

POOLBEG PHARMA

# Company Presentation

## 28 October 2026

**AIM: POLB**

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# High Value Pipeline Programmes

## Multiple near-term clinical value inflection points – positioned well for partnering

| Product | Modality | Indication | Preclinical | Phase 1 | Phase 2 | Phase 3 | Key Milestones |
|---|---|---|---|---|---|---|---|
| **POLB 001** | p38 MAPK inhibitor | Cancer Immunotherapy-induced CRS* | | | **FDA Orphan Drug Designation** | | ▪ TOPICAL trial in multiple myeloma patients<br>▪ Teclistamab provided by J&J<br>▪ Trial actively recruiting |
| **Oral Encapsulated GLP-1** | GLP-1R agonist | Obesity | | AnaBio™ Technologies LTD. | | | ▪ Progressing towards PoC trial commencement<br>▪ Planned to commence H2 2026 |
| **AI Programmes** | Novel drug discovery | Influenza | | CytoReason | | | ▪ Potential partnership |
| | | RSV | | ONETHREE BIOTECH | | | ▪ Potential partnership |

**Further life cycle opportunities, including severe influenza*

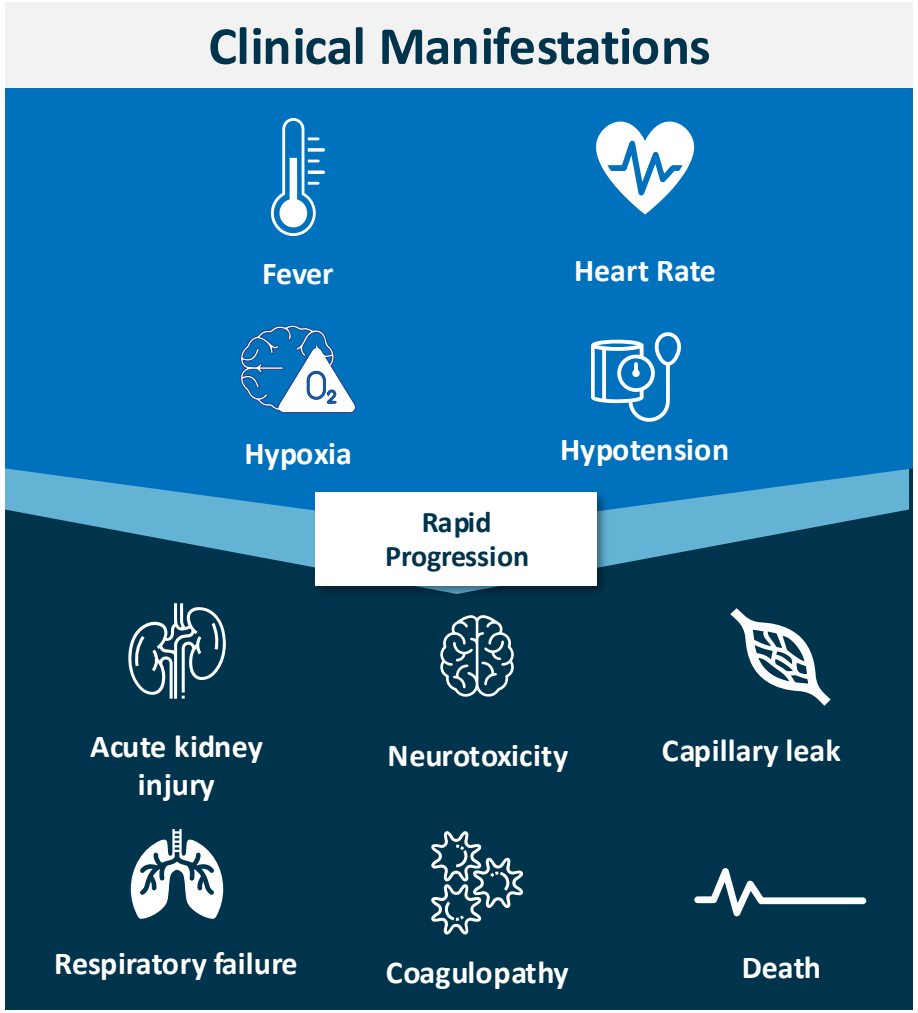
**AI**: Artificial Intelligence; **CRS**: Cytokine Release Syndrome; **GLP-1**: Glucagon-like Receptor-1; **MAPK**: Mitogen Activated protein Kinase; **PoC**: Proof of Concept; **FIP**: First-in-Patient
**TOPICAL** - Trial of Prevention of ImmunoCytokine Adverse events in Myeloma

# POLB 001 – potential first approved preventative therapy for cancer immunotherapy-induced Cytokine Release Syndrome (CRS)

***POLB 001 has the potential to transform the cancer immunotherapy field through the prevention of CRS, thereby expanding administration of these life-saving therapies from centralised specialist cancer centres into community hospitals, and ultimately, home-based treatment***

# POLB 001 as a Potential Solution For CRS

## A systemic inflammatory side effect of some cancer immunotherapies




- POLB 001 is an oral p38 MAP Kinase inhibitor
- p38 MAPK acts as a gatekeeper to inflammatory responses
- Inhibition causes a potent decrease of a wide range of pro-inflammatory cytokines **without ablating the immune system**
- Favourable safety profile distinguishes POLB 001 from existing treatment options and positions it as an attractive preventative solution

### *POLB 001: Broader Cytokine Inhibition Profile vs Competition*

| | TNF | IL-1α | IL-1β | IL-2 | IL-3 | IL-4 | IL-5 | IL-6 | IL-8 | IL-10 | IL-12 | IL-13 | IL-15 | IL-17 | IL-20 | IL-21 | IL-22 | IL-23 | IL-27 | IP-10 | CCL2 | CXCL1 | COX-2 | CSF1 | G-CSF | GM-CSF | iNOS | MIP1α | MIP1β | VEGF | uPAR | PGE2 | IFNα | IFNβ | IFNγ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *POLB 001* | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | | ● | ● | | | ● | | ● | ● | ● | ● | ● | | ● | ● | ● | ● | ● | ● | ● | | | ● |
| Tocilizumab | | | | | | ● | | ● | | ● | | | | ● | | ● | | | | | | | | | | | | | | | | | | | ● |
| Dexamethasone | ● | | ● | ● | ● | | | ● | ● | ● | | | | ● | | | | | | | ● | | | | | | | | | | | | | | ● |
| Itacitinib | ● | | | ● | | ● | | ● | | ● | | ● | ● | | | ● | ● | | | | | | | | ● | | | | | | | | ● | ● | ● |

● Direct pathway effect ● Secondary consequence

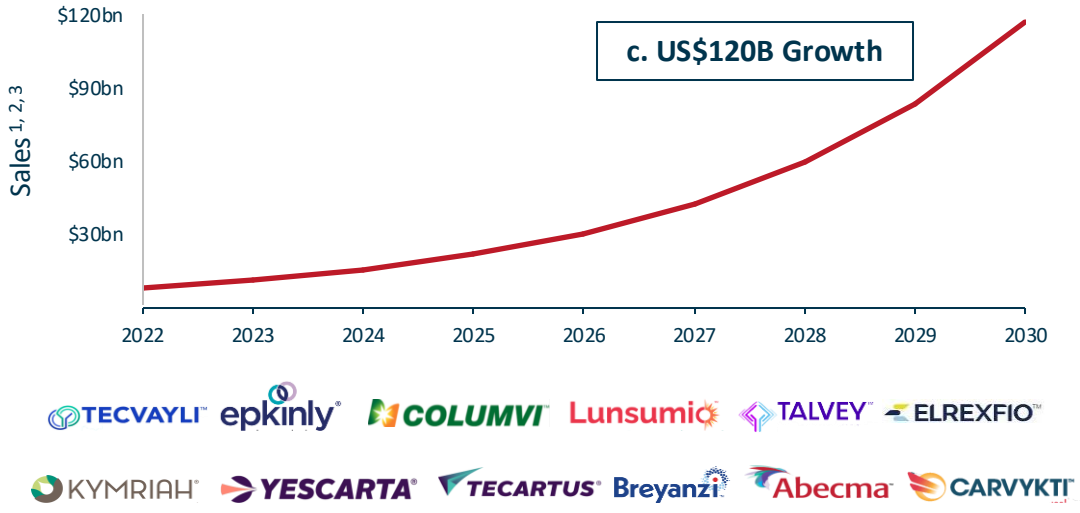
*The table presents a select overview of certain cytokines and certain comparative drugs and is not intended to depict the full pharmacological profile of each drug.

1. Gurusamy et al, Cancer Cell . 2020 Jun 8;37(6):818-833.e9. Table references: Frevel et al, Mol Cell Biol. 2003 Jan;23(2):425–436. Tiedje et al, J Interferon Cytokine Res. 2014 Apr;34(4):220-32. Ogilvie et al, J Immunol (2005) 174 (2): 953–961. Dodeller et al, Eur J Immunol . 2005 Dec;35(12):3631-42. Vockerodt et al, Int J Cancer . 2005 Apr 20;114(4):598-605. Khaber. J Leukoc Biol. 2007 Mar 30;81(6):1335–1344. noubade et al. Blood. 2011 Jul 25;118(12):3290–3300. Yanagawa and Onoé. mmunology. 2006 Apr;117(4):526–535. Johansen et al. Br J Dermatol . 2010 Dec;163(6):1194-204. Guan et al, J Biol Chem . 1998 May 22;273(21):12901-8. Lahti et al, BMC Pharmacol. 2006 Feb 21;6:5. Gonsalves et al, J Immunol . 2010 Nov 15;185(10):6253-64. Grebenciucova and VanHaerents, Front Immunol . 2023 Sep 28:14:125553. Hudson et al, Nat Commun. 2018 Apr 6;9(1):1337. Menson et al, Am J Physiol Lung Cell Mol Physiol . 2020 Oct 1;319(4):L693-L709. Franchimont et al, Regul Pept . 1998 Jan 2;73(1):59-65. Spinelli et al, Rheumatology (Oxford). 2021 May 5;60(Suppl 2):ii3–ii10. yarilina et al, Arthritis Rheum. 2012 Dec;64(12):3856–3866. Johnson et al, Bioorg Med Chem Lett . 2019 Jun 15;29(12):1522-1531.

# Significant Market Opportunity in a Rapidly Growing Field

## CRS is a major issue and rate limiting in delivering cancer immunotherapies

### BsAb & CAR T Market Expected to Grow Exponentially




***Need for effective CRS management is driven by rapid growth of CRS-inducing cancer immunotherapies***

### CRS Rates for Approved Cancer Immunotherapies

| Drug | Company | Combined % Patients with All-Grade CRS* |
|---|---|---|
| **Bispecific Antibodies** | | |
| Tecvayli | Johnson & Johnson | 72% |
| Epkinly | AbbVie / Genmab | 51% |
| Columvi | Roche | 68% |
| Lunsumio | Roche | 44% |
| Talvey | Johnson & Johnson | 77% |
| Elrexfio | Pfizer | 58% |
| **CAR T-Cell** | | |
| Kymriah | Novartis | 64% |
| Yescarta | Gilead / Kite | 88% |
| Tecartus | Gilead / Kite | 91% |
| Breyanzi | BMS | 50% |
| Abecma | BMS | 81% |
| Carvykti | Johnson & Johnson | 89% |

**1.** Grand View Research. **2.** CAR T-Cell Therapy Market Analysis 2023-2030; Grand View Research. **3.** Bispecific Antibodies Market Size, Share & Trends Analysis Report. * As per product label.
**BsAb**: Bispecific Antibody; **CAR T**: Chimeric Antigen Receptor T cell therapy; **CRS**: Cytokine Release Syndrome.

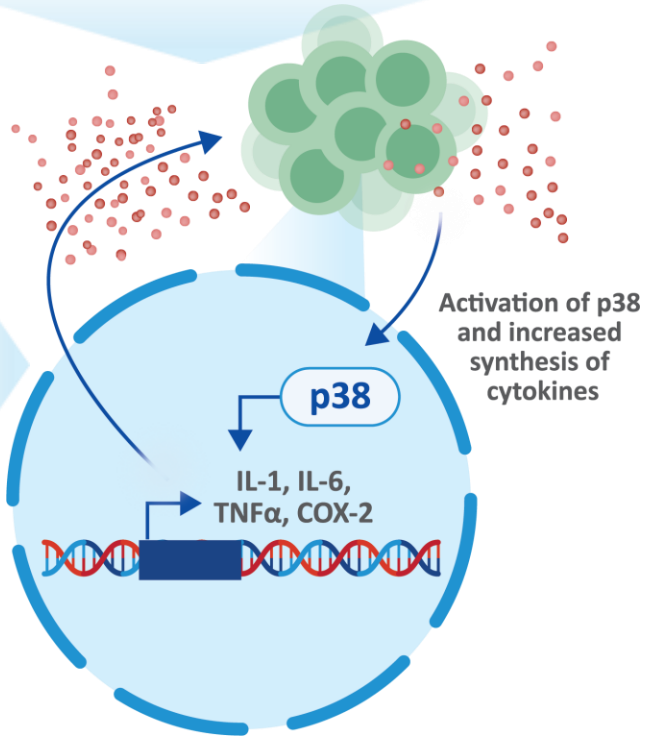
# POLB 001's Intended Impact: An Illustrative Patient Journey

## Transforming cancer care for patients and healthcare systems

### Patient 1 — Current Standard of Care



1. Cancer immunotherapies redirect the immune system to fight cancer




2. This immune activation can trigger CRS a potentially life-threatening side-effect
3. CRS can prolong hospital stay, delay treatment and/or cause discontinuation of treatment
4. Significant challenge in expanding treatment into community hospitals

### Patient 2 — Utilising POLB 001

1. Patient takes POLB 001 **before** cancer immunotherapy treatment






2. Cancer immunotherapies redirect the immune system to fight cancer
3. POLB 001 blocks p38 MAPK, a key driver of CRS
4. By preventing CRS, POLB 001 could decrease hospital stay, enable administration in community hospitals, and improves patient quality of life

# POLB 001 Phase 1b LPS Human Challenge – Potent Inhibition of Excessive Inflammation

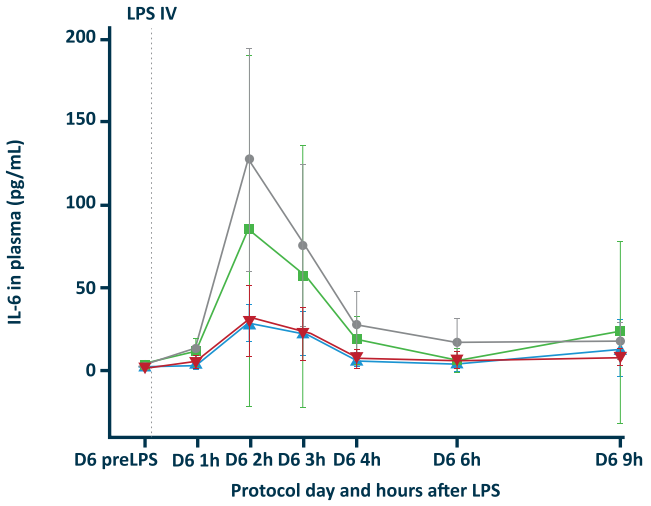
## Positive data supports the potential of POLB 001 to effectively prevent CRS

ASH '23

### Phase 1b LPS Human Challenge Trial

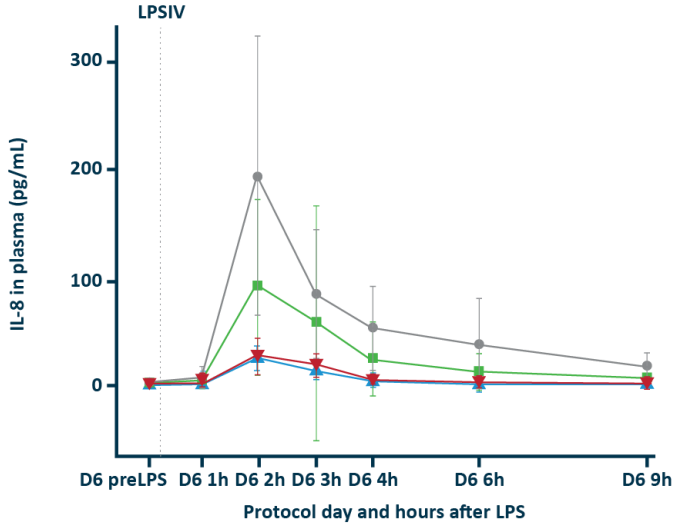
- Excellent safety & tolerability profile
- Potent target inhibition confirmed
- Clear dose response relationship observed
- Major reduction of key inflammatory markers

### IL-6 Levels




**57.4% and 63.5% decrease for 70 mg & 150 mg doses respectively (p = 0.0002)**

### IL-8 levels




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

Placebo | 30 mg POLB 001 | 70 mg POLB 001 | 150 mg POLB 001

**Potential to effectively prevent CRS while preserving key immune system functionality**

**Trial design**: Single site, randomized placebo controlled LPS challenge trial. Healthy males administered BID oral POLB 001 or vehicle only control & challenged with local dermal LPS on day 4 and systemic IV LPS on day 6 to evaluate effect of POLB 001 on local and systemic inflammatory responses respectively. n=9 per group, all endpoints were exploratory. **BID**: twice daily; **CRS**: Cytokine Release Syndrome; **ID**: Intradermal; **IV**: Intravenous; **IL-6**: Interleukin-6.

Published **Frontiers in Immunology** article available at DOI 10.3389/fimmu.2025.1684307

# POLB 001 First-in-Patient TOPICAL Trial

## J&J supplying the approved bispecific antibody teclistamab

| TOPICAL - Trial of Prevention of ImmunoCytokine Adverse events in Myeloma | |
|---|---|
| **Chief Investigator** | **Dr Emma Searle, MBChB MA MRCP FRCPath PhD** |
| **Trial run by** | Accelerating Clinical Trials (ACT) - specialist blood cancer trials organisation |
| **Objective** | To investigate the safety and efficacy of POLB 001, in particular its ability to reduce incidence of CRS in patients receiving the approved bispecific antibody teclistamab |
| **No. subjects** | c. 30 |
| **Patient population** | Relapsed/refractory multiple myeloma patients |

### Leading Cancer Research Centres

1. The Christie, Manchester
2. University College London Hospitals
3. The Royal Marsden
4. University Hospitals Birmingham
5. NHS Lothian
6. Royal Stoke University Hospital






*"I have seen first-hand the challenges that CRS presents to the delivery of cancer immunotherapies, requiring many of our patients to be hospitalised for treatment. These transformative therapies will continue to be restricted until there is a way to administer them more safely. POLB 001 holds great promise in tackling this issue; potentially leading to improved patient wellbeing, reducing the strain on healthcare systems while making these treatments more accessible to a broader patient population."*

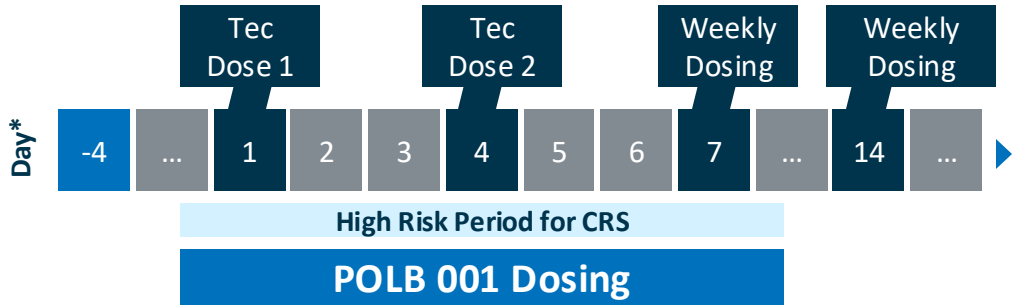
**Dr Emma Searle, Consultant Haematologist**

**CRS**: Cytokine Release Syndrome; **TOPICAL** - Trial of Prevention of ImmunoCytokine Adverse events in Myeloma

# POLB 001 First-in-Patient TOPICAL Trial

## Trial designed to produce rapid & compelling data for the effectiveness of POLB 001 to prevent CRS

### Trial Design




| 2x Daily Oral | Single Arm | N = c. 30 | Teclistamab *Provided by J&J* | Open Label |
|---|---|---|---|---|

### Key Endpoints

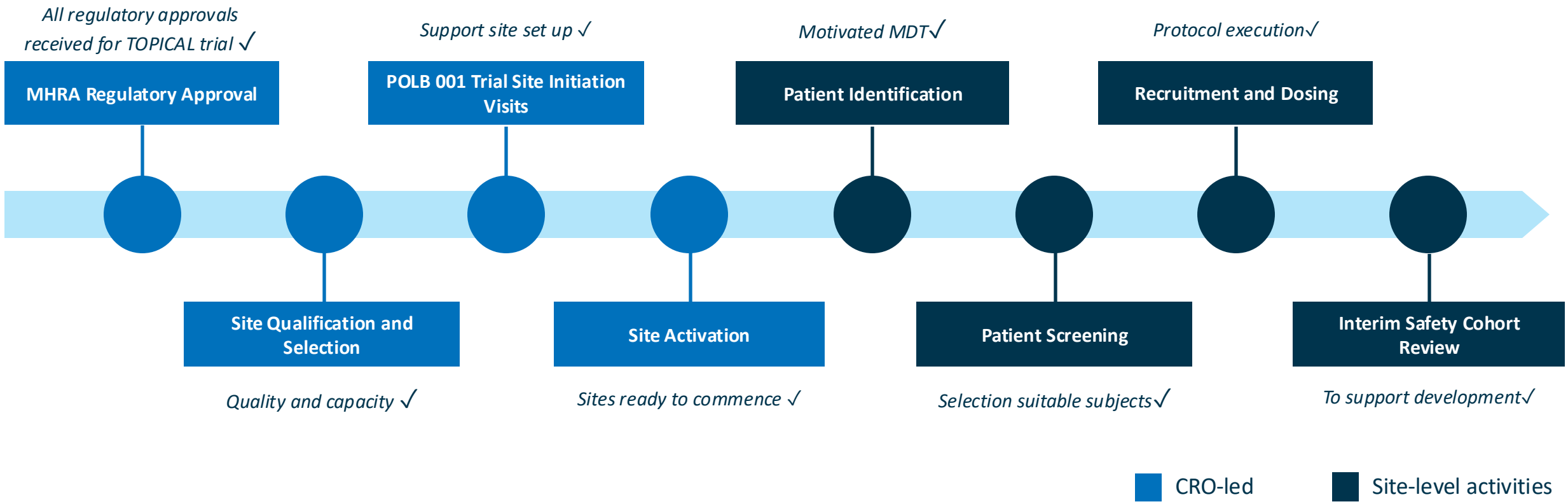
- Safety of POLB 001
- Incidence of CRS
- Severity of CRS
- Confirm safety & pharmacokinetics
- CRS management / tocilizumab usage

**Trial has progressed through a positive review of data from the interim safety cohort with the trial continuing as planned, with no changes required to the study protocol**

**Tec:** Teclistamab bispecific antibody; **CRS**: Cytokine Release Syndrome; **GMP:** Good manufacturing practice; **Tx**: Treatment; **TOPICAL** - Trial of Prevention of ImmunoCytokine Adverse events in Myeloma.
*Bispecific antibody dosing days estimated for demonstrative purposes only and may vary.

# POLB 001 – Activities Completed to Reach Key Milestones

## Motivated study team & partners efficiently advancing TOPICAL trial




**MHRA:** UK Medicines and Healthcare products Regulatory Agency. **MDT:** Multidisciplinary team

# TOPICAL Clinical Trial Interim Data

## Completion of the review represents important milestone for POLB 001 clinical development

**Positive recommendation to continue the study as planned**

### Interim Data Safety Review
Complete

- Interim safety cohort data reviewed (6 pts)
- Recommendation to continue as planned
- No study protocol changes required

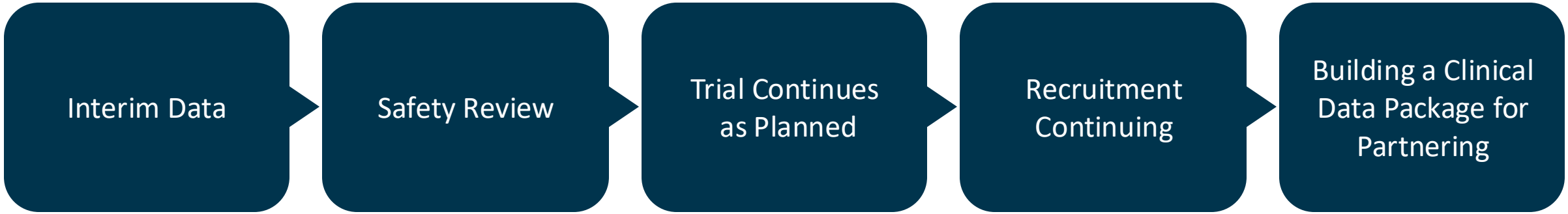
### POLB 001 TOPICAL Trial
Recruitment continues

- Recruitment continues across leading UK sites
- Additional clinical sites activation

### Business Development
Advancing Partnering Discussions

- Progression supports building a clinical data package for partnering
- Catalyst for partnering discussions

## Building towards partnering POLB 001



# Clear Route to Market

## Programme positioned for rapid clinical development following TOPICAL study

**FDA pre-IND meeting** conducted in May 2026

- Significant clarity achieved on **nonclinical package**, **indication**, **Phase 3 design** and **Phase 3 endpoints and label on approval**

- Feedback was aligned with:
  - The Company's envisioned clinical development pathway with a clear route to market and a commercially attractive Phase 3 development programme
  - Significant commercial opportunity and sales forecasts from recent US commercial payer research

- Programme has the potential to advance rapidly following TOPICAL trial - clear path to pivotal trial initiation **through partnering**

# Prevention of CRS by POLB 001 May Transform Cancer Immunotherapies

## Potential to greatly enhance uptake and access to BsAb and CAR-T therapies by removing bottleneck

From **2023** to **2030**
**~500,000 patients**[1] will be diagnosed with **DLBCL** & **MM** in the **US** & **EU5** and are eligible to receive **BsAb / CAR T** treatments, **restricting patient access**

**Bottleneck***

CRS

**An effective CRS preventative therapy may remove the bottleneck**

**>US$10B**[2]
Market opportunity

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

**Prof Martin Kaiser, Royal Marsden, UK**

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

**Myeloma specialist, FR**

**1**. Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023. **2.** Independent research by Decisive Consulting Limited.
*CRS prevention may contribute to bottleneck removal. Other issues, such as manufacturing, supply and other adverse events, may also present barriers to wider uptake.

# US Payer and Pricing Insights

## Payer willingness-to-pay research & economic arguments to support pricing readiness

## Independent Payer Research Covering ~75M Lives Across Insurance Providers, Medicare & Medicaid

**Multi-billion $**
**POLB 001 peak US sales potential**

*"This research validates both the scale of that unmet need and the appetite among payers for an effective preventative approach. We observed a* ***willingness to pay at commercially meaningful price points****, driven by the potential to reduce hospitalisation costs, potentially allowing for care to be decentralised and ultimately delivering better outcomes for some of the sickest patients****. This positions POLB 001 as a compelling CRS solution with significant market potential****."*



**Chris Grimes Crompton,**
Partner, Value Strategy, Acumetis

# POLB 001 – Built for Partnering

## Scientific, clinical, regulatory and commercial workstreams progressed in parallel to strengthen the partnering package

**SCIENTIFIC**

### Scientific rationale

- Oral p38 MAPK inhibitor
- No approved therapy for CRS prevention
- Strong pre-clinical & clinical data

**CLINICAL**

### Clinical execution

- Interim data marks positive milestone
- Active recruitment and dosing
- Interest from other leading UK cancer centres

**REGULATORY**

### Development pathway

- Positive FDA pre-IND meeting:
  - Alignment on proposed endpoint for future Phase 3
  - Greater clarity on route-to-market

**INTELLECTUAL PROPERTY**

### Market exclusivity

- FDA Orphan Drug Designation[1]
- Key patent grants (coverage to at least 2044)
- Continued expansion of patent portfolio

**COMMERCIAL**

### Commercial validation

- >US$10B global market opportunity[2]
- US payer research – strong willingness to pay[3]
- Multi-billion-dollar US peak sales potential

**PARTNERING**

### Business development

- Active discussions with data room open
- Expanding pool of potential partners
- Market dynamics increasing demand for high potential programmes with proof of concept

**Positive interim safety review marks important company milestone**

**MAPK**: Mitogen Activated protein Kinase; **CRS**: Cytokine Release Syndrome; **FDA:** U.S. Food and Drug Administration **pre-IND meeting**: pre-Investigational New Drug meeting.
**1.** FDA Orphan Dug Designation for the prevention of T cell engager bispecific antibody induced CRS. **2.** Independent research by Decisive Consulting Limited. **3.** Independent research by Acumetis

# GLP-1 Programme

Oral encapsulated GLP-1R agonist targeting the obesity market

# GLP-1 Market

## US$20.2 billion
**2025 marked a record year for obesity and diabetes deal-making**

## US$347 billion
**Economic impact of obesity on US businesses & employees 2023**

## US$150 billion
**GLP-1R agonist market projection by 2031**

Sources: J.P. Morgan Q4 2025 Biopharma Licensing and Venture Report, January 2026;. Global Data, Assessing the Economic Impact of Obesity and Overweight on Employers, Feb 2024; **3.** The Economist, March 2023. **GLP-1**: Glucagon like-peptide-1.

# Oral GLP-1

### A differentiated approach

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- Generally Recognised as Safe (GRAS) oral encapsulation technology encapsulates an approved GLP-1 receptor agonist
- Directing GLP-1 receptor agonist to a specific area of the gut using a pH sensitive release mechanism, to deliver the drug to its intended site of action
- Potential to overcome oral delivery challenges of peptide-based biologicals, and improve bioavailability

**AnaBio's Encapsulation Centre of Excellence**

- 2,000m$^2$ state of the art manufacturing facility
- FFSC2200, FDA accredited
- Commercialises encapsulated bioactives for food and beverage applications



# Proof of Concept Trial Planned to Commence H2 2026

## Successful results from the trial may support partnering & multiple opportunities for value creation

**Trial Investigator: Prof Carel le Roux**
**Site:** University of Ulster
**Objective:** Demonstrate GLP-1 uptake
**Endpoints:** Safety, tolerability & PK
**N =** Up to 20
**Population:** Obese subjects

The study has been designed to complete quickly following first subject dosing, providing a rapid path to readout once underway.



***"This trial is designed to generate impactful data that demonstrates our ability to safely and efficiently deliver an oral GLP-1R agonist using a validated technology."*** *Prof Carel le Roux*

**GLP-1**: Glucagon like-peptide-1; **PK**: Pharmacokinetics.

A clinical-stage company developing POLB 001 that has the potential to transform the lives of cancer patients by delivering their cancer immunotherapy treatment safely & locally.

Poolbeg is also developing an oral, patient-friendly obesity treatment.

1. Experienced team with proven track record of closing significant transactions
2. High value clinical-stage programmes targeting critical unmet medical needs in large & growing markets
3. Partnering focused model with clear path to strategic transactions
4. Financial runway into Q2 2028



# Appendix

# Leadership Team with Record of Delivering Value

## A clinical-stage biopharmaceutical company with a core focus on transforming the cancer immunotherapy field



**Cathal Friel**
**Executive Chairman**

hVIVO formerly Open Orphan plc · AMRYT PHARMA · Raglan Capital



**Jeremy Skillington PhD**
**Chief Executive Officer**

INFLAZOME Targeted Therapies for Inflammatory Diseases · Genentech A Member of the Roche Group · ETHRIS



**Ian O'Connell**
**Chief Financial Officer**

hVIVO formerly Open Orphan plc · AMRYT PHARMA · Deloitte.



**Liam Tremble**
**Principal Scientist**

hVIVO formerly Open Orphan plc · UCC University College Cork, Ireland Coláiste na hOllscoile Corcaigh · Trinity College Dublin The University of Dublin



**Meena Arora**
**VP Medical Affairs & Development**

ONCONOVA THERAPEUTICS · AMRYT PHARMA · Celgene

# Board Includes Leading Non-Executive Directors

## A long history of success in the life sciences industry



### Prof Luke O'Neill

**Non-Executive Director**

Trinity College Dublin, The University of Dublin · INFLAZOME Targeted Therapies for Inflammatory Diseases · GSK

- ✓ 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**

WICKENSTONES · Bristol Myers Squibb · AVEO ONCOLOGY

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



### Prof Brendan Buckley

**Non-Executive Director**

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH · UNIVERSITY OF OXFORD · ICON

- ✓ 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

POOLBEG PHARMA

## Stay in touch

**Listed on the London Stock Exchange**
**Ticker: POLB**

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