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Poolbeg Pharma PLC
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**REACH**

# Poolbeg Pharma plc presents POLB 001 pre-clinical study data at the 66th American Society of Hematology (ASH) Annual Meeting

*All doses of POLB 001 significantly reduced clinically observed Cytokine Release Syndrome scores*

*POLB 001 treatment showed statistically significant reductions in key cytokines*

*Positive results reinforce the use case for POLB 001 in the prevention and treatment of cancer immunotherapy-induced CRS*

9 December 2024 - Poolbeg Pharma (AIM: POLB, 'Poolbeg' or the 'Company'), a clinical-stage biopharmaceutical company focused on the development and commercialisation of innovative medicines targeting diseases with a high unmet medical need, today announces key insights from its poster presentation at the 66th American Society of Hematology ('ASH') Annual Meeting and Exposition, San Diego, California.

The poster, which detailed POLB 001 as a promising preventative therapy for Cytokine Release Syndrome (CRS) associated with cancer immunotherapies, was presented by the Company's Chief Executive Officer, Jeremy Skillington, PhD on Saturday 7 December.

The study was designed to evaluate the effect of POLB 001 on CRS compared to Adalimumaban anti-TNF antibody which is a gold standard potent inhibitor of CRS in humanised tumour-bearing mouse models. Mice were treated twice daily with either placebo or POLB 001 at low, medium, or high doses for five days.

**Key Highlights:**

- POLB 001 effectively reduced CRS and demonstrated superior cytokine inhibition compared to Adalimumab
- In a model of anti-CD28 induced CRS, POLB 001 was shown to dose dependently reduce clinical CRS scores
- POLB 001 reduced peak serum levels of TNF, IL-4, IL-6, IL-8 and MIP-1α and the results were statistically significant
- All other cytokines tested, including IFN-γ, IL-8, IL-10 and IL-2, demonstrated trends of reduced peak serum levels
- Other immunological and malignancy-related endpoints were monitored with no harmful effects of POLB 001 observed
- Positive results reinforce the use case for POLB 001 in the prevention and treatment of cancer immunotherapy-induced CRS

**Mark Sumeray, MD, Consultant Clinical Advisor forPoolbeg, commented:** *"Addressing cancer immunotherapy-induced CRS holds the potential to greatly impact the treatment of hematological malignancies - enhancing safety and reaching more patients. These data presented at ASH are promising, demonstrating statistically significant cytokine inhibition and a dose dependent reduction in clinical CRS. The results of this animal study support development of POLB 001 in a Phase 2 clinical study as a prophylactic for the prevention of immunotherapy-induced CRS. The previous successful LPS trial in healthy human volunteers also provides ratification."*

**Poster Presentation Details:**

**Title:** POLB 001, an Oral p38 MAPK Inhibitor, Reduces Cytokine Release Syndrome (CRS) in a Mouse Model of Immunotherapy-Induced CRS
**Session Name:** 703. Cellular Immunotherapies other than CAR-T Cells: Basic and Translational: Poster I
**Session Date and Time:** Saturday, 7 December 2024, 5:30 PM - 7:30 PM PST
**Location:** San Diego Convention Center, Halls G-H
**Authors:** Liam Tremble, PhD, MSc, BSc, Paula Maguire, PhD, Jiwon Yang, PhD, James G Keck, Laura Maher, MSc, Mark Graham, Martin F Kaiser, MD, FRCP, FRCPath, Emma Searle, MD, PhD and Mark Sumeray, MD
**Abstract Number:** 2061

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**About POLB 001**

CRS can occur in >70%[1] of patients treated with T cell engaging bispecific antibodies, or CAR T cell therapies. CRS of any grade can lead to prolonged hospital stays and mortality risk. The administration of these cancer immunotherapies is therefore restricted only to specialist cancer centres, which has created a "bottleneck" in providing seamless, cost-efficient access to these treatments for the patients who need them.

There are currently very few approved therapies for the management of CRS and no approved therapies for the prevention of CRS. As an oral therapy to prevent or treat CRS, POLB 001 has the potential to enable broader use of cancer immunotherapies in an outpatient setting to reduce the risk of a bottleneck occurring, and to make these life-saving therapeutics more readily accessible to patients.

Independent research commissioned by Poolbeg confirmed a market potential for POLB 001 of c.US 10 billion in Multiple Myeloma and Diffuse Large B-Cell Lymphoma alone due to the significant advances in bispecific antibody and CAR T-cell therapies for these indications.[2] Cancer immunotherapies are being widely developed across a broader range of hematological malignancies (including many rare or orphan cancers) and solid tumours, which Poolbeg believe will expand the opportunity for POLB 001 far beyond the estimate of c.US 10 billion.

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.

**About Poolbeg Pharma plc**

Poolbeg Pharma plc is a clinical-stage biopharmaceutical company focussed on acquiring, developing and commercialising innovative medicines that will help improve the lives of patients with rare and orphan diseases and where there is a high unmet medical need. Poolbeg comprises a strong and growing portfolio of development assets. For more information, please go to www.poolbegpharma.com or follow us on Twitter and LinkedIn @PoolbegPharma.

**Forward-Looking Statements**

This announcement may contain forward-looking statements and the words "expect", "anticipate", "intends", "plan", "estimate", "aim", "forecast", "project" and similar expressions (or their negative) identify certain of these forward-looking statements. The forward-looking statements in this announcement are based on numerous assumptions and Poolbeg's present and future business strategies and the environment in which Poolbeg expects to operate in the future. Forward-looking statements involve inherent known and unknown risks, uncertainties and contingencies because they relate to events and depend on circumstances that may or may not occur in the future and may cause the actual results, performance or achievements to be materially different from those expressed or implied by such forward-looking statements. These statements are not guarantees of future performance or the ability to identify and consummate investments. Many of these risks and uncertainties relate to factors that are beyond Poolbeg's ability to control or estimate precisely, such as future market conditions, currency fluctuations, the behaviour of other market participants, the outcome of clinical trials, the actions of regulators and other factors such as Poolbeg's ability to obtain financing, changes in the political, social and regulatory framework in which Poolbeg operates or in economic, technological or consumer trends or conditions. Past performance should not be taken as an indication or guarantee of future results, and no representation or warranty, express or implied, is made regarding future performance. No person is under any obligation to update or keep current the information contained in this announcement or to provide the recipient of it with access to any additional relevant information.



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