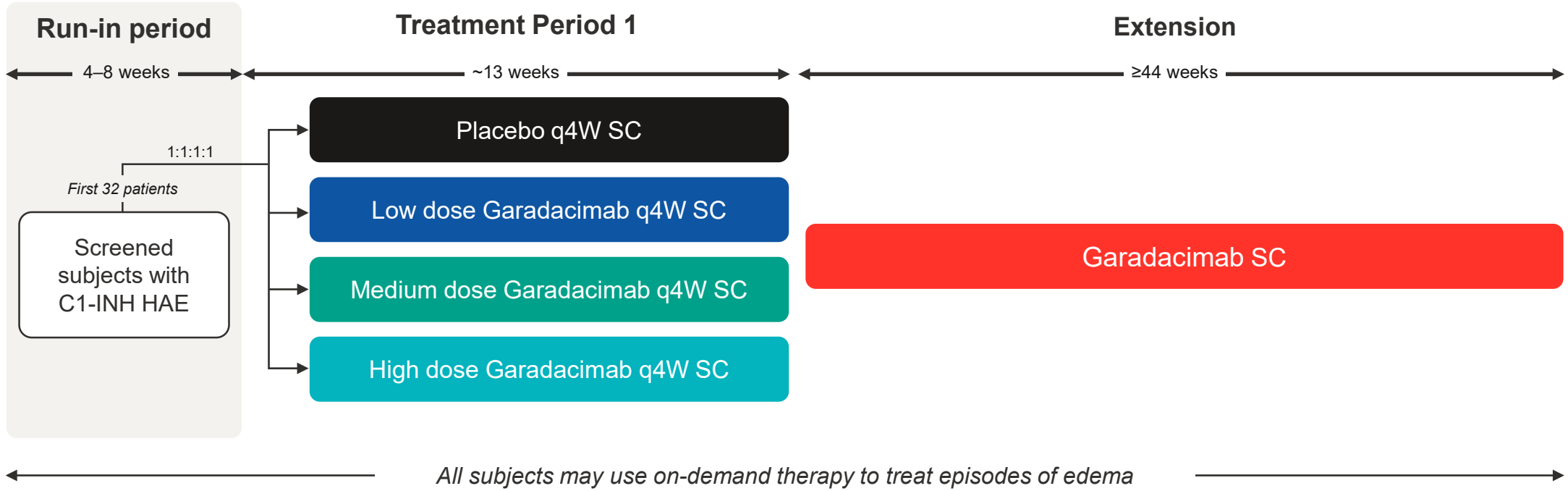
RECLAIIM

HIZENTRA® DM Treatment Study Design



Garadacimab Phase II Hereditary Angioedema (HAE) Study

Completed Double Blind Period



CSL Pipeline Progressing into Multiple New Disease Areas Using All Three Product Development Platforms

- **Sickle Cell Anaemia** – CSL200 (lentiviral stem cell gene therapy), CSL889 (Hemopexin)
- **Contact-Mediated Thrombosis** – CSL312 Garadacimab (Anti-Factor XIIa)
- **Respiratory Disease** – CSL311 (Anti-Beta common)
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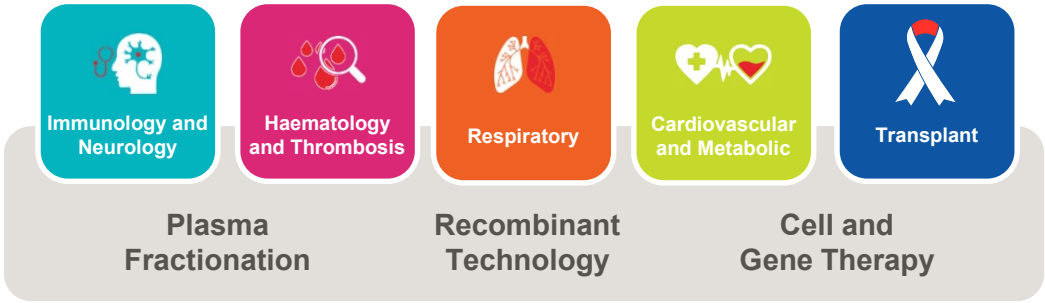


Commercial – Part 1

Mr. Bill Campbell

Executive Vice President and Chief Commercial Officer
CSL Behring

Global Commercial Operations at a Glance

~1,800

Commercial employees

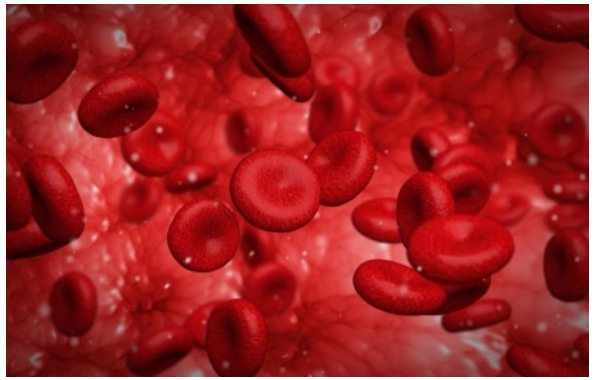
35 **Affiliate Offices**

Conducting business in **100+ Countries**

US$7.2

Billion in annual revenue

4 Commercial **Regions**



5 **Therapeutic** Areas

FY’19 Highlights

Strong Business Performance

Balanced Regional Growth:

9% – 17%

Executing to Plan on New Launches

Ig Growth well Above Market

Expanding Market Presence through New Affiliates

China GSP License Establishment

Implemented TA Structure / Model

Strong Demand Across the Portfolio

privigen® Immune Globulin Intravenous (Human), 10% Liquid; Hizentra® Immune Globulin Subcutaneous (Human) 20% Liquid	**Ig**	• Strong underlying market growth • Disciplined approach to market expansion • Growth driven by volume and mix improvements
IDELVION® Coagulation Factor IX (Recombinant), Albumin Fusion Protein; AFSTYLA® Antihemophilic Factor (Recombinant), Single Chain	**Coagulation**	• Market leadership with IDELVION® in key markets • Additional launch opportunities for AFSTYLA® / IDELVION® • Life-cycle expansion (21-day dosing)
HAEGARDA® C1 Esterase Inhibitor Subcutaneous (Human); Kcentra® Prothrombin Complex Concentrate (Human)	**Specialty**	• New launches with HAEGARDA® • Continued growth of KCENTRA® in the US
AlbuRx®; Albuminar® Albumin (Human) USP, 5%/25%	**Albumin**	• Disciplined approach in China • Volume growth in all regions

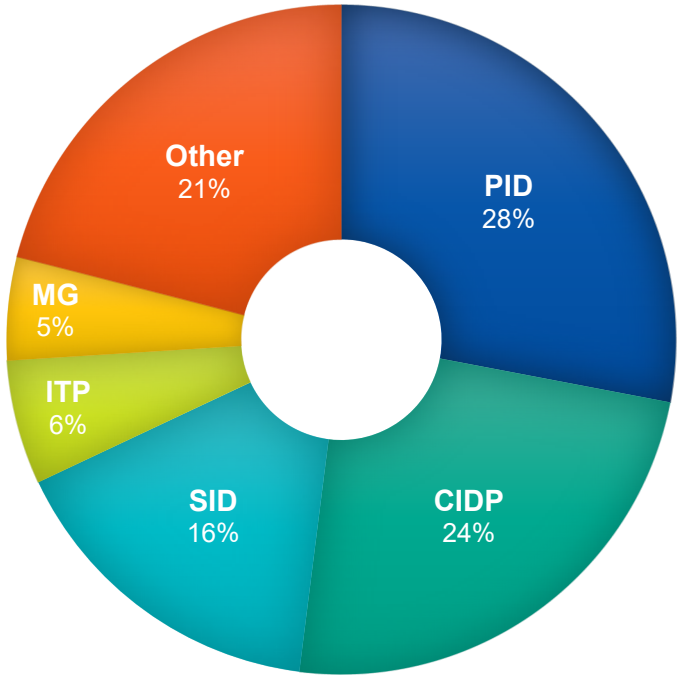
CSL™

Immunoglobulin Market

Market Dynamics

- Increasing awareness and diagnosis
- Growth in PID and CIDP
- Expanding usage for SID
- Potential new indications
- Continued market supply tightness

Global IG Volume by Indication 8% Growth



Source: Data on file

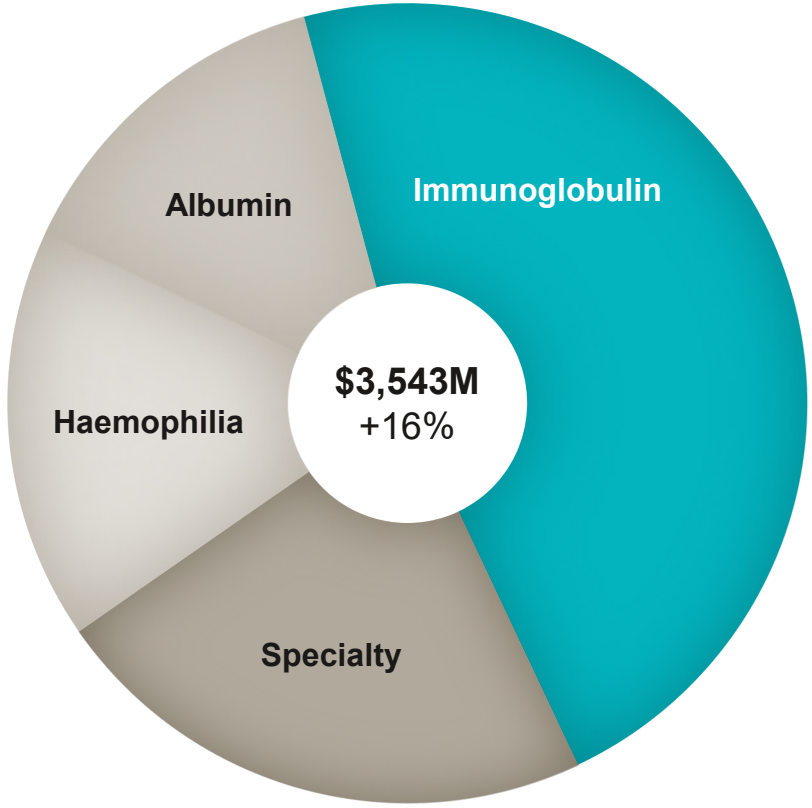
CSL Portfolio: Immunoglobulin

privigen®

Hizentra®

Positioned for Continued Growth

- Market Leading Products
- Substantial volume and share growth
- Balanced growth across all regions
- IV and SC for CIDP
- History of Innovation



Source: Data on file
M = US$ millions

PRIVIGEN®

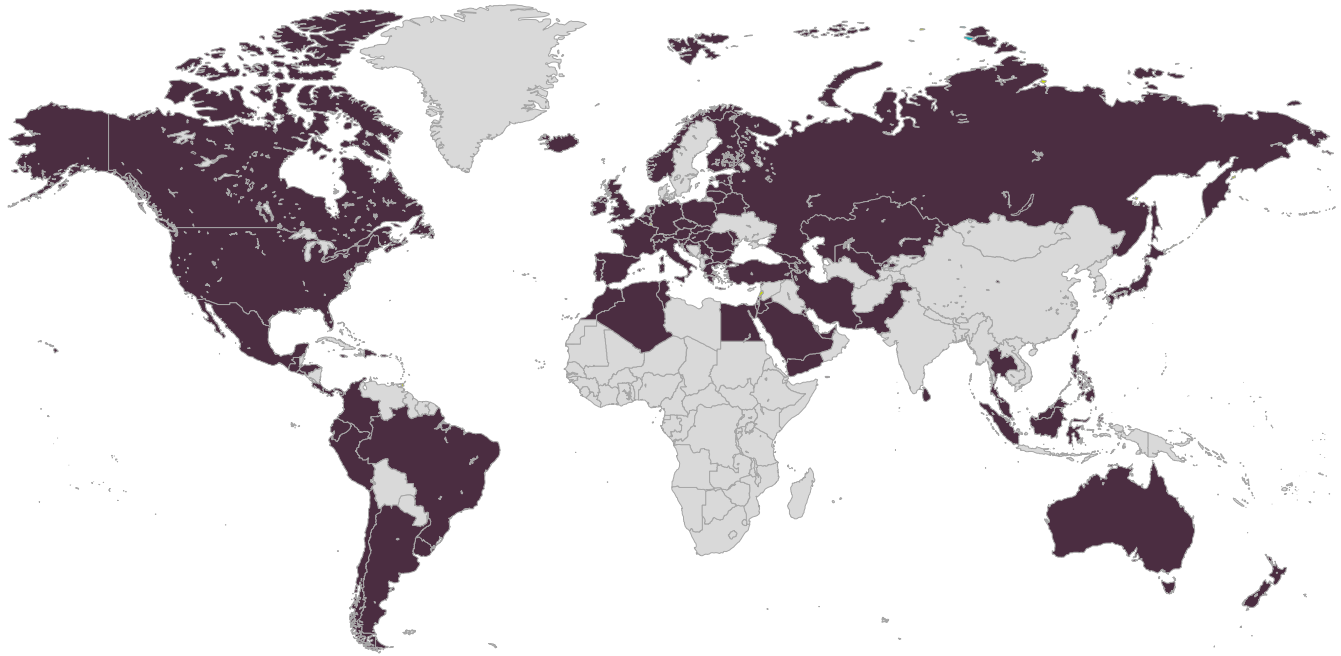
Expanding Global Market Leadership: 87 countries

#1 Prescribed IVIG Worldwide

Proven effective and well tolerated in **12+ years**

Used in **>100,000 patients** with chronic disease in the last year

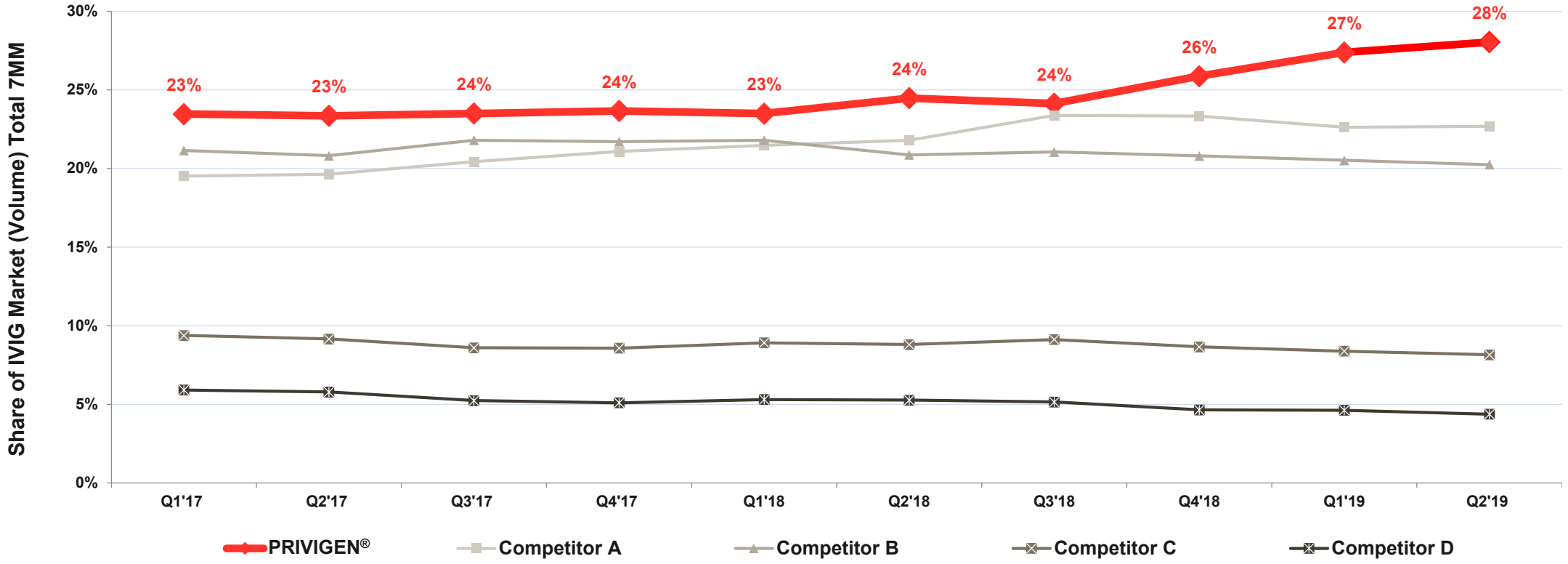
Approved for use in multiple indications



Indications:
EU: PID, SID, ITP, GBS, KD, CIDP, MMN
US: PID, ITP, CIDP
CA: PID, SID, ITP, CIDP
JP: CIDP
AUS: PID, SID, ITP, GBS, CDP, MMN, MG, Lambert-Eaton Myasthenic Syndrome (LEMS), Stiff Person Syndrome (SPS)

Source: Data on file

PRIVIGEN® Performance Through Q2’19



Source: Data on file

HIZENTRA®

Expanding Global Market Leadership: 57 Countries

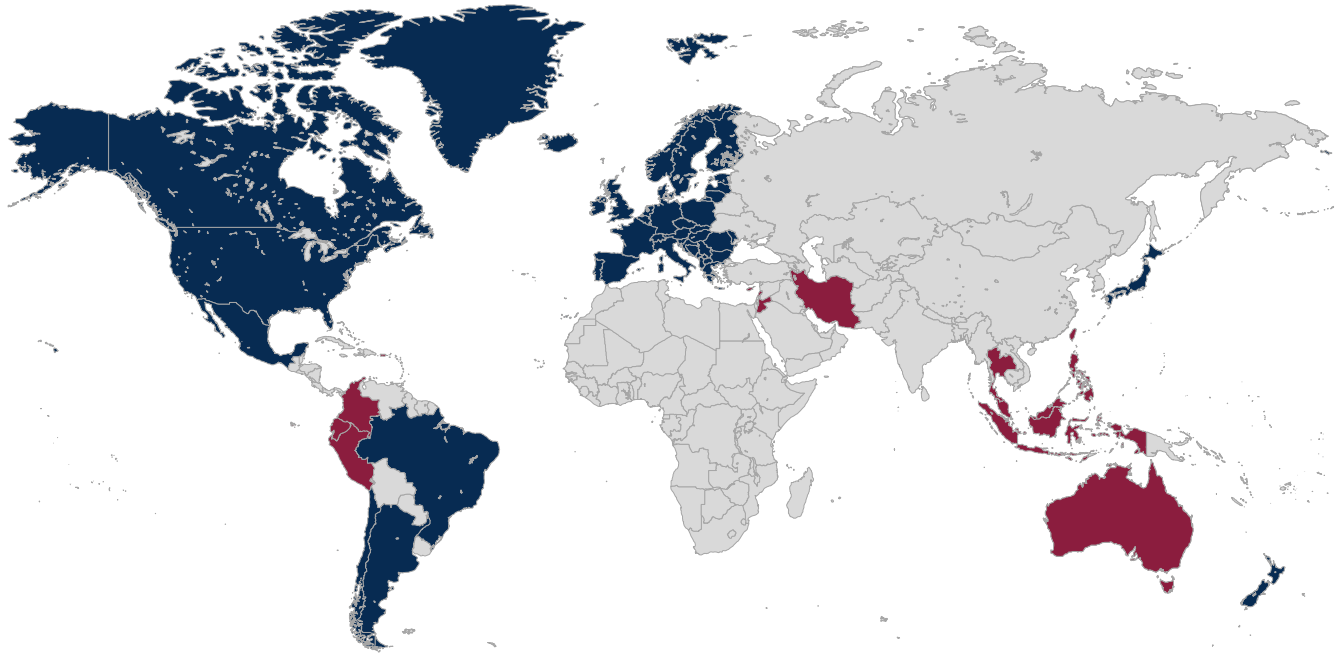
Hizentra®

Innovator, Market Leader, Most Prescribed SCIG Worldwide

Proven efficacy and tolerability since **2010**

100,000 patient-years of experience

More than **6,000,000** exposures worldwide*



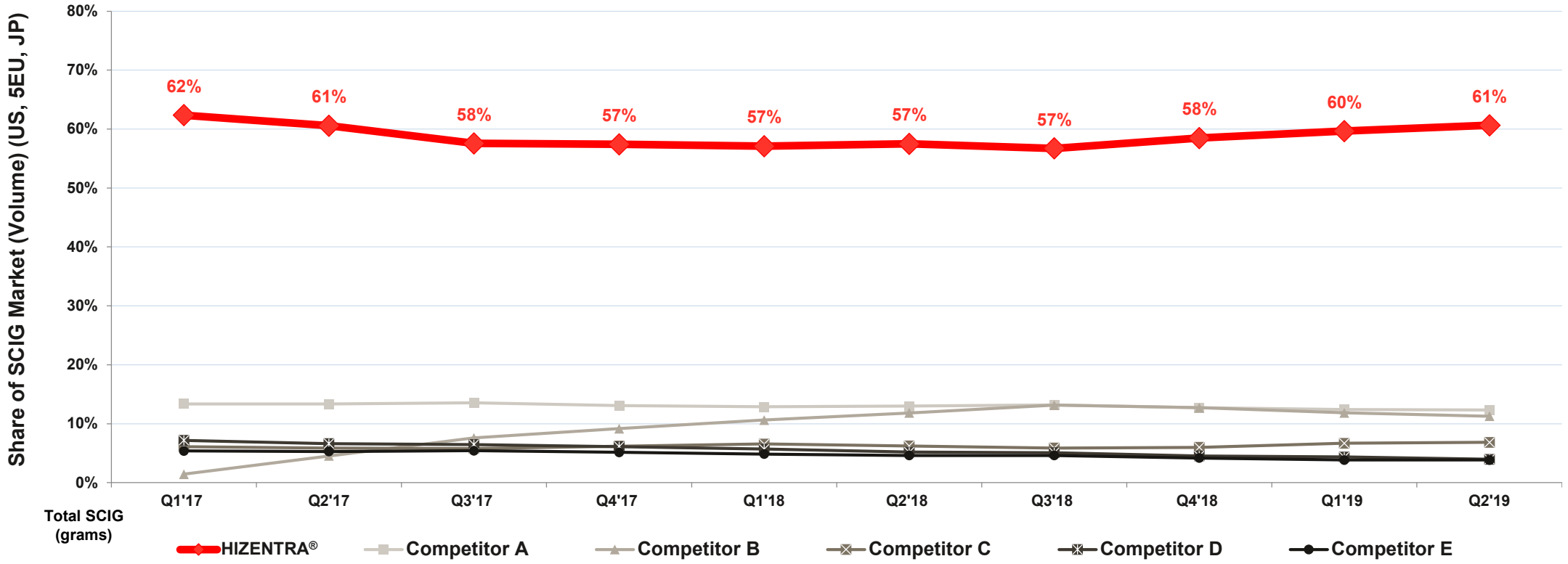
PID

PID + CIDP

Source: Data on file

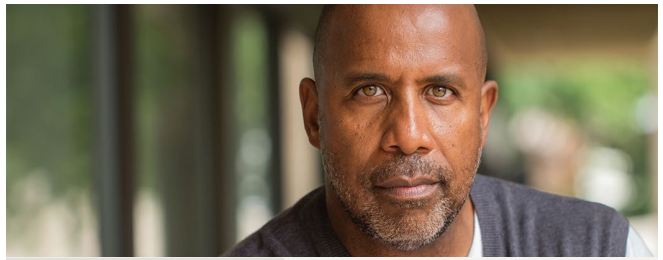
*Hizentra® also has SID indication in most countries outside of the US.

HIZENTRA® Undisputed Market Leader in SCIG



Source: Data on file

HIZENTRA® Addresses Unmet Needs in CIDP



Experience IV-related systemic adverse reactions

5x as many patients said they felt fewer side effects with HIZENTRA®

Seek the flexibility, freedom, and control of self-infusing

8x as many patients said HIZENTRA® offers more freedom than IVIG

Approved March ‘18 US & EU
Approved March ‘19 Japan

Interest & Awareness Remains High

Market Share Growth With Both Privigen & Hizentra

Orphan Exclusivity Granted for Hizentra CIDP

Have venous access issues

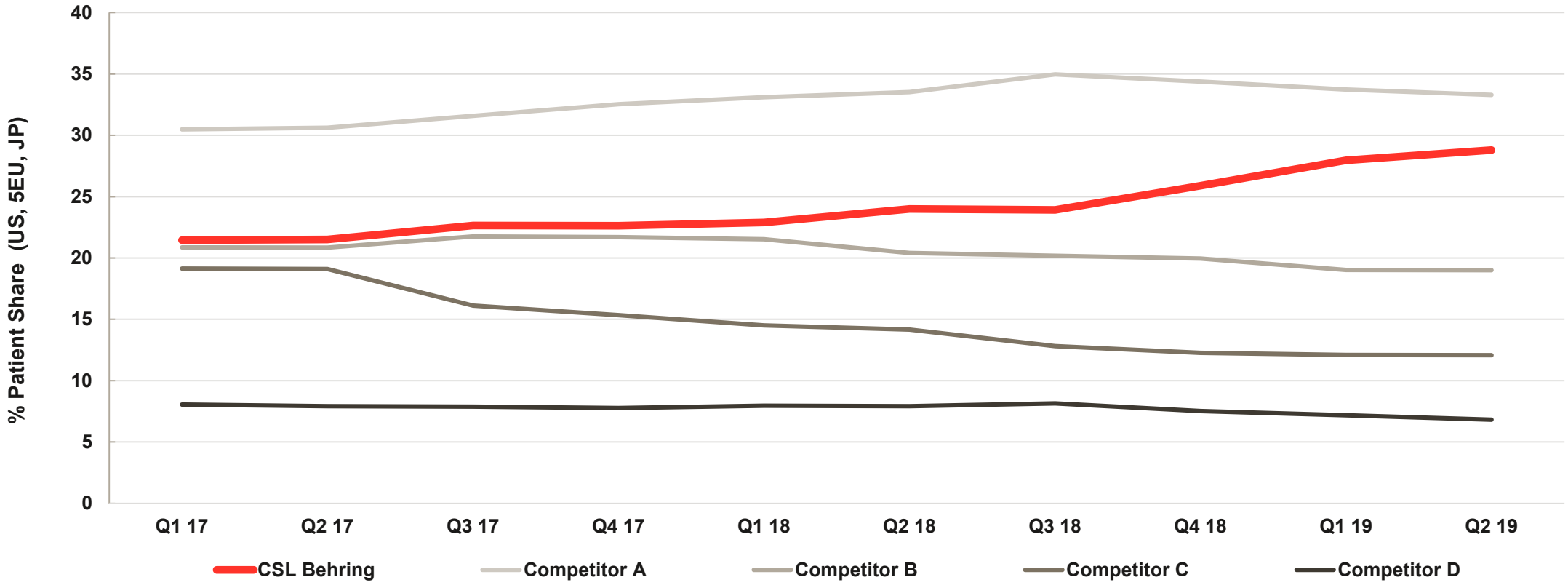
HIZENTRA® does not require venous access

Require more frequent infusions to manage their disease

HIZENTRA® provides steady state Ig levels for continuous control

Source: Data represents patients reporting a preference between IVIG in the pre-randomised phase and HIZENTRA® in the randomised phase of the phase III study of subcutaneous immunoglobulin for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) – the PATH study.

CSL Behring on Track to Become Market Leader in CIDP



Source: Data on file

Market Leadership in Ig Therapy

Past

- **1979** 1st IVIG Sandoglobulin®
- **2006** 1st SCIG Vivaglobin®
- **2007** Next generation IVIG PRIVIGEN®
- **2010** 1st 20% SCIG HIZENTRA®
- **2013** 1st SCIG in Japan HIZENTRA®
- **2013** CIDP in EU PRIVIGEN®
- **2015** 1st flexible dosing HIZENTRA®

Present

- **2017** CIDP in US PRIVIGEN®
- **2018** 1st SCIG in CIDP HIZENTRA®
- **2018** 1st SCIG in PFS HIZENTRA® (Canada)
- **2019** MMN EU PRIVIGEN®

Future

- 1st SCIG up to 100 mL/hour HIZENTRA®
- 1st SCIG with manual push HIZENTRA®
- 1st SCIG in 5, 10 & 20 ml PFS HIZENTRA®
- IsoLo label enhancement PRIVIGEN®
- New indications: Dermatomyositis Systemic Sclerosis

Panel Q&A Session

Break – 15 minutes

Commercial – Part 2

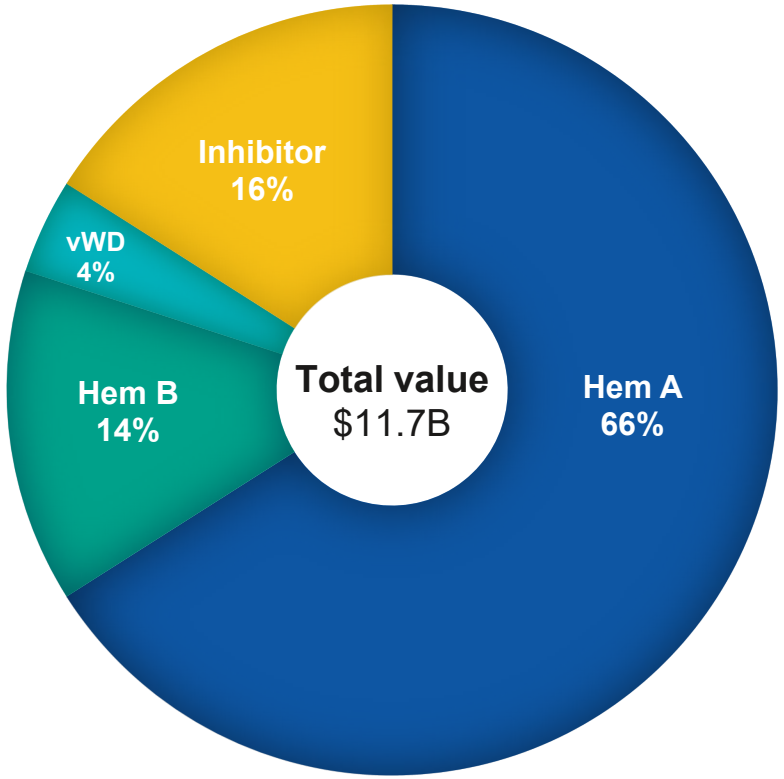
Mr. Bill Campbell

Executive Vice President and Chief Commercial Officer
CSL Behring

Haemophilia Market

Market Dynamics

- New therapies continue to increase competitiveness in Hem A segment
- Patient education about Prophylaxis in Hem B driving utilization of long acting products
- VWD is underserved due to lack of awareness/understanding of the disease



Source: Data on file
B = US$ billions

Haemophilia Portfolio

IDELVION®
Coagulation Factor IX (Recombinant), Albumin Fusion Protein

- 40% growth*
- Continued patient switching
- Additional countries to launch
- 21 day dosing
- Transformational product

AFSTYLA®
Antihemophilic Factor (Recombinant), Single Chain

- 85% growth*
- Long lasting and reliable bleed protection
- Successful product transition

HELIXATE® phased out

Haemate® P
Von Willebrand factor/factor VIII

VONCENTO®

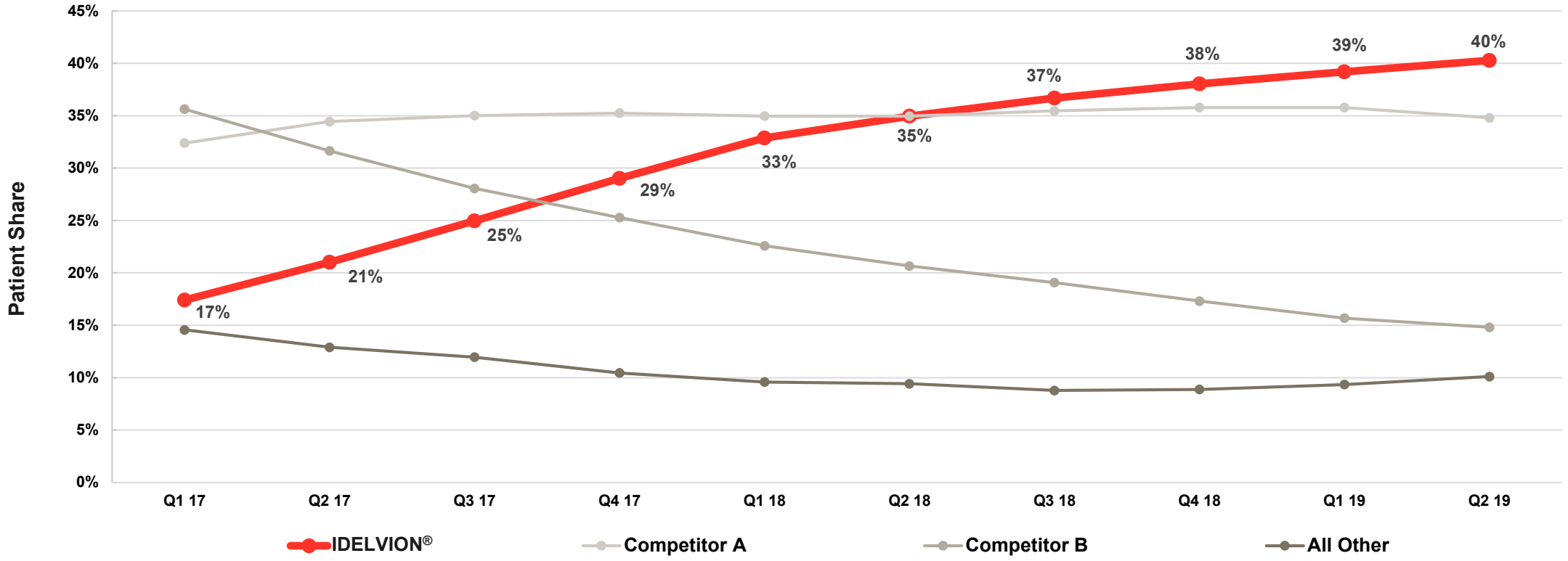
- Leadership position in VWD: 59%^ market share globally

Recombinant Coags +7%*

vWD +7.5%*

* Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance.
^Source: Data on File

IDELVION® Prophylaxis Market Leadership



Based on 5 major markets (US, Japan, Germany, Italy and UK) where IDELVION® is reimbursed and commercially available.
Source: Data on File

Positioning AFSTYLA® in a Competitive Market

Higher binding affinity to vWF	• Unique single-chain molecular structure provides increased binding • Enhanced binding affinity protects AFSTYLA® from degradation, extending time in circulation
2x weekly dosing	• FDA-approved for 2x or 3x weekly dosing • Factor trough levels above 1.9% with 2x weekly dosing
Excellent bleed protection	• ZERO bleeds (median AsBR*) in all patients, regardless of age and dosing frequency
Low annual consumption	• AFSTYLA® delivers the benefits of an EHL† with the lowest annual consumption

* AsBR: Annualised spontaneous bleeding rate
† EHL: Extended half life

CSL Portfolio: Specialty Products

BERINERT® C1 Esterase Inhibitor, Human
On-Demand Treatment

HAEGARDA® C1 Esterase Inhibitor Subcutaneous (Human)

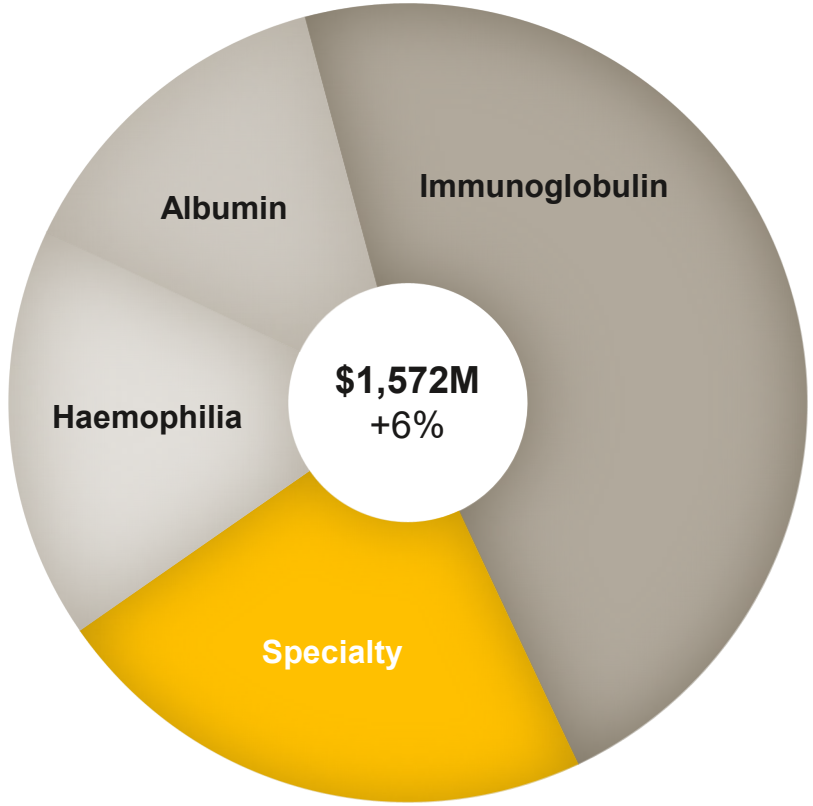
Kcentra® Prothrombin Complex Concentrate (Human)

Zemaira® alpha$_1$-proteinase inhibitor (Human)

Respreeza® alpha$_1$-proteinase inhibitor (Human)

RiaSTAP® Fibrinogen Concentrate (Human)
Strengthens clots. Supports hemostasis.

HAEMOCOMPLETTAN P



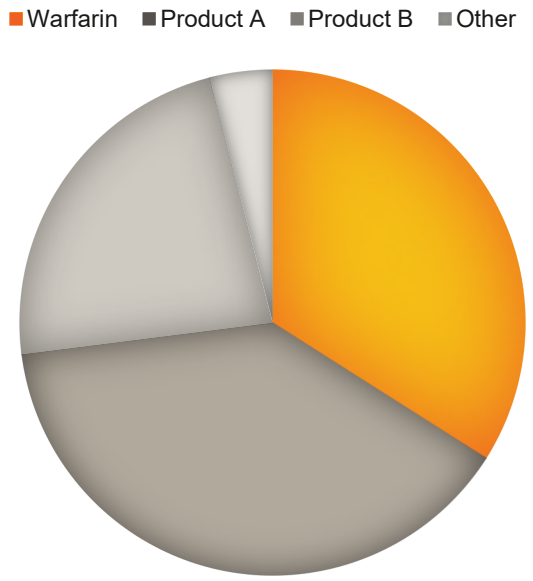
M = US$ millions

Continued Growth Opportunity for KCENTRA®

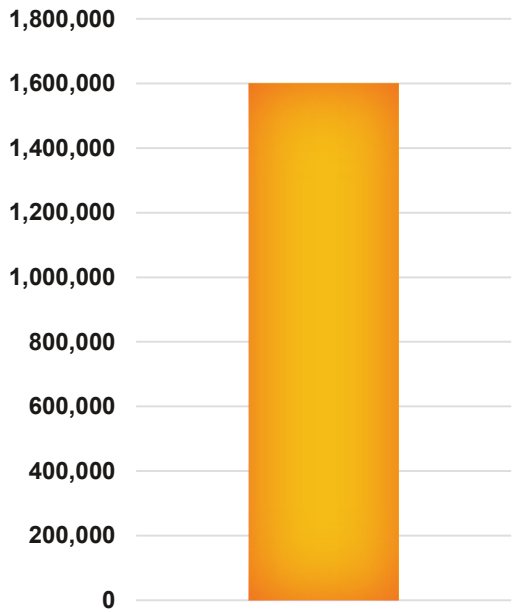
Kcentra® Prothrombin Complex Concentrate (Human)

US clinical practice guidelines recommend KCENTRA® over FFP to reverse the effects of Warfarin*

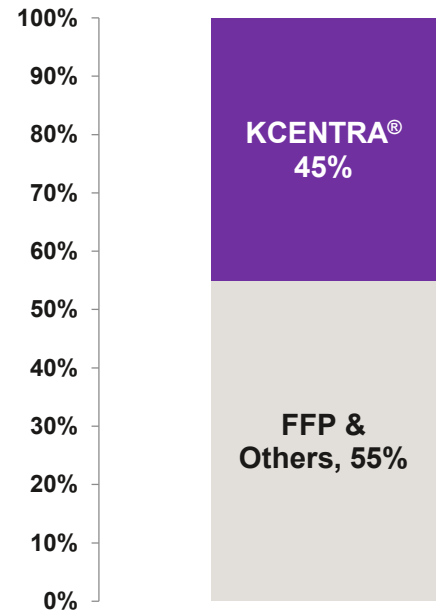
Anticoagulation Market US[1]



Warfarin Market US (Patients)[1]



Warfarin Reversal Market US[2]



*Neurocritical Care Society, Society of Critical Care Medicine, American College of Cardiology, American College of Chest Physicians, American Society of Gastrointestinal Endoscopy, American College of Surgeons

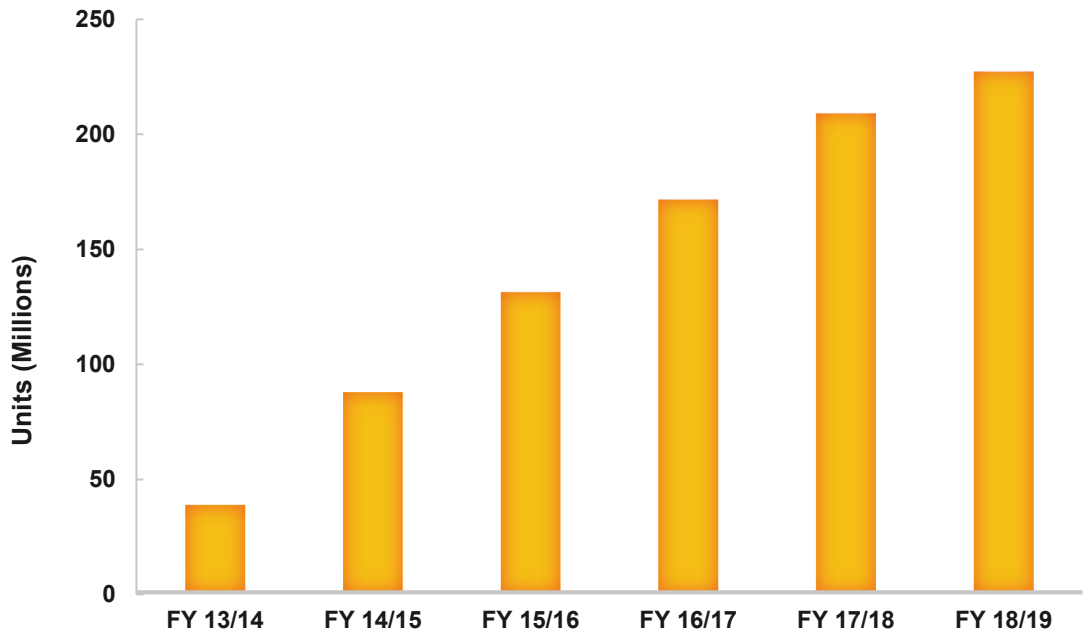
Sources: 1. Data on File. **2.** (RWD) Charge Master Data & Medical History Data.

KCENTRA® Growth in US Since Launch

Kcentra®
Prothrombin Complex Concentrate (Human)

KCENTRA®

- KCENTRA® remains the first and only FDA approved 4F-PCC for reversing patients on warfarin
- KCENTRA® is supported by multiple clinical guidelines as the preferred reversal agent
- KCENTRA® growth driven by:
  - Penetration within existing large hospital systems
  - Expansion into new regional accounts



Source: Data on file

#1 prescribed therapy in the US for the prevention of HAE attacks

Address C1-INH deficiency with HAEGARDA®

C1-INH has been used in HAE **> 35 years**

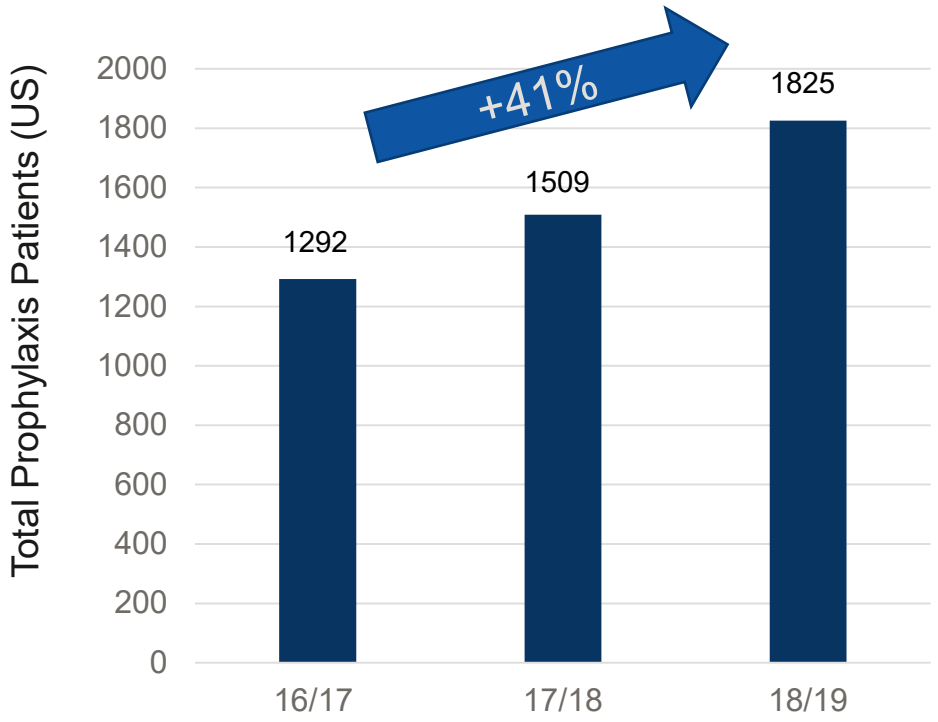
HAEGARDA® **reduced HAE attacks by 95%***

Rescue medication use was **reduced by >99%**†‡[1]

*Median reduction in number of attacks in patients receiving 60 IU/kg of HAEGARDA® vs placebo.
†Median reduction in rescue medication use in patients receiving 60 IU/kg of HAEGARDA® vs placebo.
‡The World Allergy Organization (WAO) guidelines for the management of HAE state that patients should have HAE rescue medication available at all times.

References: 1. Data on file

HAE Prophylaxis Market



- HAEGARDA® is the market leader in HAE prophylaxis in the US
- Rapid uptake at launch
- Significant brand loyalty
- Additional capacity to support new launches

Source: Data on file

Why HAEGARDA® ?

HAEGARDA® C1 Esterase Inhibitor Subcutaneous (Human)

HAEGARDA® Patients Rely On C1-INH For Efficacy And Safety

"I've been on HAEGARDA for one year, and I haven't had an attack. It allows me to be more independent, confident, and free because I can take it with me wherever I go and don't have to depend on anyone." – Zahra

"Having a therapy that addresses the root cause of HAE is important to me. It's like filling in the missing puzzle piece of C1-INH my body doesn't make, versus putting a mystery compound in my body." –Cheryl

"For me, I find it's easier to give myself injections at night so it's just part of my routine. And knowing how HAEGARDA works motivates me to take it on schedule." –Cheryl B-J.

Physicians Highly Satisfied with HAEGARDA®, Delivering On Its Promise of Efficacy With a Known MOA

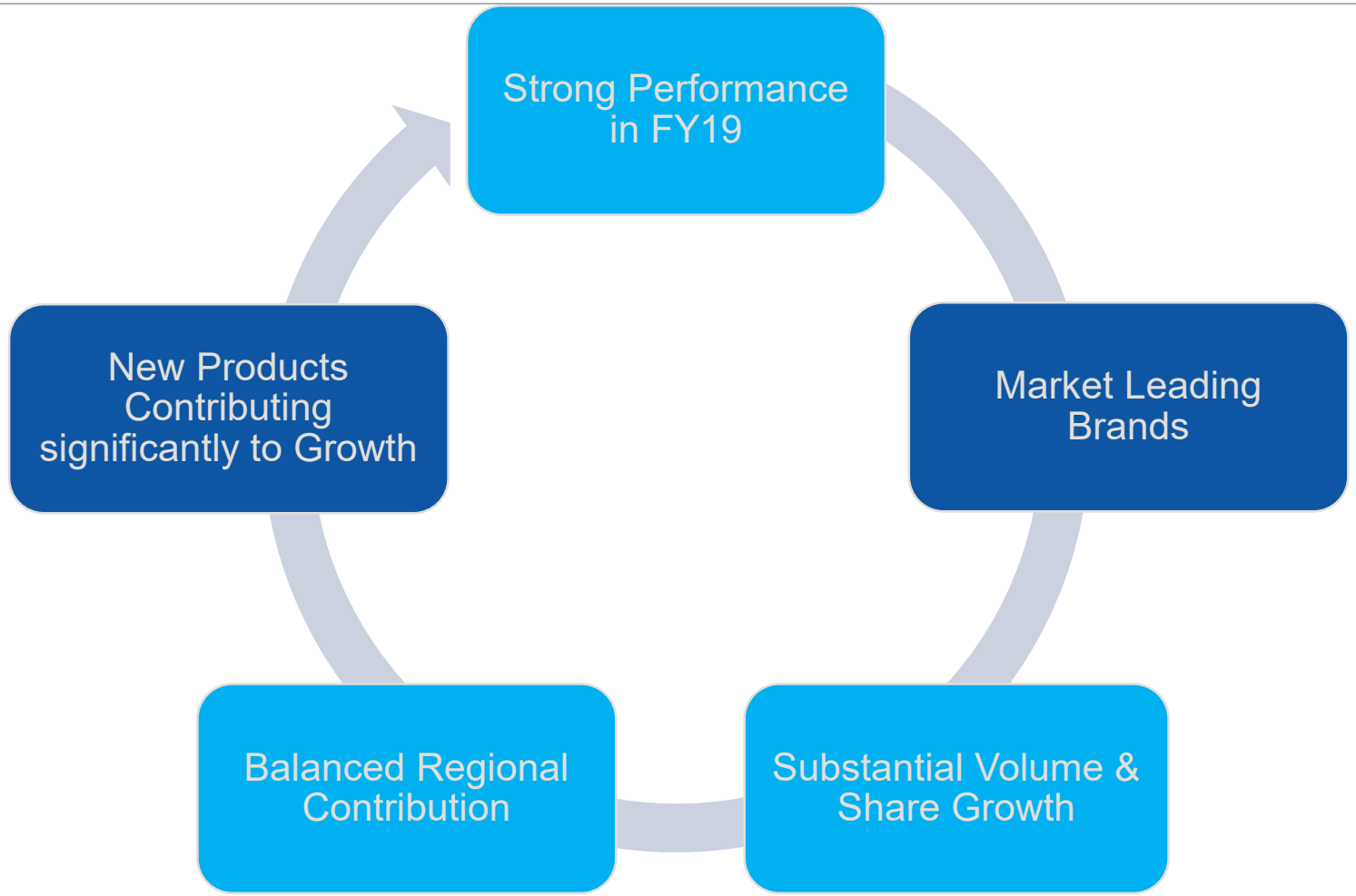
"People ask about Takhzyro but they're so well controlled on HAEGARDA® that they don't want to take a chance on it"

– February 2019 KOL Advisory Board Participant

"HAEGARDA® represents a "natural approach, which some of my female patients prefer"

– February 2019 KOL Advisory Board Participant

Commercial Summary



Seqirus

Dr. Russell Basser

Senior Vice President, Research and Development

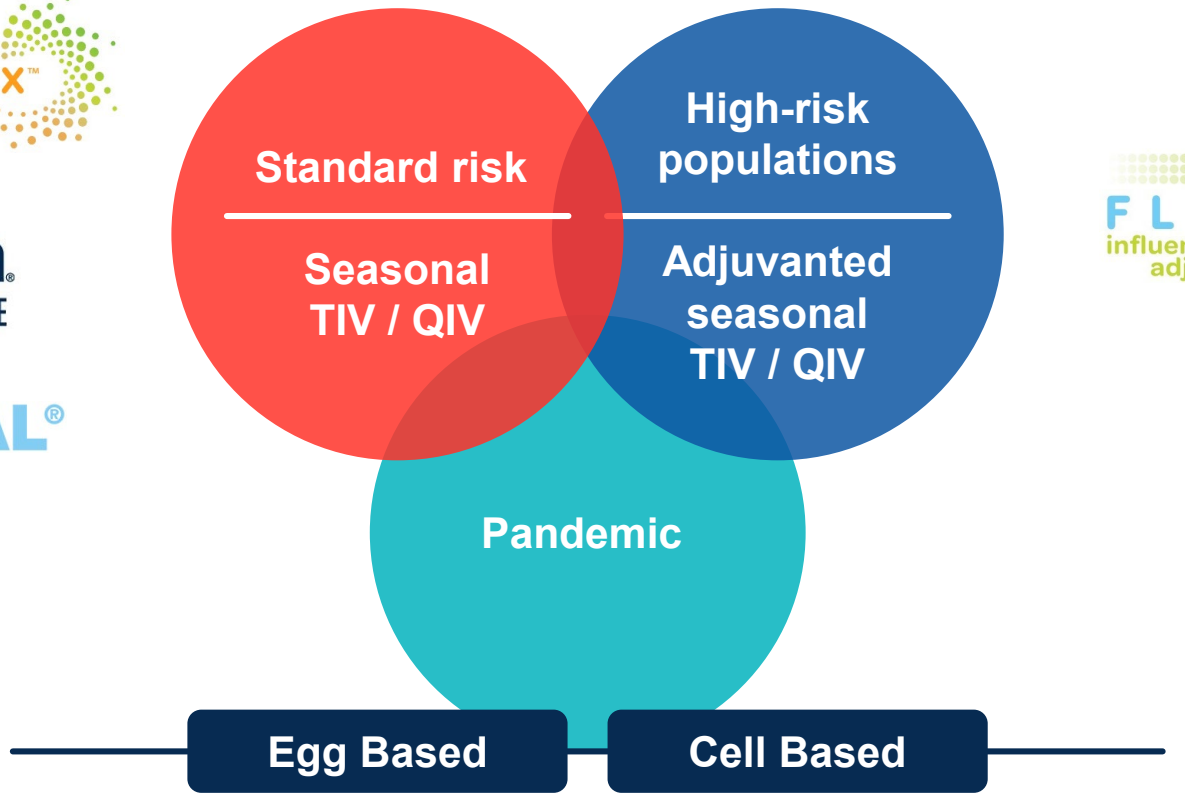
Seqirus

Seqirus Influenza Vaccines

Influenza Vaccine
FLUCELVAX™
QUADRIVALENT

afluria
INFLUENZA VACCINE

AGRIPPAL®



FLUAD™
influenza vaccine, adjuvanted

Influenza Science

Milestones in 2019

AFLURIA® QUADRIVALENT

- AUS approval for 6M – 4yrs

FLUCELVAX® QUADRIVALENT

- European approval for 9yrs and older
- Paediatric efficacy study (2 - 17yrs) – met all clinical endpoints
- Canadian approval for 9yrs and older

FLUAD® TRIVALENT

- Strong effectiveness data in UK – again recommended by JCVI for people 65yrs and older

FLUAD® QUADRIVALENT

- AUS approval for 65yrs and older, with positive PBAC recommendation
- Submission of dossier EU

Pre-Pandemic vaccine (MF59-adjuvanted H5N1 cell = aH5N1c)

- US submission

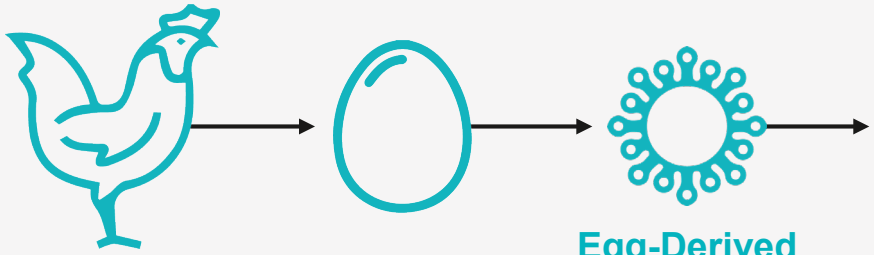
aQIVc (MF59 plus FLUCELVAX® antigen) product development commenced

JCVI - Joint Committee on Vaccination and Immunisation

Influenza Vaccine Innovation Through Cell-based Manufacturing

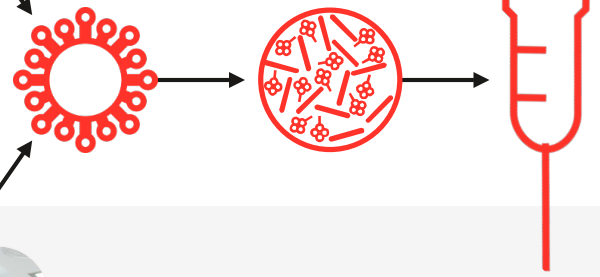
Eggs

- Most influenza vaccines
- Egg supply – long lead times
- Low flexibility



Egg-Derived Virus Seed

Circulating Virus



Cell Culture

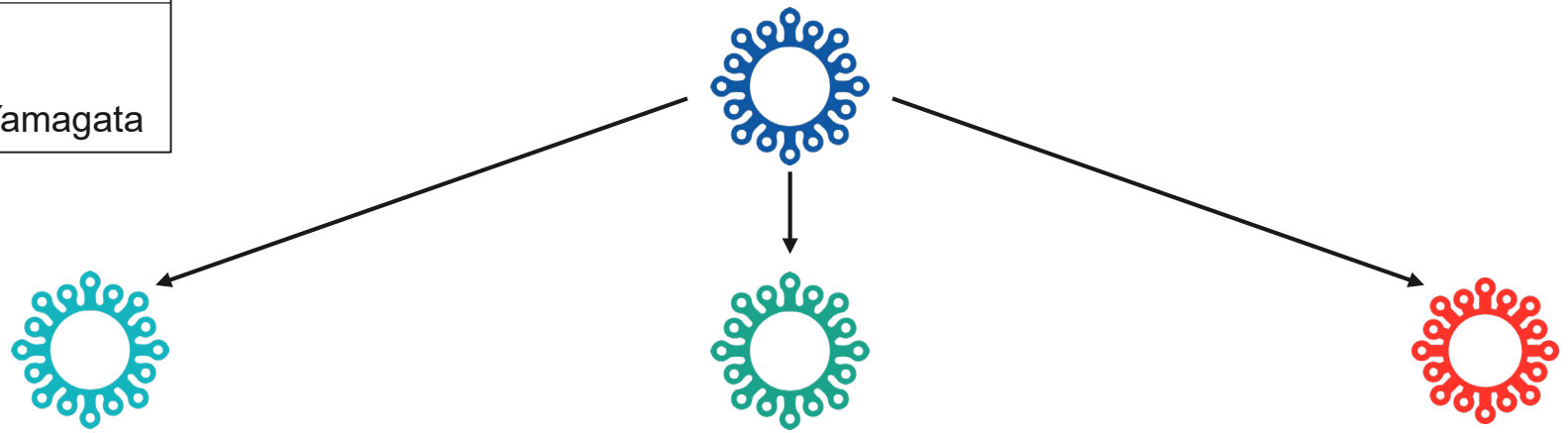
- Closed reactor
- High yield and volume
- Potential for rapid pandemic response

Cell-Derived Virus Seed

Science of Influenza Virus Mutation and the Rationale for Non-egg Vaccines

Yearly seasonal vaccine
4 strains – currently 2 x “A” – H3N2, H1N1 2 x “B” – B/Victoria, B/Yamagata

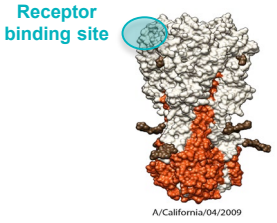
Circulating virus



Manufacturing change
→ altered strain
→ **egg adaptation**

Environmental drift
→ altered strain
→ **seasonal mismatch**

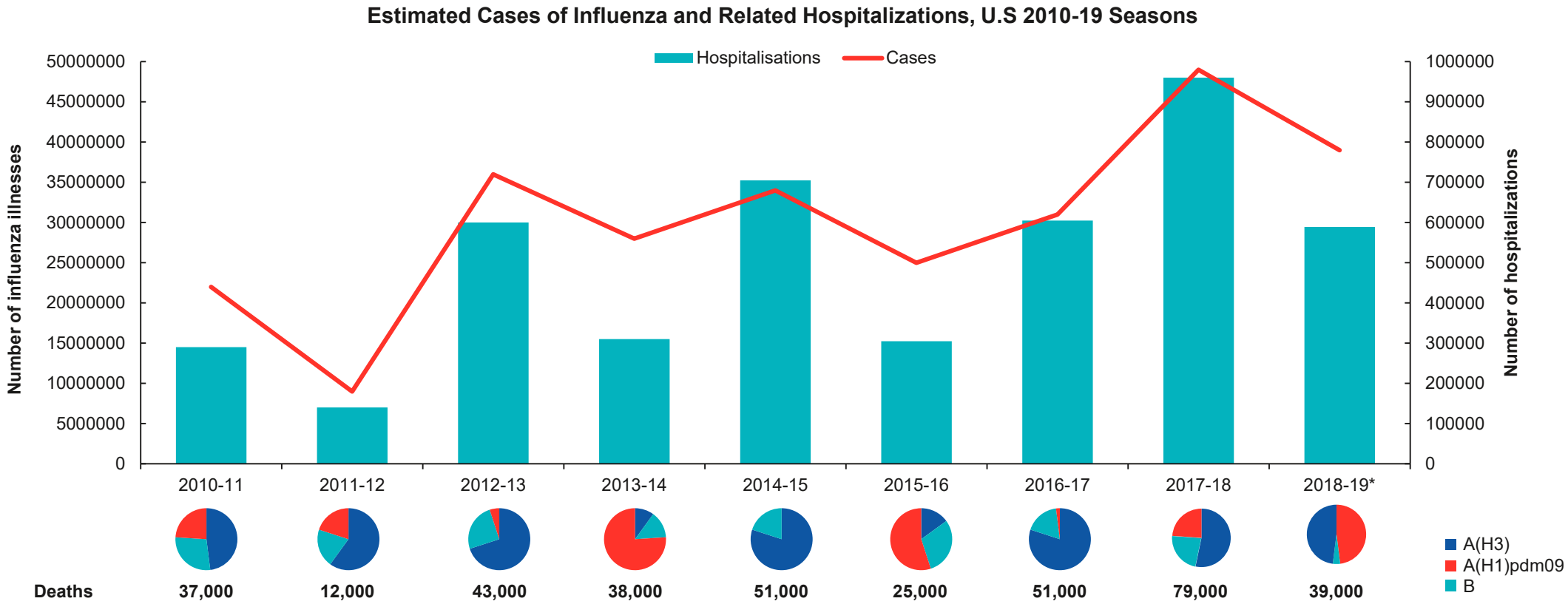
Environmental shift
→ new virus
→ **pandemic**



HEMAGGLUTININ

Especially H3N2
Evidence emerging for other strains

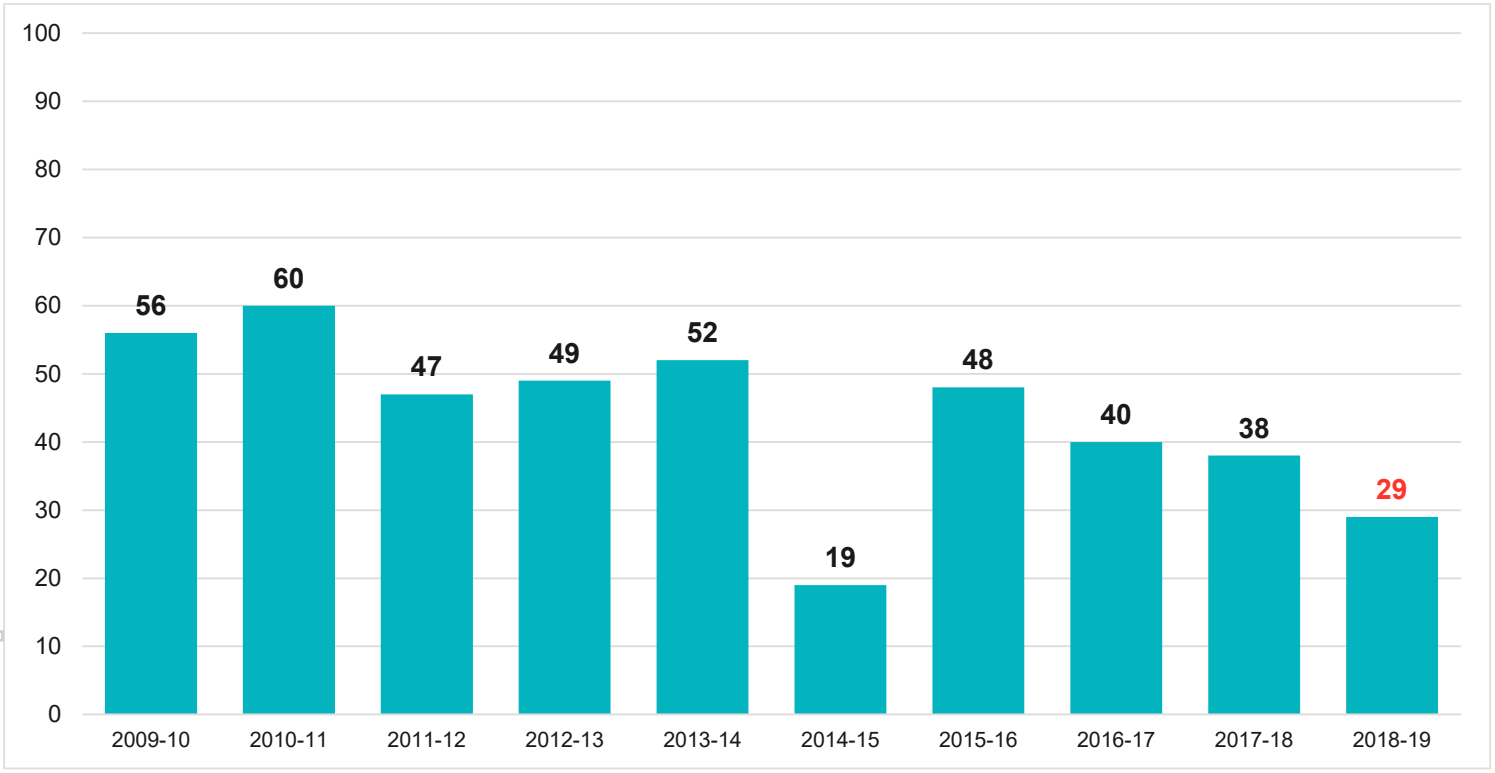
2018-19 was a Moderate Influenza Season in US (and elsewhere)



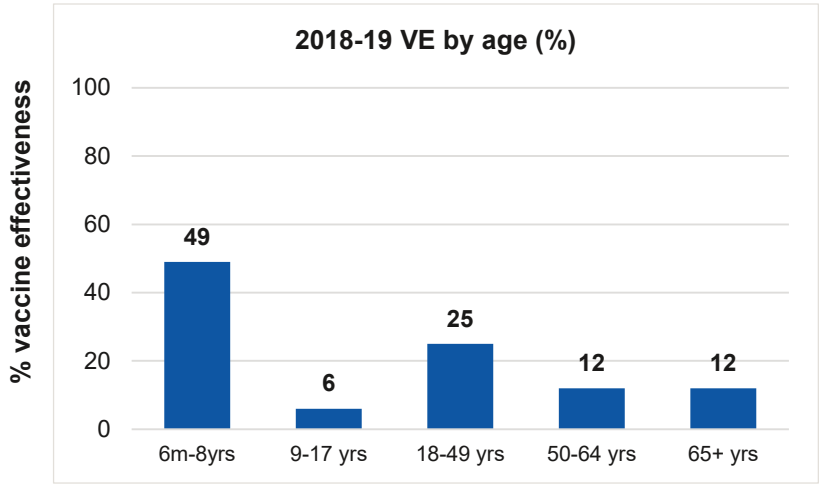
Source: US data from CDC. https://www.cdc.gov/flu/about/burden/2017-2018.htmc.
*2018-19 data are current estimates, https://www.cdc.gov/flu/about/burden/preliminary-in-season-estimates.htm

Influenza Vaccine Effectiveness Varies by Year and Age

2018-19 affected by strain mismatch due to “drift” in US

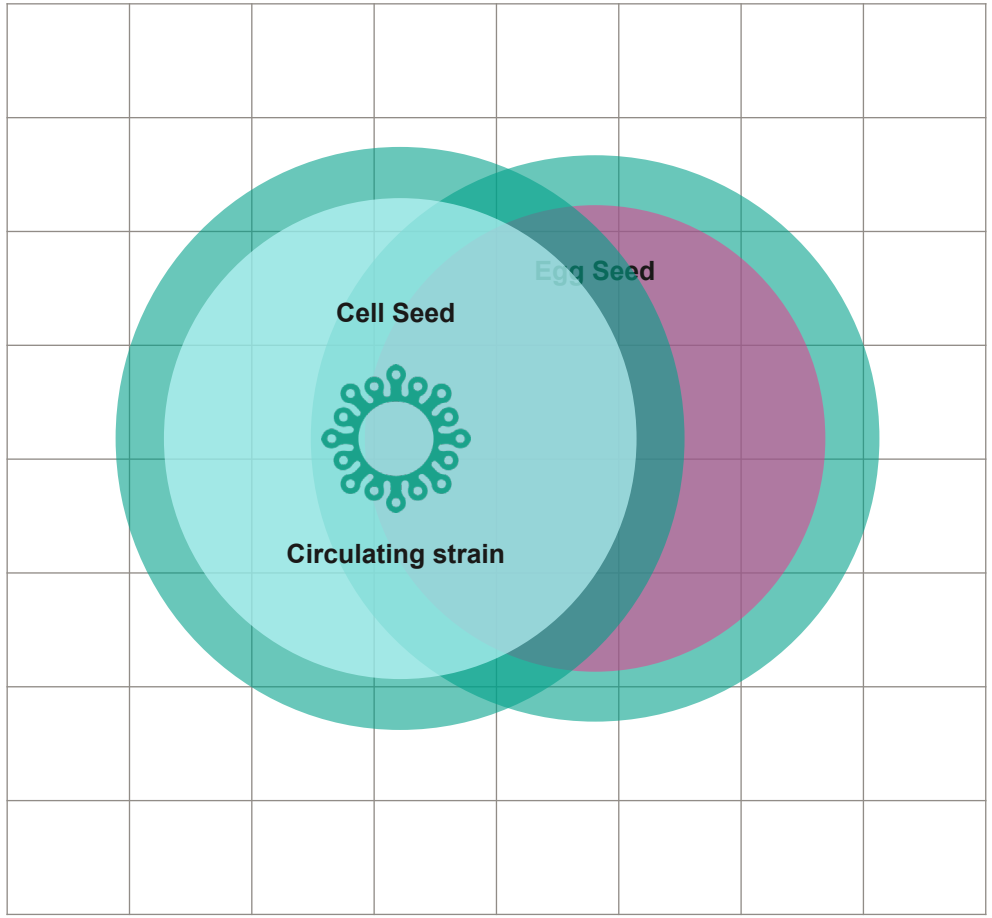


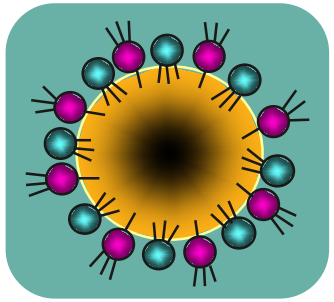
Vaccines least effective in older adults



Source: US VE Network estimates of seasonal influenza vaccine effectiveness. https://www.cdc.gov/flu/vaccines-work/effectiveness-studies.htm

Bringing the Benefits of MF59 Adjuvant and Cell-based Vaccine Together - aQIVc





MF59 adjuvant

Increases “breadth” of immunity

Increases antibody response

Potential Benefits* of Cell-based Vaccine

- Evidence of egg adaptation strongly supported by non-clinical data#
- Studies of *Real World Evidence* from 2017-18 season show benefit of cell-based vs egg-based vaccine in a season dominated by H3N2 strain (~2 of every 4 years)
  - **36% reduction in outpatient Influenza-like Illness** (electronic health record+)
  - **11% reduction in influenza-related hospital encounters** (CMS/claims data**)
  - 43% reduction in H3N2-related influenza positive hospitalisation in people less than 65yrs old (Kaiser Permanente Southern California^)
- **Executive Order** from White House September 2019 called for modernisation of influenza vaccines and overhaul of seasonal flu vaccine production

* Superior efficacy has not been demonstrated in RCT

Kishida et al. Clin Vaccine Immunol 2012. PMID 22492743; Raymond, et al. Nat Med 2016. PMID 27820604; Parker et al. J Gen Virol 2016. PMID 26974849; Wu et al. PLoS Pathog 2017. PMID 29059230; Zost, et al. Proc Natl Acad Sci U S A 2017. PMID 29109276; Garretson, et al. Vaccine 2018. PMID 29861178.

\+ Boikos et al, US National Foundation for Infectious Disease 2018 Clinical Vaccinology Course, November 2018, (Poster), Bethesda MD.

** Izurieta, et al. J Infect Dis 2019 220(8): 1255-1264.

^ Bruxvoort KJ et al. Vaccine. 2019 37(39):5807-5811.

Real World Evidence and the Important Impact of FLUAD®

- Recent data comparing **FLUAD®** to non-adjuvanted egg-based vaccines in people 65 years and above
  - US nursing home observational study* in 52,000 residents in 2016-17
    - **6% reduction in all-cause hospitalisation**
  - Public Health England# analysis of first season of FLUAD® (2018-19) for older population
    - **30% reduction in influenza-related hospitalisation**
  - 15 year experience in Italy^ in 43,000 people from 2002 - 2016
    - **39% reduction in hospitalisation due to pneumonia and cardiovascular events**

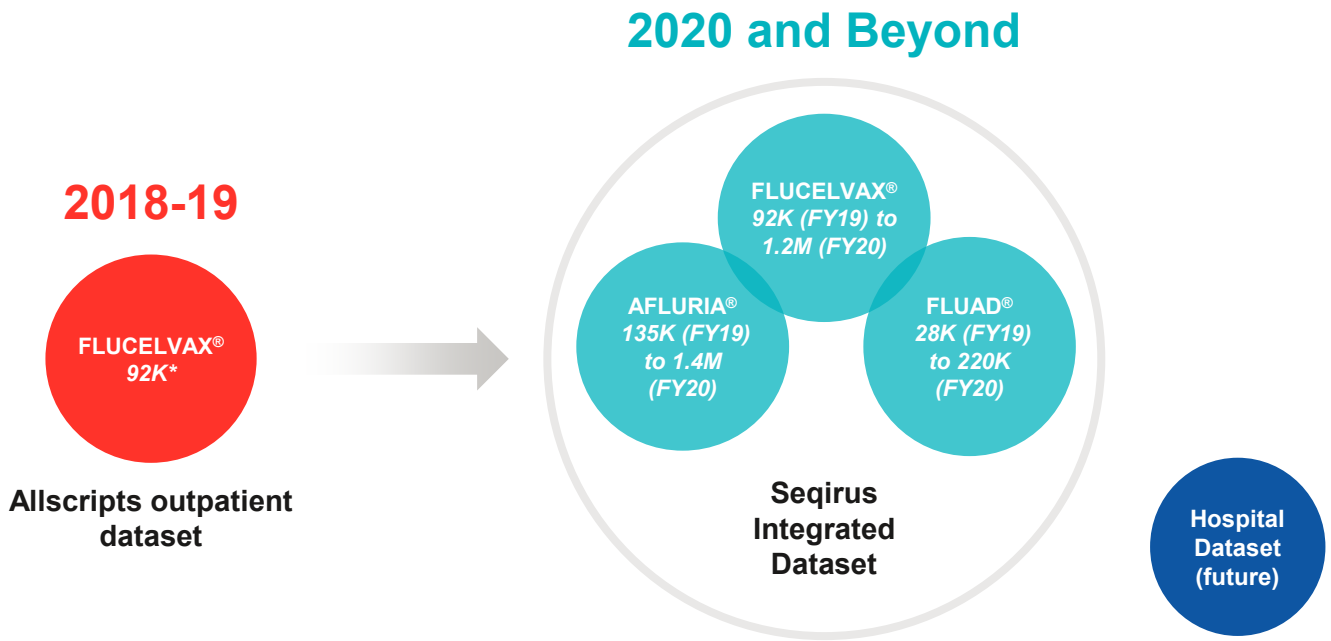
- **Ongoing recommendation for FLUAD® (TIV) by National Immunisation Advisory Groups in US, UK and Australia for people 65 years and older**
- **Rapid approval and reimbursement support for FLUAD® QIV in Australia – launch 2020**

* Presented at National Foundation for Infectious Diseases, November 2019.
# Pebody et al. Vaccine 2019 Oct 22. pii: S0264-410X(19)31405-7. doi: 10.1016/j.vaccine.2019.10.032. [Epub ahead of print]
^ Lapi, F., et al. Expert Rev Vaccines 2019 18(6): 663-670.

Strengthening the Power of RWE at Seqirus

From Electronic Medical Record to Integrated Understanding

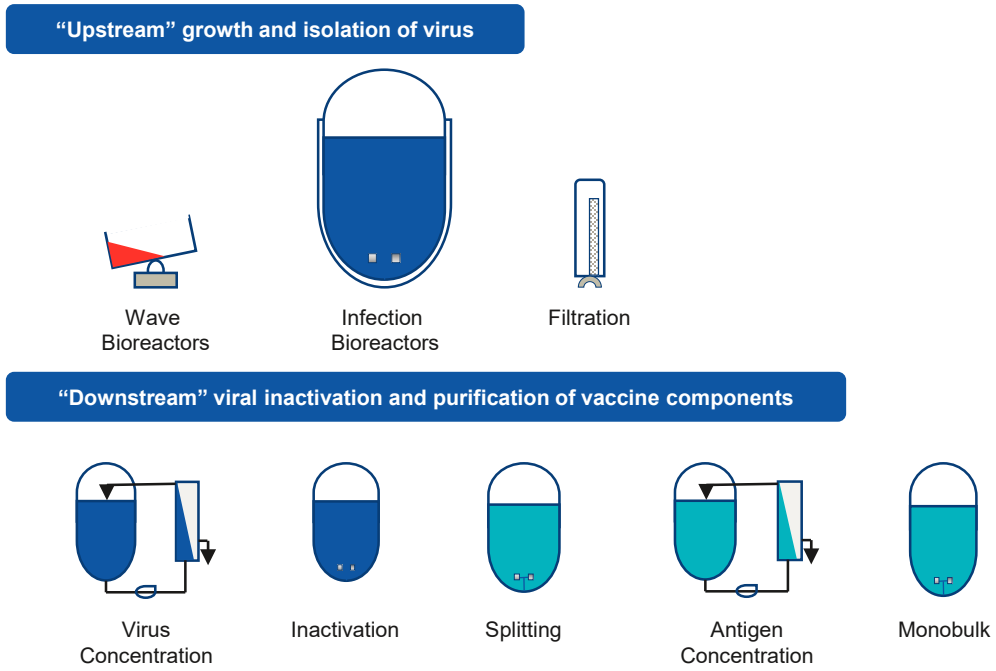
- **Real world evidence** (RWE) is data regarding potential benefits or risks of a vaccine from sources other than traditional randomised clinical trials
- Influences decisions of policy makers, healthcare professionals, Regulatory Agencies (FDA *Framework for RWE Program,* December 2018)



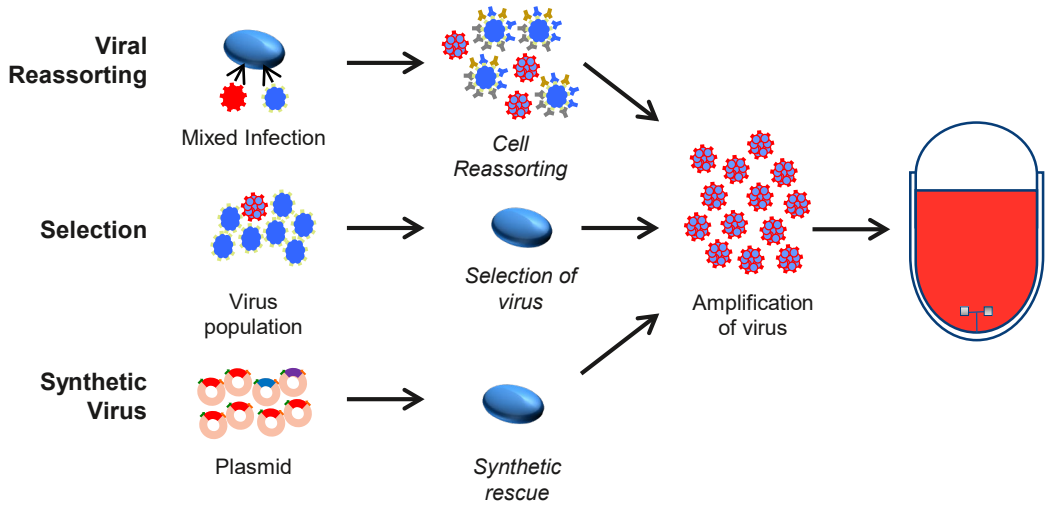
*Refers to number of vaccinated people included in database for which healthcare outcomes can be assessed

Focus on Influenza – Ongoing Process and Seed Innovation

Process Improvement



Seed Innovation



Shift to Differentiated Products is Expected to Drive Future Value Growth

- Global influenza vaccine market volumes between 500-600 million doses
  - 150 million doses distributed in US* in 2018-2019 season
  - Slow future growth, largely due to ageing population

- Seasonal global market value ~US$4B

- Differentiation a key driver of growth, especially in US – doses shifting to
  - Cell-based vaccines
  - Enhanced vaccines in 65 years and older segment (currently US, UK, AUS, Sth EU)
    - Potential for benefit in infants (6 months - 6 years)
  - Variable pace in geographical uptake

*** Source:** https://www.cdc.gov/flu/prevent/vaccine-supply-historical.htm

Anticipated Milestones in 2020

FLUCELVAX® QUADRIVALENT

- AUS approval 9yrs+
- Clinical study data for 6M - 4yrs

FLUAD® QUADRIVALENT

- US approval for 65yrs+
- EU approval for 65yrs+

Pre-Pandemic aH5N1c

- US approval

aQIVc

- Commence clinical program

Clinical Development – Part 2

William Mezzanotte, M.D.

Executive Vice President, Head of Research and Development
CSL Behring

Investigating the Benefit of Alpha-1 Antitrypsin in Graft vs Host Disease (GvHD)

Alpha-1 Antitrypsin (CSL964) for GvHD Prevention

MODULAATE
Immunomodulation by Alpha-1 Antitrypsin to Enable Prevention of GVHD

Part 1

Cohorts 1-3
Dose Levels 1-3
Open Label

→

Part 2

Cohorts 4
Selected Dose
Placebo-controlled

Cohort 1 completed

Bone Marrow Transplant Clinical Trial Network Collaborative Study CSL964 for GvHD Treatment

AAT
2x weekly

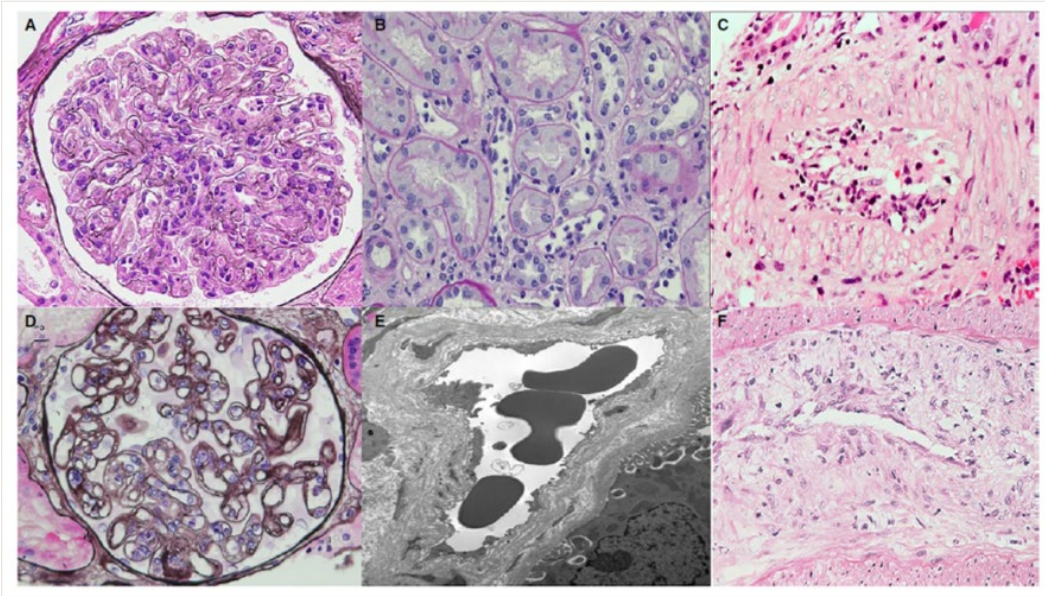
Placebo

→ Primary Endpoint at Day 28 → Follow up

Study startup activities commenced

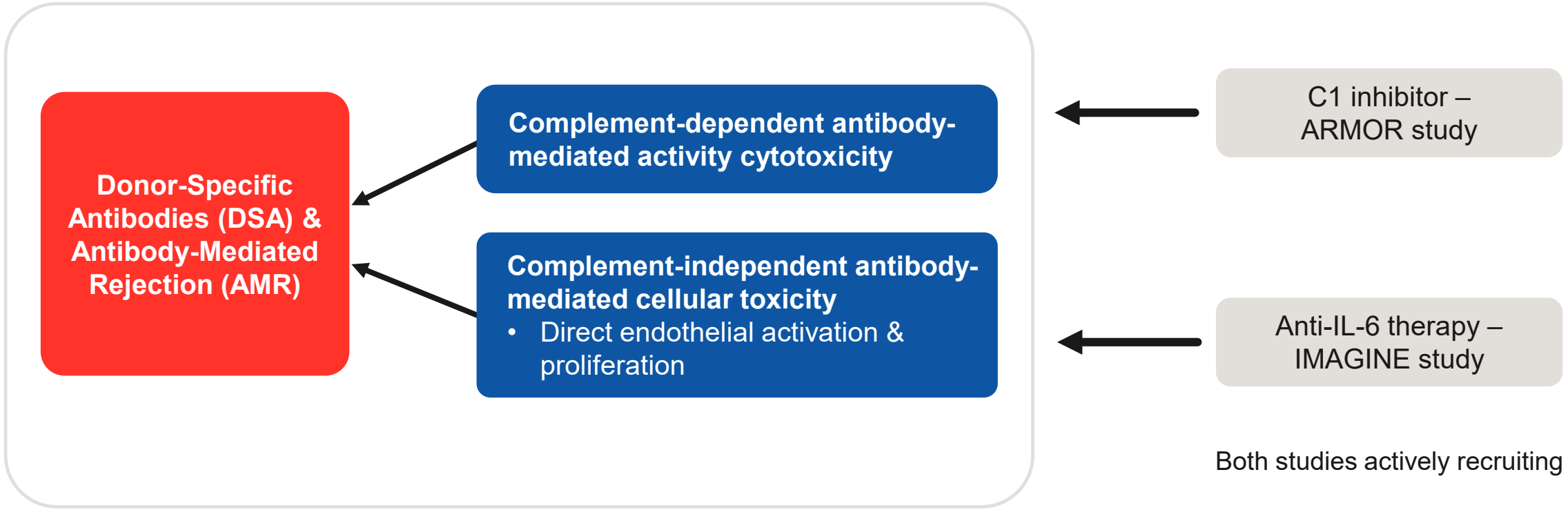
Antibody-Mediated Rejection (AMR) in Renal Allografts

- Development of Donor Specific Antibodies (DSAs)
- Late in the post-transplant period
- Progressive decline in kidney function
- Loss of graft
- No approved therapies
  - Pilot data for C1 inhibitor and anti-IL-6



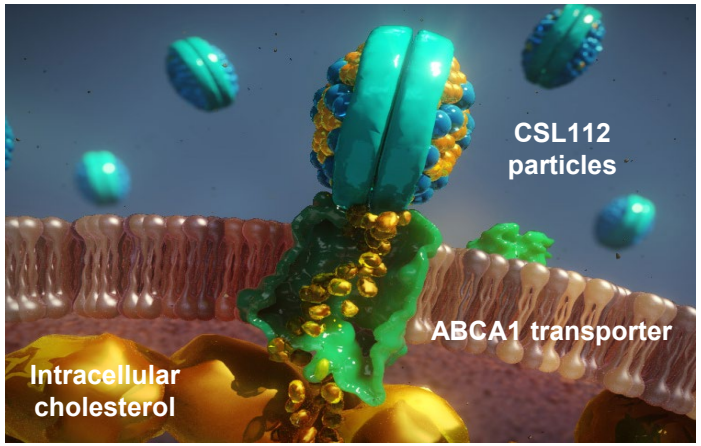
Source: Am J Transplant. 2018; 18:2849-2856

AMR: Complement Dependent and Independent Pathways



CSL112 ApoA-1

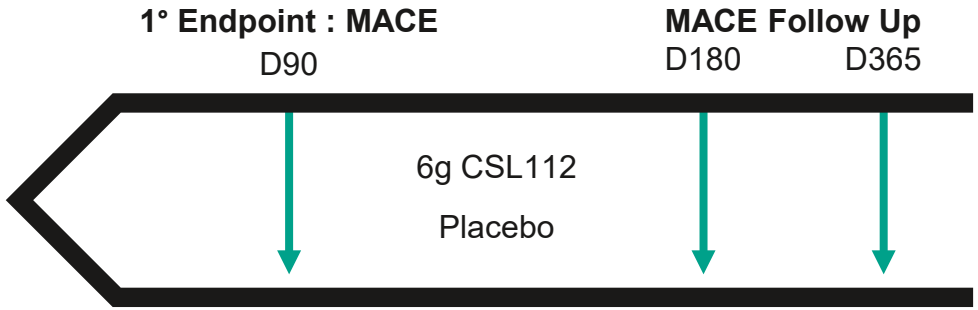
- Study enrolment is active in >45 countries and progressing well
  - PMDA approval for Japan to join trial
- Independent Data Monitoring Committee – no safety concerns
- First futility analysis in 2020



>17,000 AMI subjects
≥18yrs of age with Acute Coronary Syndrome

Screening

Randomisation



Summary

William Mezzanotte, M.D.

Executive Vice President, Head of Research and Development
CSL Behring

R&D Portfolio – December 2019

RESEARCH	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	REGISTRATION	POST-REGISTRATION
Discovery Projects	Improved Fibrinogen	CSL730 rFc Multimer	CSL312 Anti-FXIIa HAE	HIZENTRA® DM	PRIVIGEN® PID Japan	CSL830 C1-INH Subcut EU
Discovery Projects	CSL787 Nebulised Ig	CSL324 Anti-G-CSFR	HIZENTRA® SSc	CSL112 ApoA-I	FLUAD® QIV 65yrs+ US/EU/Canada	PRIVIGEN® CIDP US, Japan
Discovery Projects	aQIVc (MF59 plus FLUCELVAX® antigen)	CSL200 (CAL-H) SCD	PRIVIGEN® SSc	Clazakizumab AMR	Pre-Pandemic aH5N1c	HIZENTRA® CIDP US, Japan
Discovery Projects	P. gingivalis/POD	CSL889 Hemopexin SCD	HAEGARDA® Japan	CSL842 C1-INH rAMR		HAEGARDA® US
Discovery Projects		CSL312 Anti-FXIIa Thrombosis	CSL630 pdFVIII Ruide	CSL964 GvHD Prevention		IDELVION®
		CSL311 Anti-Beta Common	Mavrilimumab GM-CSFR	CSL964 GvHD Treatment		AFSTYLA®
		CSL346 Anti-VEGF-B		FLUCELVAX® 6M+		KCENTRA® Japan
		CSL334 / ASLAN004 IL-13R				ZEMAIRA® / RESPREEZA® AAT
						AFLURIA® QIV 6M+ US, AUS

◤ Partnered Projects

Immunology and Neurology | Haematology and Thrombosis | Respiratory | Cardiovascular and Metabolic | Transplant | Influenza Vaccines

Expected Progress in Next 12 Months

PRE-CLINICAL	PHASE I	PHASE II	PHASE III	POST-REGISTRATION
recC1-INH	CSL362 Anti-IL-3Ra	CSL346 Anti-VEGF-B	HAEGARDA® Japan	PRIVIGEN® PID Japan
Novel Complement Inhibitor	CSL787 Nebulised Ig	aQIVc (MF59 plus FLUCELVAX® antigen)	Garadacimab (Anti-FXIIa) HAE	IDELVION® 21 Day Dosing
Haptoglobin SAH				FLUCELVAX® QIV 9yrs+ AUS
				FLUAD® QIV 65yrs+ US, EU, Canada
				Pre-Pandemic aH5N1c

Immunology and Neurology | Haematology and Thrombosis | Respiratory | Cardiovascular and Metabolic | Transplant | Influenza Vaccines

Significant Target Launch Dates

2019	2020	2021-2025	
HIZENTRA® CIDP Japan	PRIVIGEN® PID Japan	Garadacimab (Anti-FXIIa) HAE	Clazakizumab AMR
PRIVIGEN® CIDP Japan	IDELVION® 21 Day Dosing	HIZENTRA® DM	IVIG Kidney AMR
AFLURIA® QIV 6m+ (AUS)	FLUAD® QIV 65yrs+ US, EU	HAEGARDA® Japan	CSL842 C1-INH rAMR
FLUCELVAX® QIV 9yrs+ EU		Improved Fibrinogen	CSL964 GvHD
		FLUCELVAX® 6m+ US, EU, AUS	CSL112 ApoA-I
		aQIVc 50yrs+	

◤ Partnered Projects

Immunology and Neurology | Haematology and Thrombosis | Respiratory | Cardiovascular & Metabolic | Transplant | Influenza Vaccines

2019 Highlights

Immunology and Neurology	• HIZENTRA® and PRIVIGEN® approved for treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in Japan • HIZENTRA® granted Orphan Drug Exclusivity for CIDP • HIZENTRA® Dermatomyositis (DM) Phase III Study initiated • Garadacimab (Anti-FXIIa) in Hereditary Angioedema (HAE) Phase II double blind period complete
Haematology and Thrombosis	• CSL200 (CAL-H) in Sickle Cell Disease (SCD) Phase I Study initiated • CSL889 Hemopexin in SCD Phase I Study initiated
Respiratory	• CSL311 (Anti-Beta Common) Phase I study commenced • Approval of convenient single-vial dosing for ZEMAIRA® (Alpha1-Proteinase Inhibitor) in the US
Cardiovascular and Metabolic	• CSL112 (ApoA-1) Phase III study (AEGIS-II) progressing well with >7000 patients recruited • CSL346 (Anti-VEGF-B) Phase II Diabetic Nephropathy study initiation planned for 1H20
Transplant	• CSL964 Alpha-1 Antitrypsin (AAT) for prevention of Graft versus Host Disease (GvHD) after Transplantation of Allogenic Hematopoietic Cell Transplantation (HCT) Phase III study actively recruiting and on track
Influenza Vaccines	• First cell-based quadrivalent seasonal influenza vaccine, FLUCELVAX® TETRA, approved in Europe • AFLURIA® QUAD (quadrivalent influenza vaccine) granted expanded indication for use in children 6M+ in Australia • aQIVc (MF59 plus FLUCELVAX® antigen) new product development commenced

Panel Q&A Session

News Release

For immediate release

CSL Continues to Advance R&D Capabilities

Unique portfolio mix of plasma, cell and gene therapy, recombinant proteins and antibody assets highlighted at Research & Development Briefing

Sydney, Australia, 4 December 2019 – CSL Limited (ASX:CSL; USOTC:CSLLY) is steadily advancing its Research & Development (R&D) pipeline and capabilities to deliver a highly differentiated product portfolio mix, addressing a broader range of patients' unmet needs," said Head of Research & Development Dr. William Mezzanotte today.

At CSL's annual R&D briefing to investors, Dr. Mezzanotte noted the company is building on its leadership in plasma therapies through the identification of emerging new medicines from both within its existing portfolio of plasma-derived products, and through newer platforms such as gene and cell therapies and recombinant proteins.

To support this approach, CSL has forged targeted innovation partnerships in close proximity to its R&D locations, including at the Bio21 Institute in Melbourne, Australia, the Swiss Center for Translational Medicine in Bern, Switzerland and the University Science Center in Philadelphia, US.

"Our Phase 3 clinical program targeting the reduction of early recurrent cardiovascular events in heart attack survivors, CSL112, continues to track well.

"We continue our focus on developing new medical indications for immunoglobulins while improving manufacturing efficiencies across our plasma product portfolio," Dr Mezzanotte said.

In FY19, CSL invested US$832 million into its R&D portfolio, representing 9.7% of total revenues.

R&D Pipeline Highlights

A novel treatment for asthma which has this month advanced to Phase 1, first-inhuman trials for patients with mild to moderate asthma. Asthma is a common chronic respiratory disease that is estimated to affect as many as 235 million[1] people worldwide and is the most common chronic disease among children. Despite advances in the treatment of asthma, it is estimated that every year, more than 1,000[2] people around the world die each day from this disease.

CSL's trial will test for the safety of a therapy delivered by subcutaneous injection that asthma sufferers could self-administer at home once every two to four weeks, acting prophylactically to prevent asthma attacks.

[1] World Health Organisation: https://who.int/respiratory/asthma/en/
[2] The Global Asthma Report 2018: http://globalasthmareport.org/burden/mortality.php

The potential therapy, which currently holds the working title “CSL311,” is a monoclonal antibody that targets multiple inflammatory agents involved in various diseases.

CSL311 is the first monoclonal antibody to simultaneously target three cell-signaling cytokines, or molecules, that are responsible for the immune response that causes asthma and in doing so, suppresses inflammation of airways.

Commenting on the potential of the research, University of Melbourne Professor Jo Douglass, Head of the Immunology and Allergy Department at the Royal Melbourne Hospital and a research collaborator on the project, said, “Asthma is a serious disease that in extreme cases can be fatal. Currently, our treatment options for severe asthma are limited. We are excited by the potential of CSL311 to address a problem that affects the lives of so many.”

Addressing Severe Muscle Disease

Another pipeline project featured today is a Phase 3 clinical trial for novel use of CSL Behring‘s existing subcutaneous Immunoglobulin (Ig) product in patients with a severe condition called Dermatomyositis. The Ig product is currently indicated for use in a rare neurological disorder, Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) as well as primary and secondary immunodeficiencies.

Dermatomyositis is one of a group of acquired muscle diseases called inflammatory myopathies which are characterized by chronic muscle inflammation accompanied by muscle weakness. If the disease goes untreated it can lead to difficulty in walking or the need for a wheelchair or even becoming bedridden.

“Our pipeline is as robust and promising as ever,” Dr. Mezzanotte said. “Our R&D portfolio holds the potential to unlock a broad range of new therapies for people with challenging medical conditions. That promise is what drives our 1,700-plus scientists to work every day as if someone’s life depends on it – because it really does.”

About CSL: CSL (ASX:CSL) is a leading global biotechnology company with a dynamic portfolio of life-saving medicines, including those that treat haemophilia and immune deficiencies, as well as vaccines to prevent influenza. Since our start in 1916, we have been driven by our promise to save lives using the latest technologies. Today, CSL — including our two businesses, CSL Behring and Seqirus - provides life-saving products to more than 70 countries and employs more than 25,000 people. Our unique combination of commercial strength, R&D focus and operational excellence enables us to identify, develop and deliver innovations so our patients can live life to the fullest.

For more information about CSL Limited, visit www.csl.com

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