



Poolbeg Pharma plc

Peer-Reviewed POLB 001 LPS Challenge Trial Paper Published in *Frontiers in Immunology*

28 January 2026- **Poolbeg Pharma** (AIM: POLB, 'Poolbeg' or the 'Company'), a clinical-stage biopharmaceutical company with a core focus on transforming the cancer immunotherapy field, announces the publication of a peer-reviewed paper from the POLB 001 LPS human challenge trial in *Frontiers in Immunology*. Key conclusions from the paper include:

- POLB 001 significantly reduced key inflammatory biomarkers and immune cell recruitment following LPS challenge in healthy volunteers
- POLB 001 was safe and well tolerated across all dose levels
- Study confirms POLB 001 potently inhibits p38 MAPK driven cytokine responses
- Publication endorses significant potential of POLB 001 with the interim data anticipated from the [TOPICAL trial](#) this summer

The paper entitled, "*POLB 001, a p38 MAPK inhibitor, decreases local and systemic inflammatory responses following in vivo LPS administration in healthy volunteers: a randomised, double-blind, placebo-controlled study*" by Digna T. de Bruin, et al is available in [Frontiers in Immunology](#), DOI: <https://doi.org/10.3389/fimmu.2025.1684307>

The bacterial lipopolysaccharide ("LPS") challenge trial was a randomised, double-blind, placebo-controlled study, examining POLB 001's ability to suppress both local and systematic inflammatory responses in healthy volunteers. Key findings include:

- The suppression of immune cell recruitment was most pronounced in neutrophils (72.4%-81.5%, p = 0.0091), classical monocytes (68.4%-73.6%, p = 0.0036), CD3+ T cells (56.4%-65.9%, p = 0.0047), and myeloid dendritic cells (59%-64.4%, p = 0.0174).
- The suppression of cytokine responses was most pronounced for TNF (35.3%-65.1%, p = 0.0099).
- Overall, POLB 001 did not substantially modulate the intradermal LPS-driven increase in local erythema and perfusion.
- POLB 001 significantly reduced the IV LPS-driven increase in IL-6, IL-8, and TNF (37.7%-80.7%, all p < 0.0003), p38 MAPK phosphorylation levels in target cells (16.7%-60.9%, all p < 0.0001), and heart rate increase (4-9.3 bpm, p < 0.0001).

As [previously announced](#), the trial demonstrated that POLB 001 was safe and well-tolerated, with a clear dose-response relationship, inhibition of p38 MAPK activation, and reduction in all measured pro-inflammatory cytokines. The results agree with previous observations that POLB 001 has the potential to prevent an excessive immune response without ablating normal immune function.

The findings provide strong validation of POLB 001's method of action and supports its progression towards further clinical development. The publication further strengthens the rationale for POLB 001 as a potential solution for the prevention of cancer immunotherapy-induced Cytokine Release Syndrome ("CRS").

POLB 001 to prevent CRS

The Directors believe that POLB 001 has the potential to transform the cancer immunotherapy field by expanding administration from centralised specialist cancer centres into community hospitals by making the treatments safer through the prevention of CRS, a potentially life-threatening side effect. As such,

POLB 001 could make these treatments more accessible to a broader patient population, increase the number of patients that can receive these life-saving treatments, and reduce the burden on healthcare systems.

Jeremy Skillington, PhD, CEO of Poolbeg Pharma, said: *"The publication of peer-reviewed clinical data from our LPS challenge trial in *Frontiers in Immunology* is an important milestone for Poolbeg. The positive data from this trial highlights that oral treatment of POLB 001 holds great promise in addressing cancer immunotherapy-induced CRS and supports further clinical development of the asset, including the POLB 001 TOPICAL clinical trial."*

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About Poolbeg Pharma plc

Poolbeg Pharma plc (AIM: POLB) is a clinical-stage biopharmaceutical company with a core focus on transforming the cancer immunotherapy field. The Company's lead asset, POLB 001, has the potential to expand administration of cancer immunotherapies from centralised specialist cancer centres into community hospitals by making the treatments safer through the prevention of the life-threatening side effect, Cytokine Release Syndrome (CRS). As such, POLB 001 could increase the number of patients that can receive these life-saving treatments, thereby increasing the market opportunity. Poolbeg is also advancing the development of a patient-friendly therapy for obesity with an oral encapsulated GLP-1, offering a differentiated approach within one of the world's largest markets. With multiple near-term clinical value inflection points, and an experienced team with a proven track record, Poolbeg is focussed on partnering its high value programmes that are targeting large markets and addressing critical unmet medical needs.

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