POOLBEG PHARMA

Company Presentation

September 2024

AIM: POLB

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Proven Leadership Team

Experience in commercialising and developing innovative medicines

Cathal Friel
Executive Chairman

- ✓ Founder of Raglan Capital, completed 5 IPOs (incl. Amryt Pharma, hVIVO & Poolbeg Pharma)

Jeremy Skillington PhD
Chief Executive Officer

- ✓ Employee #3 at Inflazome - €380m+ exit to Roche
- ✓ Extensive BD experience with Genentech & HS Lifesciences

Ian O'Connell
Chief Financial Officer

- ✓ Co-founder of Open Orphan plc (renamed hVIVO plc) and one of Amryt Pharma's first team members
- ✓ Chartered Accountant with deep corporate finance experience

David Allmond
Chief Business Officer

- ✓ Former CBO at Amryt Pharma – pivotal in establishing sales & marketing in EU, US and ex-US
- ✓ Previously CVP Global Marketing at Celgene and EMEA lead at Aegerion Pharmaceuticals

John McEvoy
Chief Legal Officer

- ✓ Former GC at Amryt Pharma – pivotal in rapid growth through acquisition & Nasdaq listing
- ✓ Qualified lawyer in the US (New York), England & Wales, and Ireland

Laura Maher
VP Clinical Operations

- ✓ Former AD of Clinical Operations at Amryt Pharma
- ✓ Led the clinical research in Amryt Pharma's pipeline including Filsuvez®, the world's first approved epidermolysis bullosa treatment

Poolbeg Pharma - Well Positioned for Success

Industry Leading Team

- Successfully built three public life science companies and achieved multiple exits
- Three key former Amryt Pharma leaders recruited with a **track record** of establishing and scaling sales infrastructures in the US and RoW

Revenue Focused Business Model

- Targeting **near-term revenue generation** from partnering and commercial stage rare and orphan drugs
- Focused on partnering to maximise near term **value** from in-house programmes

High Value Programmes for Partnering

- **POLB 001**: Phase 2 ready **US$10bn market** opportunity in cancer immunotherapy-induced CRS. Additional opportunity for the treatment of severe influenza
- Oral delivery technology: targeting obesity with Oral **GLP-1R agonist**; clinical trial expected to commence 2024
- **AI-led discovery programmes**, leveraging unique disease progression data in Influenza and RSV

Robust Financial Position

- Cash balance of **£12.2m** (31 December 2023)
- Focused on near-term **revenue generation and profitability**

High Value Programmes

Actively engaging in partnering discussions to generate near term value

Product / Programme	Pre-Clinical	Phase I	Phase II	Phase III
POLB 001 Cancer immunotherapy-induced CRS — >$10bn Market Opportunity	→	→	→	
POLB 001 Severe influenza	→	→	→	
Oral GLP-1R Agonist Obesity & diabetes treatment — AnaBio™ Technologies	→	→		
Influenza AI Programme Utilising unique licensed human viral challenge data — CytoReason	→	→		
RSV AI Programme Utilising unique licensed human viral challenge data — ONETHREE BIOTECH	→	→		
Exclusive Option Agreement				
Topical muco-adherent Pentoxifylline (tPTX) Orphan drug candidate for Behçet's Disease	Positioned for a potential 505(b)(2) approval pathway in the U.S. →			

Other Partnerships/Collaborations

- ✓ €2.3m in non-dilutive grant funding secured to develop a Phase I clinical trial ready oral vaccine candidate
- ✓ Strategic collaboration with Nasdaq listed company for the development of an optimised oral drug to treat a metabolic condition

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POLB 001

Large market opportunity while addressing significant unmet medical needs

Cancer Immunotherapy-Induced CRS

Severe Influenza

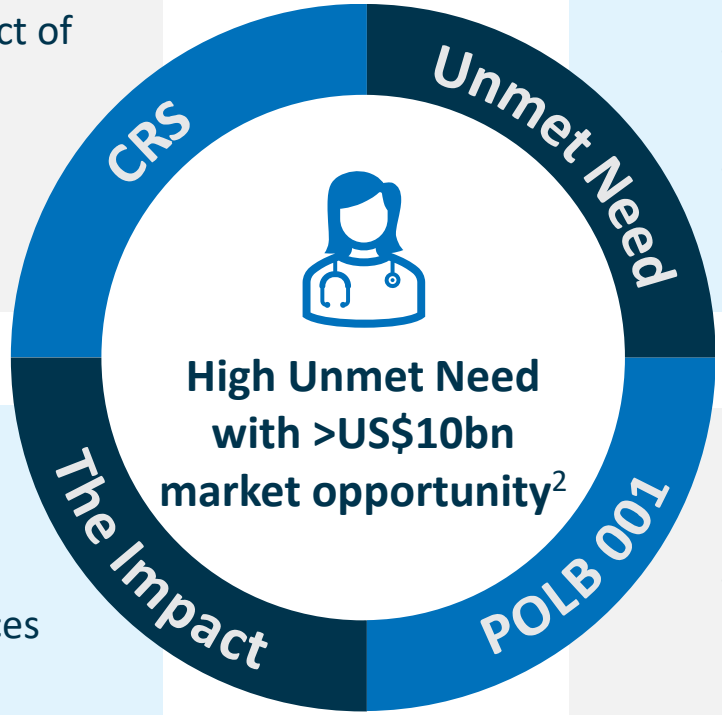
Cancer Immunotherapy-Induced CRS is a Rate-Limiting Side Effect

Cytokine Release Syndrome

- Severe, potentially life-threatening side effect of cancer immunotherapies
- >70%[1] of patients undergoing CAR T / Bispecific Antibody therapies are affected

The Unmet Need

- Cancer immunotherapies can only be delivered in specialist cancer centres
- No approved therapy for prevention of CRS and very few approved for CRS management



The Impact

- Extended hospitalisation, mortality risk, and high consumption of healthcare resources
- Estimated direct costs of managing CRS of US$5.5Bn per year by 2030[3,4]

POLB 001

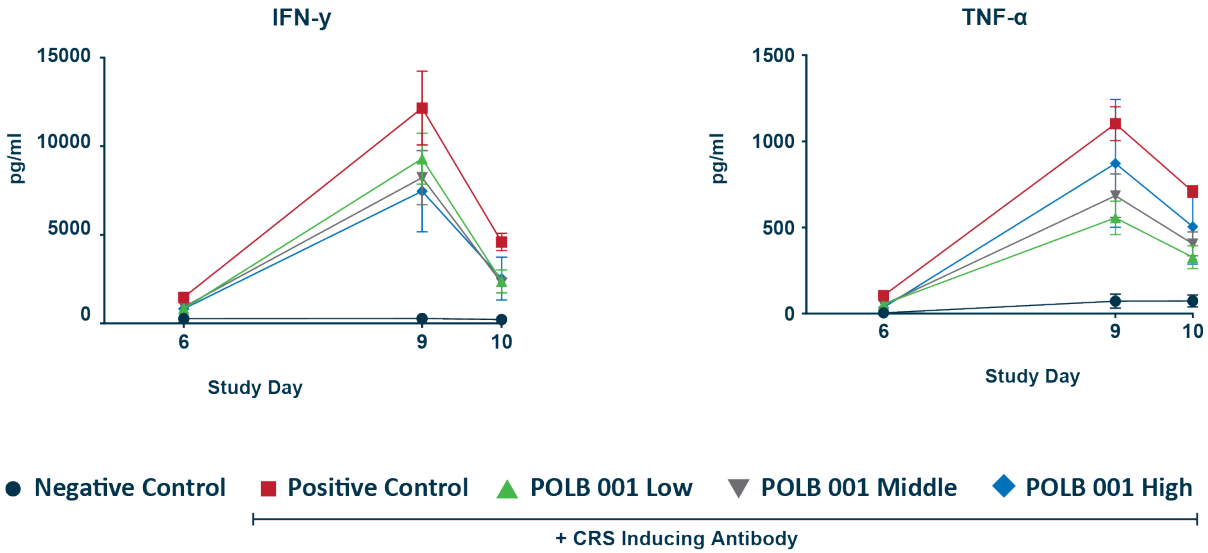
- Oral administration of POLB 001 to prevent and treat CRS has the potential to enable broader, safer delivery of cancer immunotherapies in an outpatient setting

1. Average rate from Summary of Product Characteristics (SmPCs) for Yescarta, Tecartus, Abecma, Kymriah, Carvykti, Breyanzi, Elrexfio, Columvi, Epkinly, Tecvayli and Talvey.
2. Independent research commissioned by Poolbeg. **3**. Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023**. 4.** Abramson JS et al. Blood Adv. 2021 Mar 23;5(6):1695-1705

Demonstrated a Strong Efficacy/Safety Profile

Compelling pre-clinical and clinical data

POLB 001 Effectively Prevented CRS Validated in an *in vivo* Animal Model



Phase 1b LPS Human Challenge Clinical Trial

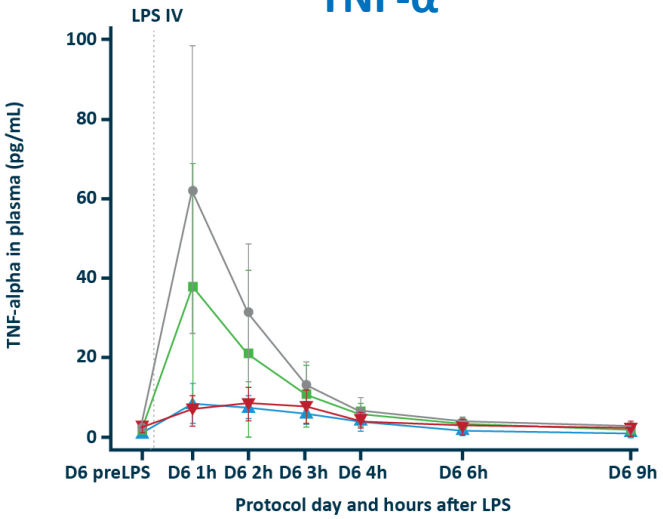
- **Excellent safety & tolerability profile**
- **Potent target inhibition confirmed**
- **Clear dose response relationship**
- **Major reduction of key inflammatory markers**

Well-tolerated drug that attenuates excessive immune responses, without ablating the immune function

Major Reduction of Key Inflammatory Markers Following LPS Challenge

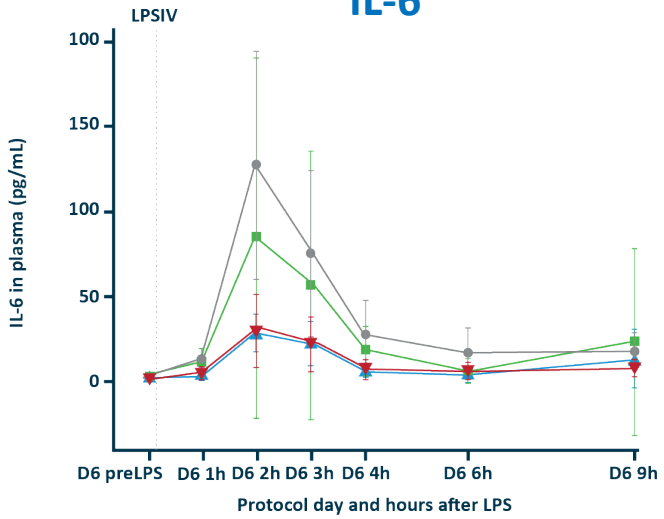
Dose dependent reductions of pro-inflammatory cytokines without ablation of immune function

TNF-α



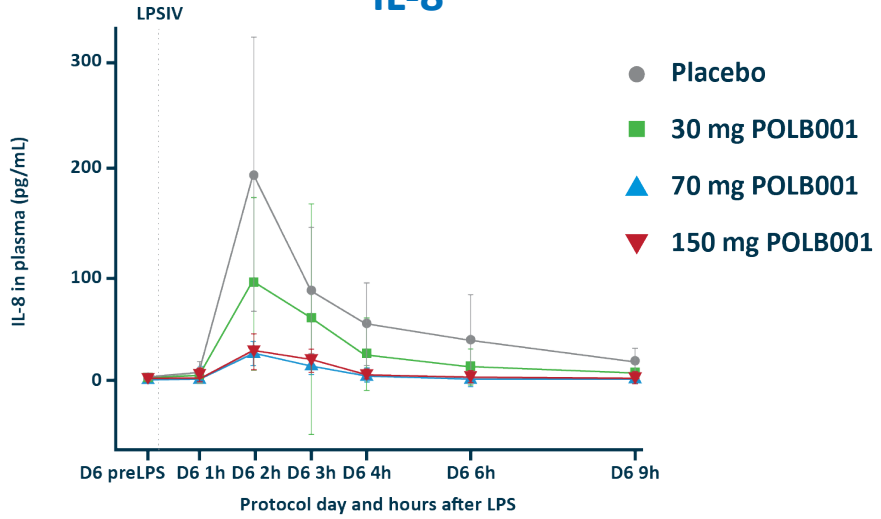
TNF-α reduction of **73.5% and 56.2%** seen for **70 mg and 150 mg doses respectively** (p = 0.0003†)

IL-6



IL-6 reduction of **57.4% and 63.5%** seen for **70 mg and 150 mg doses respectively** (p = 0.0002†)

IL-8



IL-8 reduction of **80.7% and 76.7%** seen for **70 mg and 150 mg doses respectively** (p < 0.0001†)

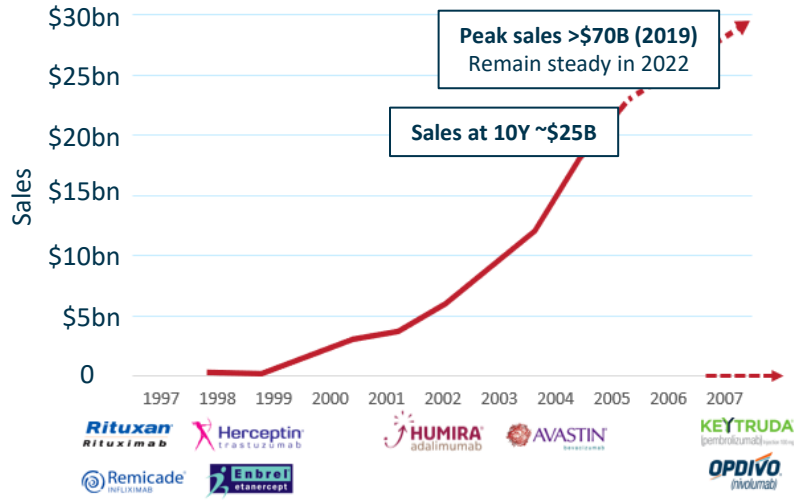
TNF-α, IL-6 and IL-8 levels decreased between 56-81% in subjects treated with 70 mg or 150 mg POLB 001 twice daily

†The exploratory analysis suggested statistically significant improvement in treatment (p<0.05) for the endpoints examined.

Significant Market Opportunity in a Rapidly Growing Field

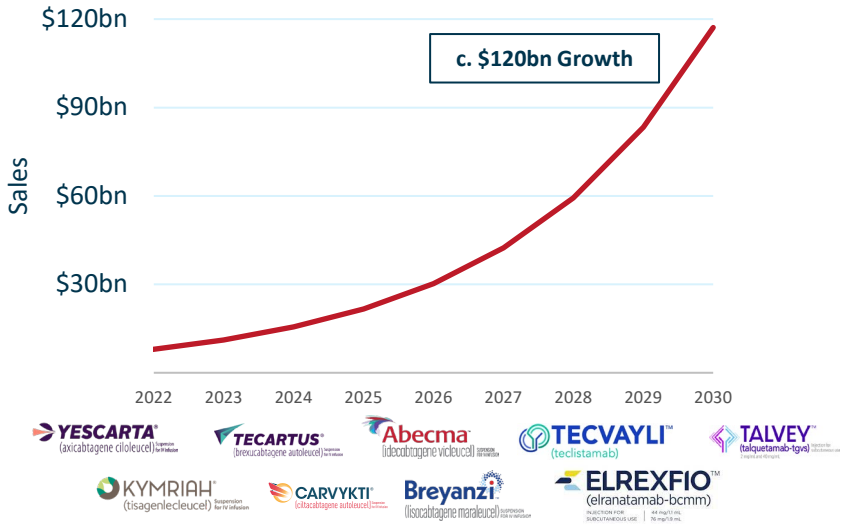
CRS is rate limiting in seamlessly delivering cancer immunotherapies

Monoclonal Antibodies



Bispecific Antibody and CAR T Therapy market expected to **grow exponentially,** similar to antibodies in the early 2000s. This growth could be even greater with an effective CRS preventative

Bispecific Antibodies & CAR T Therapies[1,2,3]



- Currently no approved therapy for prevention of CRS and very few approved therapies for CRS management
- POLB 001 has the potential to enable broader, safer delivery of therapies to cancer patients in an outpatient setting
- **Advancement of cancer immunotherapies is driving the need for effective CRS management**

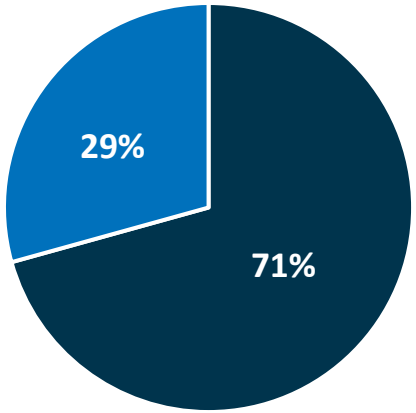
1. Grand View Research. CAR T-Cell Therapy Market Analysis 2023-2030. **2.** Grand View Research. Bispecific Antibodies Market Size, Share & Trends Analysis Report.
3. Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023.

CRS Preventative Therapy: a >US$10bn Market Opportunity

A significant opportunity exists for POLB 001 as adjunct therapy to BsAb and CAR T treatment

- Cancer immunotherapies are used to treat a growing number of cancers, rapid advancements are being made in multiple myeloma (MM), diffuse large B-cell lymphoma (DLBCL) and other cancers
- **1st, 2nd and 3rd line+ MM and DLBCL patients in the US and EU5,** receive CAR T cell and Bispecific Antibody therapy[1]
- An effective CRS preventative therapy could enable wider uptake of cancer immunotherapies beyond current forecasts due to potential for outpatient administration[2]
- **Significant upside** potential across additional haematological malignancies, solid tumours and future indications in separate therapeutic areas such as severe influenza

Addressable MM and DLBCL population by 2030 in the US and EU5



n = ~500,000 patients[1]

Estimate encompasses solely MM and DLBCL due to the rapid advancements in BsAb and CAR T treatment for these indications

ALL, Acute Lymphoblastic Leukemia**; BsAb,** Bispecific Antibody**; CAR T,** Chimeric Antigen Receptor T-cell therapy; **CRS**, Cytokine Release Syndrome**; DLBCL,** Diffuse Large B-Cell Lymphoma**; MM,** Multiple Myeloma

1. Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023. **2.** Hansen DK et al., Cancers (Basel). 2023. 7;15(24):5746

CRS Creating a "Bottleneck"

Effective prevention of CRS by POLB 001 may enable broader access to cancer immunotherapies

≈ 500,000 Patients

Eligible CAR T / Bispecific patients in US & EU for DLBCL and MM alone far exceeds treatment capacity[1]

CAR-T

BsAb

"Bottleneck"

Delivery of cancer immunotherapies in **specialist cancer centres** limits access

An effective CRS prevention could remove the bottleneck

US$5.5Bn in 2030

Estimated direct costs of managing CRS

GRADE 1 CRS
56% *Trial population*
US$7,517 *Treatment cost* [2]

GRADE 2 CRS
37% *Trial population*
US$18,013 *Treatment cost* [2]

GRADE 3+ CRS
7% *Trial population*
US$61,228 *Treatment cost* [2]

500,000 patients for treatment by 2030[1]
71% CRS incidence in trials
360,000 patients to experience a CRS event

BsAb, Bispecific Antibody**; CAR T,** Chimeric Antigen Receptor T-cell therapy; **CRS,** Cytokine Release Syndrome; **DLBCL**, Diffuse Large B-Cell Lymphoma; **MM**, Multiple Myeloma

1. Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023**. 2.** Abramson JS et al. Blood Adv. 2021 Mar 23;5(6):1695-1705.

Key Opinion Leaders Supportive of POLB 001's Significant Potential

"CAR T therapy inpatient capacity is a challenge, hence measures that reduce hospital stay or make treatment mobile are needed."

Dr Graham Collins, Lymphoma specialist, UK

"Bispecific antibodies will only be delivered in specialist cancer centres until there is a way to make them safer.
POLB 001 could make treatment safe enough to extend bispecifics to a much wider patient population."

Professor Gareth Morgan, US

"The development of an oral CRS preventive therapy will mean no or shorter hospital stays."

Myeloma specialist, FR

"If there was a therapy that was orally delivered, a whole lot of infrastructure requirement falls away."

Dr Martin Kaiser, Myeloma specialist, UK

- Access to CAR T and Bispecific Antibody therapy is restricted to specialist centres and limited by inpatient capacity due to management of CRS
- Prevention of CRS would allow for outpatient administration to enable safer broader delivery of cancer immunotherapies
- POLB 001 profile attractive as a potential oral therapy to prevent and treat CRS

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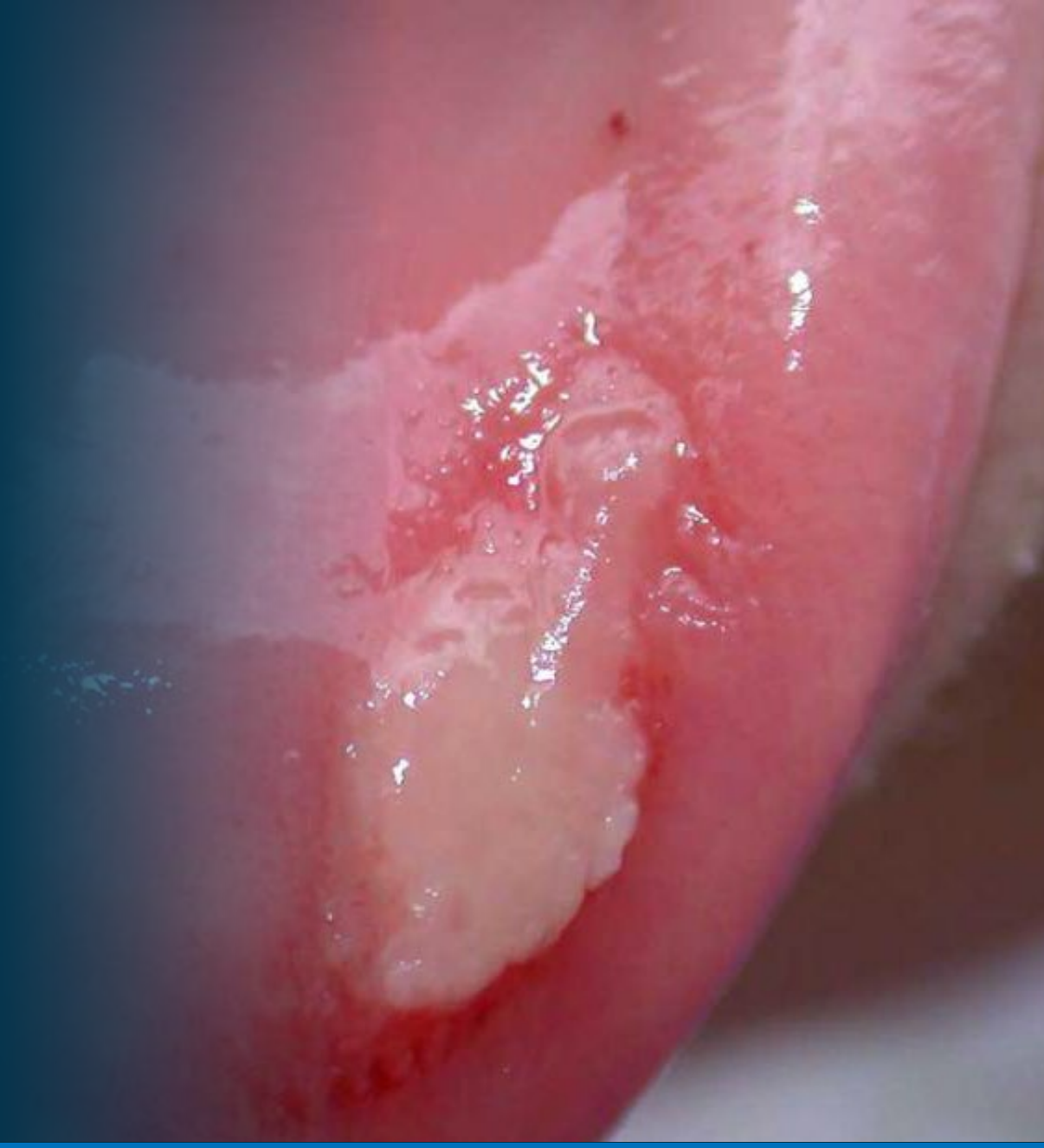
Topical PTX

Potential to transform the lives of patients

Behçet's Disease



Behçet's Disease

Debilitating disease with no cure

- **Oral ulcers** - impact essential functions like eating, drinking and speaking
- Inflammation of blood vessels and tissues
- **Life-long symptoms** after onset
- Current **standard of care is inadequate** with safety concerns

No. of Patients [1]	Country
~ 350,000	Turkey
~ 19,000[2]	Japan
~ 18,000	USA
~ 4,800	France
~ 4,800	UK
~ 3,400	Saudi Arabia
~ 1,500	Israel
~ 500	Sweden

Prevalence is highly variable by country, occurring along the Silk Road and in significant numbers in western countries

. Patient numbers estimated from: **1.** International Journal of Rheumatology, Volume 2015, Article ID 94526. **2.** Kirino Y, Nakajima H. Clinical and Genetic Aspects of Behçet's Disease in Japan. Intern Med. 2019 May 1;58(9):1199-1207

Topical Muco-Adherent Formulation of Pentoxifylline (tPTX)

Orphan drug candidate for Behçet's Disease

Novel therapeutic with Fast Track and Orphan Designation

Timothy R. Coté, M.D., M.P.H.

- Silk Road Therapeutics CEO
- Former Director of **FDA Office of Orphan Products Development**
- Implemented **Orphan Drug Act**
- Presided over decisions on **>1,400** orphan drug designation applications

Potentially transformative

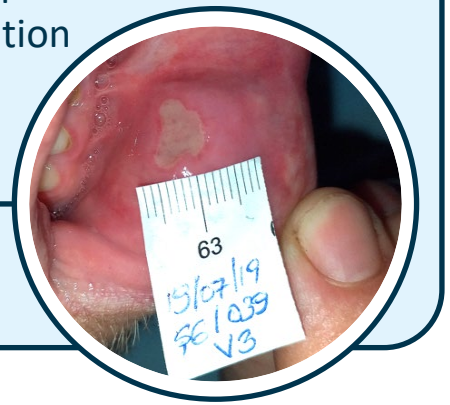
- Formulation designed to deliver **therapeutic dose** to affected areas
- **Phase 2 trial –** tPTX demonstrated superiority over standard of care
- Secured **FDA Orphan Drug Designation** and **Fast Track Designation**
- Positioned for a potential **505(b)(2) approval pathway** in the U.S.

12-month option agreement

Signed April 2024

- Complete due diligence process and engage with Silk Road Therapeutics to further understand the clinical pathway to approval & commercialisation

Behçet's patient in Silk Road Phase II trial



Phase 2 Proof-of-Concept Trial Conducted by Silk Road Therapeutics*

Novel therapeutic with Fast Track and Orphan Designation

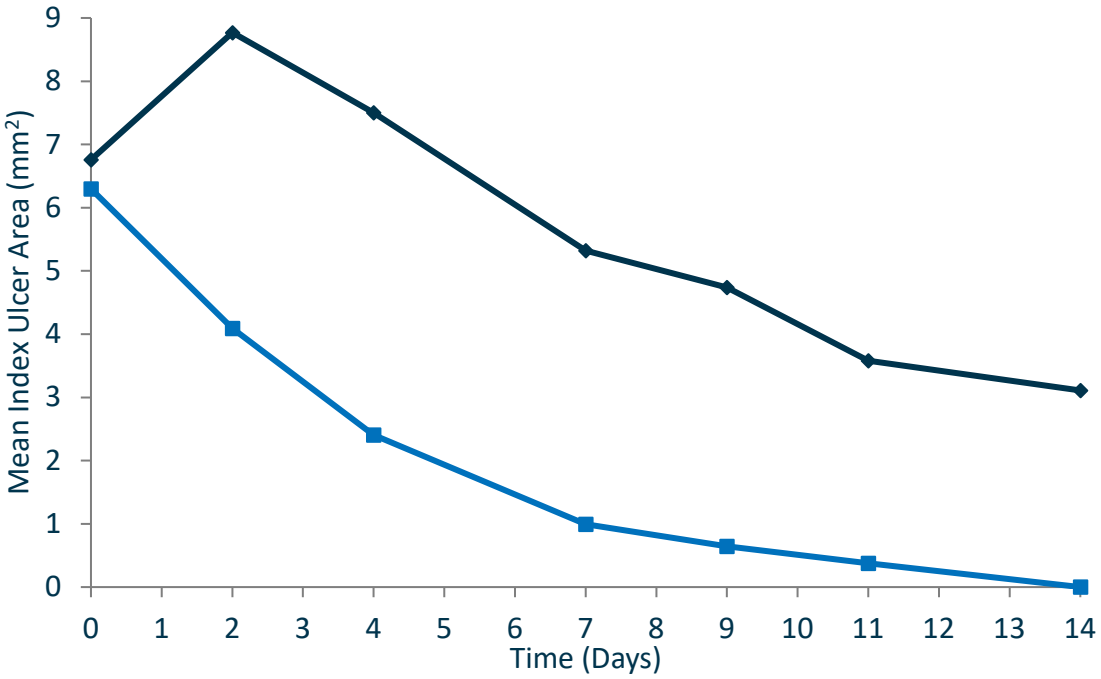
Metrics	Phase 2 Trial
Trial Design	• March – July 2019 • Conducted under FDA IND in Turkey • Randomized **41 patients** to SOC (colchicine therapy) or SOC + topical PTX • Enrolled patients were required to have at least one new oral ulcer within previous 48 hours
Duration	• 14 consecutive days
Protocol	• tPTX gel applied topically to all existing oral ulcers no less than four times daily using one tube per day
Primary Endpoint	• **Average index ulcer area**
Secondary Endpoints	• Pain scores • Average number of daily ulcers

*Trial results as provided by Silk Road Therapeutics

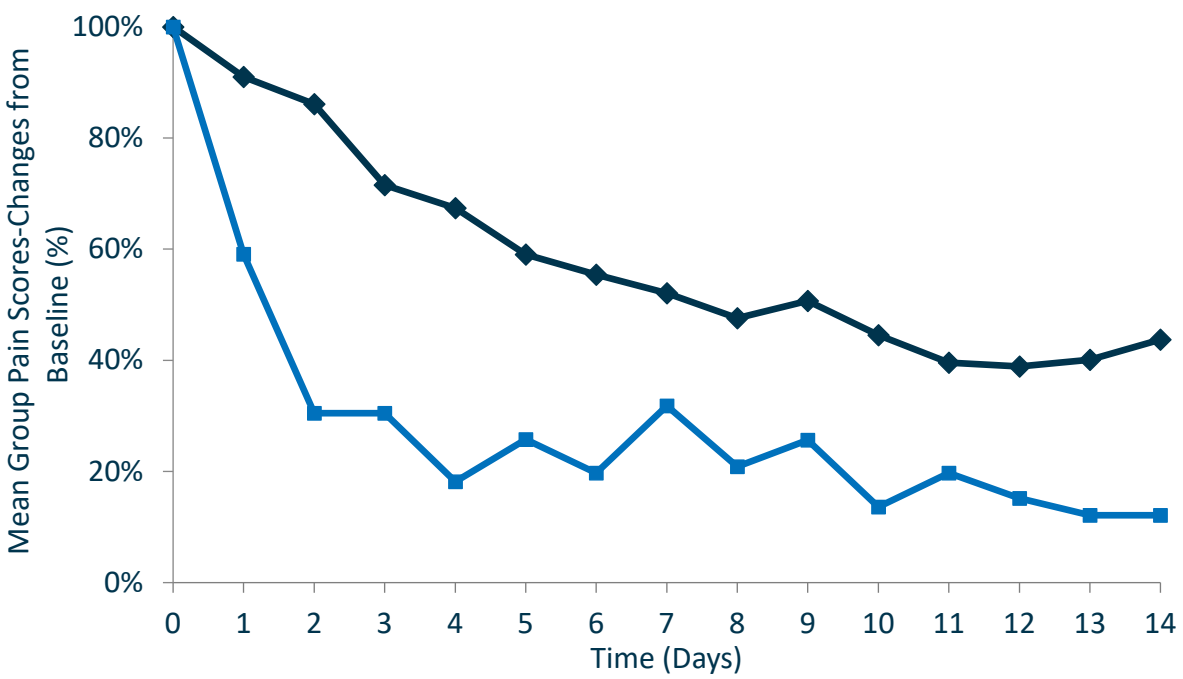
Phase 2 Proof-of-Concept Trial Conduced by Silk Road Therapeutics*

tPTX demonstrates accelerated ulcer healing and decreased pain compared to SOC

Accelerated Ulcer Healing Compared to Standard of Care



Decreased Pain Compared to Standard of Care



tPTX + Standard of Care (Colchicine therapy) (n=18)

Standard of Care (Colchicine therapy) alone (n=21)

- Index Ulcer = Largest ulcer at presentation which first appeared within 48 hours of enrollment

*Trial results as provided by Silk Road Therapeutics

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Oral Delivery Platform

Proprietary delivery platform to enhance drug stability and uptake

Oral GLP-1R Agonist

Metabolic Diseases

Oral Vaccines

Proprietary Oral Delivery Platform

Capital-light prototype and piloting process enables further strategic collaborations

Obesity: Oral GLP-1R Agonist

- Preparing a proof-of-technology clinical trial to determine that a Glucagon-like Peptide 1 receptor (GLP-1R) agonist can be successfully delivered orally in humans
- GLP-1R agonist market expected to exceed US$150bn by 2031[1]
- **Oral GLP-1R agonist trial expected to commence in 2024**

Oral Vaccine Programme

- €2.3m in non-dilutive grant funding awarded to Poolbeg-led consortium to develop a Phase I clinical trial ready oral vaccine candidate
- Consortium include UCD, TCD, and AnaBio Technologies

Strategic Collaborations

- Signed a strategic collaboration with a Nasdaq listed biopharma company in Q4 2023 to produce a prototype oral drug for a metabolic condition
- Opportunity to do other similar deals

[1]The Economist, March 2023

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Artificial Intelligence Programmes

Unlocking insights from unique human challenge trial data

Influenza

Respiratory Syncytial Virus (RSV)

Combining AI and Unique Human Challenge Trial Data to Develop Novel Solutions

Unique and leading human challenge trial data

- Unique RSV and influenza disease progression data from human challenge trials has revolutionised the insights generated using AI analysis
- Multi-parametric dataset – clinical, biological and digital
- Controlled environment and clean data – maximised signal, minimized noise

Using AI to analyse data

- Unique disease progression data from human challenge trials has revolutionised the insights generated using AI analysis
- Poolbeg has already identified a number of novel targets for influenza and potential treatments for RSV
- Looking to partner to develop these into the clinic

Targeting the host response

- Vaccines and antivirals target the virus itself
- Poolbeg utilises a data-first approach to identify novel targets based on **host response** to stop or slow disease progression
- This strategy less likely to be impacted by viral resistance

AI-Led Discovery Programmes

Extensive database analysed using leading artificial intelligence technology

CytoReason

AI analysis of Influenza data

Novel influenza drug targets identified and prioritised following positive feedback from Scientific Advisory Board

CytoReason's Partners

Pfizer | Roche | sanofi | MERCK

ONETHREE BIOTECH

AI analysis of RSV data

Novel application of existing treatments for RSV identified and prioritised following positive outputs from lab-based analyses

OneThree Biotech's Partners

AstraZeneca | Boehringer Ingelheim | LEO | Stanford University

Actively discussing the exciting outputs from our AI-led drug discovery programmes with prospective partners

Positioned to Generate Value for Shareholders while Addressing Significant Unmet Medical Needs

High Value Programmes for Partnering

- Focused on partnering to maximise **near term value** from in-house programmes
- **>US$10bn market opportunity** for **POLB 001** in oncology alone
- Proof of concept clinical trial commencement for Oral **GLP-1RA** targeting **Obesity** in 2024
- **AI-led** discovery programmes identified drug targets & treatments for **Influenza** and **RSV**

Revenue-Focused Business Model

- Targeting **near-term revenue generation & profitability** from commercial stage rare and orphan drugs
- **Option to acquire orphan drug candidate** tPTX for Behçet's Disease

Appendix

Non-Executive Directors

A long history of success in the life sciences industry

Prof Luke O'Neill

Non-Executive Director

- ✓ Co-Founder Inflazome which was acquired by Roche in 2020 for €380m + milestones
- ✓ Previously scientific advisory board member of GSK & Pfizer

Eddie Gibson

Non-Executive Director

- ✓ Market access expert
- ✓ Supported numerous drug companies secure pricing and reimbursement

Prof Brendan Buckley

Non-Executive Director

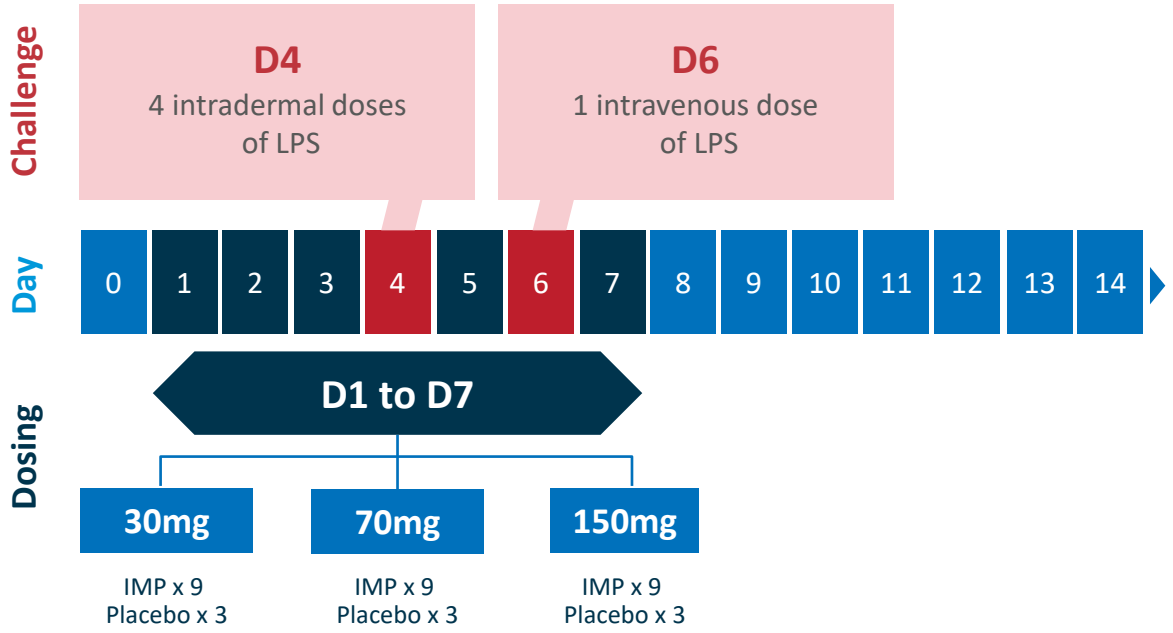
- ✓ Former Chief Medical Officer at ICON plc
- ✓ Former member of Committee for Orphan Medicinal Products & Scientific Advisory Group for Diabetes and Endocrinology at the EMA

POLB 001 – A Human LPS Challenge Trial

Evidence for benefit of POLB 001 in the therapy of LPS-induced inflammation

Randomised, double-blind, placebo-controlled, multiple dose, inflammatory challenge trial in healthy volunteers

Trial design



Endpoints

Intravenous LPS challenge

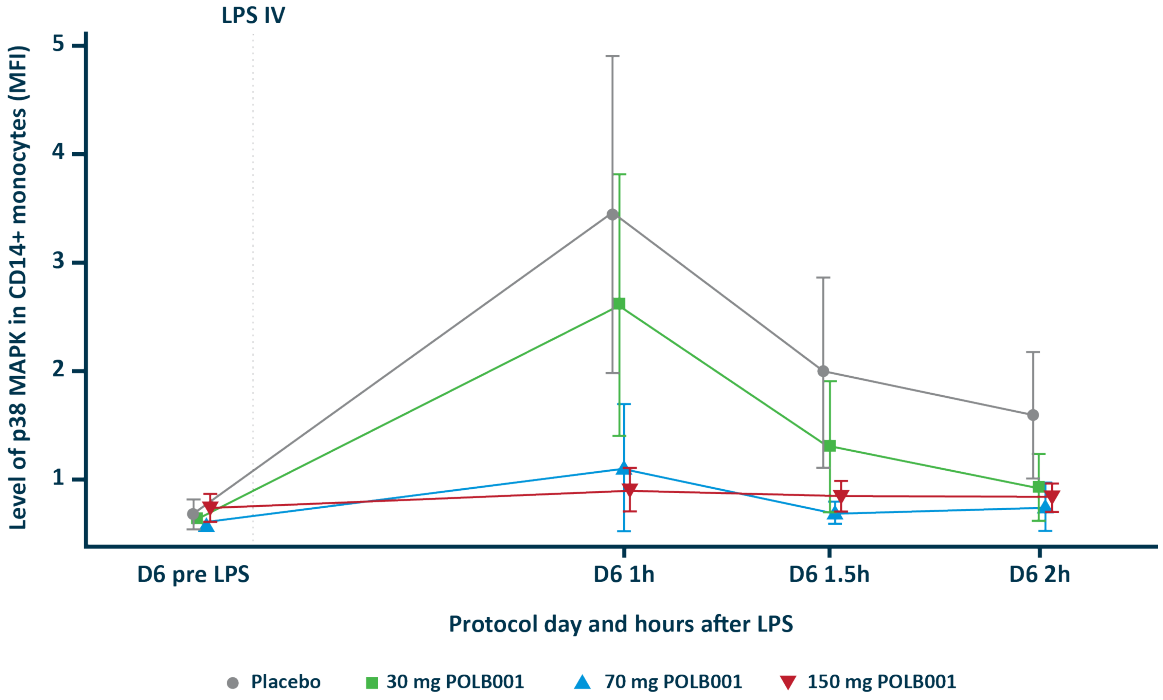
- Bloods (cytokines, vascular markers, CRP)
- *Ex-vivo* LPS response
- Safety & tolerability (inc. vital signs, AE's, ECG, Haematology)

- **Local inflammatory responses** were also measured

Potent and Selective Inhibition of p38 MAPK Signaling

Effective target engagement demonstrated in LPS human challenge trial

Levels of Phosphorylated p38 MAPK in Circulating Monocytes



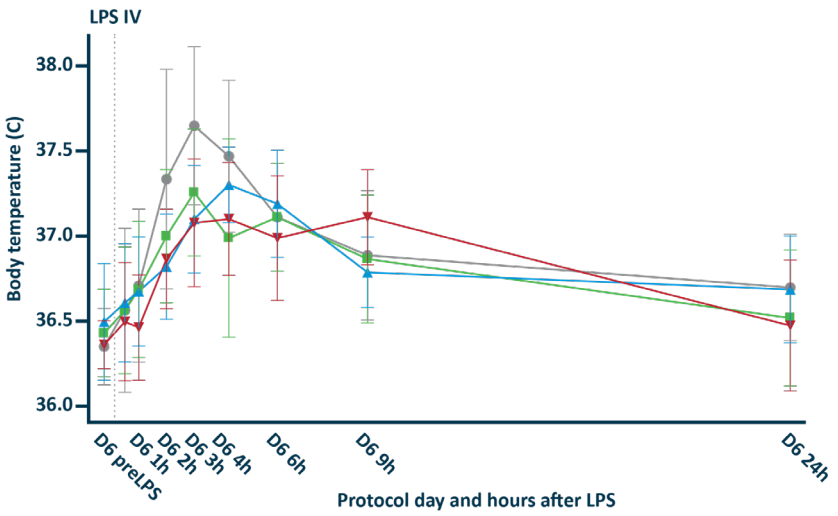
Blood samples were taken before and after administration of intravenous LPS. Peripheral blood samples were analyzed by flow cytometry. Monocytes were gated by FSC, SSC and CD14+. Data is presented as mean MFI values of phospho-p38 +/- SEM

- POLB 001 was **widely distributed**
- POLB 001 **inhibited p38 MAPK activation**, direct measurement of activation
- POLB 001 i**nhibited in vivo and ex vivo responses** to LPS-induced TNF-α, indirect measurement p38 activity

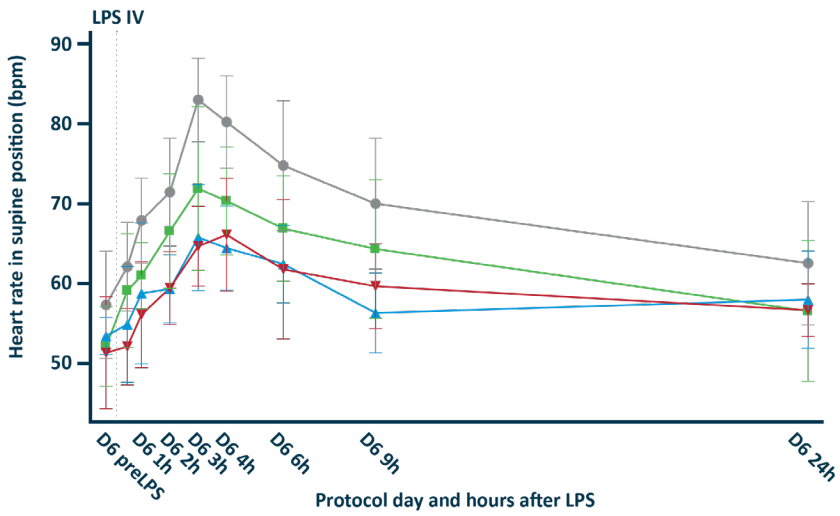
Reduced Key Indicators of LPS-Induced Systemic Inflammation

The reduction of systemic cytokines align with improvement in clinically meaningful endpoints

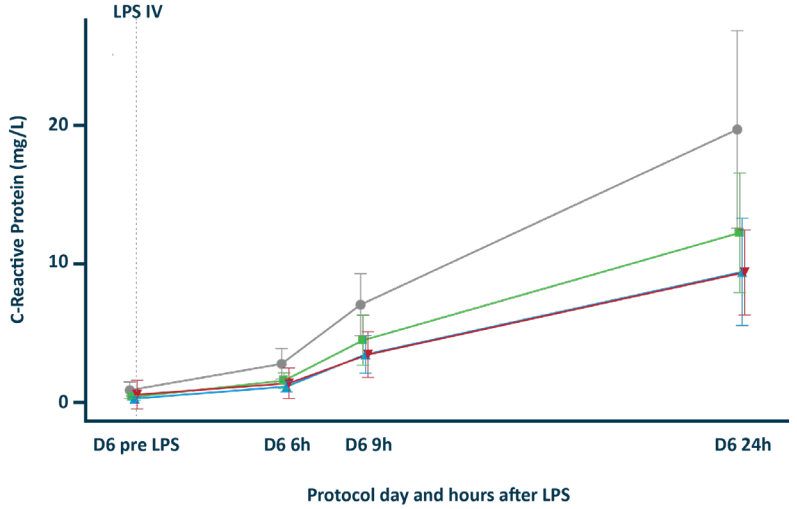
Mean Body Temperature



Heart Rate Rise (bpm)



C-Reactive Protein (CRP)



● Placebo ■ 30 mg POLB001 ▲ 70 mg POLB001 ▼ 150 mg POLB001

No significant effect on body temperature with a trend towards reduction compared to placebo.

Suppressed increase in heart rate following IV LPS administration

CRP level reduction of **33.1% and 33.3%** seen for **70mg and 150mg** doses respectively

Grades & Severity of CRS

CRS occurs in the majority of CAR-T and Bispecific Antibody treatments

CRS Parameter[1]	Grade 1	Grade 2	Grade 3	Grade 4
Fever	Fever ≥ 38°C (not attributable to any other cause). In patients who have CRS then receive antipyretics or anticytokine therapy such as tocilizumab or steroids, fever is no longer required to grade subsequent CRS severity. In this case, CRS grading is driven by hospitalisation and/or hypoxia			
Hypotension	None	Not requiring vasopressors	Requiring a vasopressor ± vasopressin	Requiring multiple vasopressors (excluding vasopressin)
Hypoxia	None	Requiring low-flow oxygen (≤6 L/min)	Requiring high-flow oxygen (>6 L/min)	Requiring oxygen by positive pressure

CRS, Cytokine Release Syndrome. **1.** Ayuketang FA, Jäger U. Management of Cytokine Release Syndrome (CRS) and HLH. 2022. The EBMT/EHA CAR-T Cell Handbook. Chapter 26.

ASH Abstract And Poster Presentation

Presentation at 65th American Society of Hematology (ASH) Annual Meeting to provide insight into POLB 001's potential to treat CRS associated with cancer immunotherapies

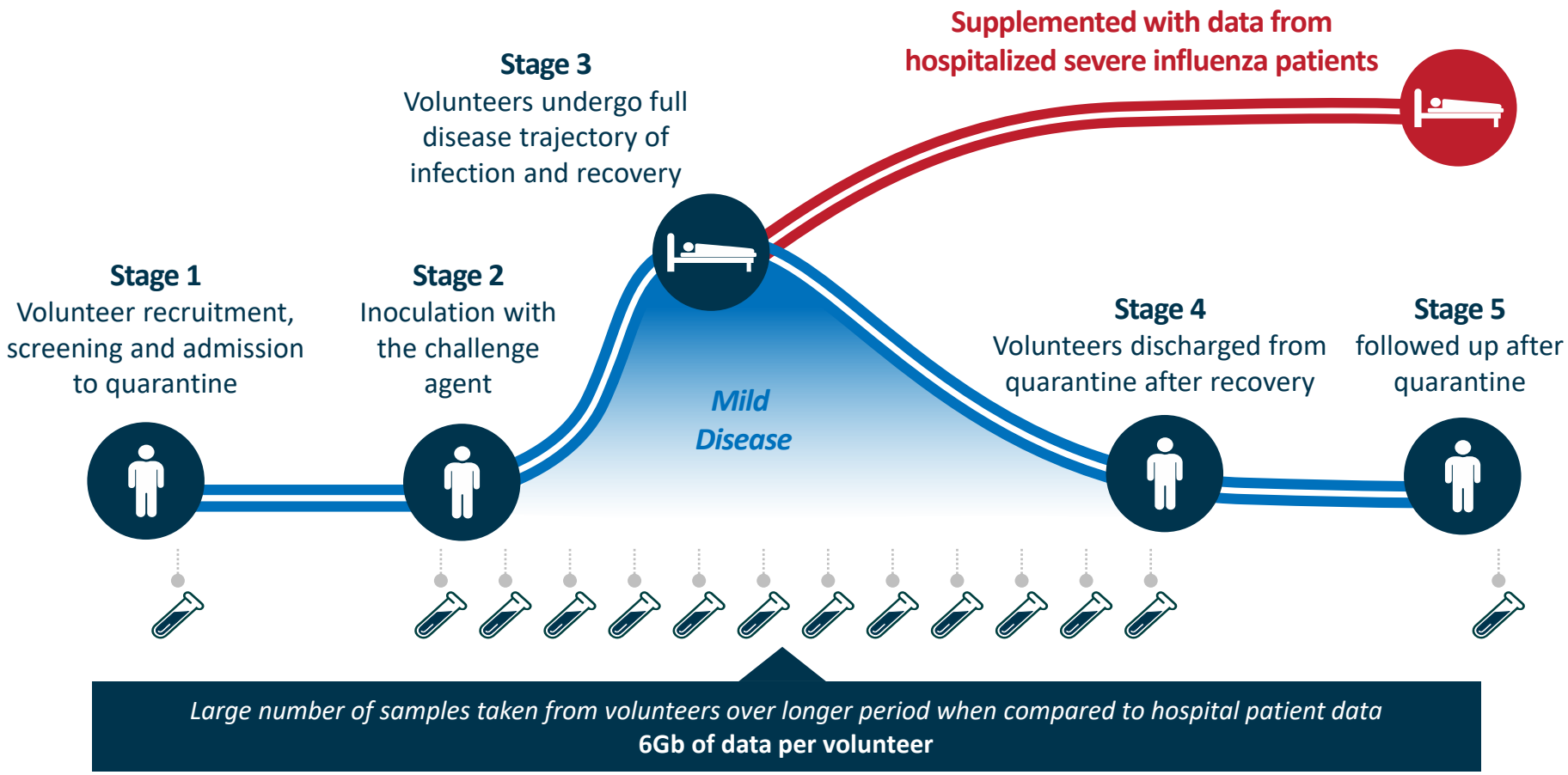
#2093. POLB 001, an oral broad-spectrum anti-inflammatory with the potential to prevent Cytokine Release Syndrome

Emma Searle, MD, Liam Tremble, PhD, Rakesh Popat, MBBS, PhD, Digna de Bruin, MD. PhD., Matthijs Moerland, PhD., and Brendan Buckley, Prof, MD.

- Garnered interest from global industry leaders in the field of bispecific antibodies and CAR T cell therapies
- Encouraging discussions have been held with Pharma as they seek solutions for CRS to improve the safety profile and increase the market potential of their therapies

AI Programmes Underpinned by Unique Human Challenge Trial Data

Proprietary data set enables training of cutting-edge AI algorithms leading to higher quality outputs



Benefits of Challenge Data

- **Multi-parametric dataset – clinical, biological and digital**
- **Known infection time and dose**
- **Clean data – maximised signal, minimized noise**
- **Verifiable clinical assessment – Controlled environment**

POOLBEG PHARMA

Stay in touch

Listed on the London Stock Exchange AIM ticker: POLB