

Poolbeg Pharma plc

Independent Research Confirms >\$10bn Market Opportunity for POLB 001 as a Preventative Therapy for Cancer Immunotherapy-Induced Cytokine Release Syndrome (CRS)

Former Amryt team's arrival supports increasing focus upon Rare and Orphan Diseases

12 February 2024 - [Poolbeg Pharma](#) (AIM: POLB, OTCQB: POLBF, 'Poolbeg' or the 'Company') a biopharmaceutical company focused on the development and commercialisation of innovative medicines targeting diseases with a high unmet medical need, today announces that independent research^[i] ^[ii] conducted on behalf of Poolbeg confirms a >\$10 billion market opportunity for POLB 001 in Cancer Immunotherapy-Induced CRS as an orally delivered preventative therapy. Cancer immunotherapies have been approved in rare and orphan blood cancers and so the Company can see potential for POLB 001 in one or more of these cancer types. POLB 001 in cancer immunotherapy-induced CRS will be developed alongside Poolbeg's existing portfolio of assets including its influenza programme; its AI drug discovery programmes; and oral delivery of GLP-1 for obesity and other metabolic diseases.

Rare and orphan diseases represent a significant value creation opportunity for the Company and its shareholders as they are underserved and there remains a substantial opportunity for innovative medicines to treat these severe and often chronic conditions. It is anticipated that acquiring and commercialising rare and orphan drugs could potentially lead to attractive revenue generation opportunities. Poolbeg will draw on the expertise of the wider team, including the individuals of the former Amryt team, who have a proven track record of successfully building and commercialising orphan drugs. Regulatory authorities offer incentives to companies developing orphan drugs, such as reduced filing fees, tax breaks and market exclusivity post approval and the Company Directors believe that Poolbeg is well positioned to benefit from these opportunities.

The Company also announced further detail on the significant market opportunity for POLB 001 CRS induced by CAR-T and bispecific antibody treatments (BsAb), where CRS can affect the majority of patients and can lead to extended hospital stays, discontinuation of treatment and mortality risk. There are currently few approved therapies for the management of acute CRS and no preventative therapies indicated for CRS.

The size and attractiveness of this market has encouraged the Company, as the field of cancer immunotherapies, including CAR-T and BsAb, is burgeoning and is expected to grow to US\$100bn - US\$140bn^[iii] by 2030. CRS occurs in the majority of CAR-T and BsAb treatments frequently impacting >70%^[iv] of patients and cannot be predicted. All grades of CRS can lead to extended hospital stays, causing an estimated US\$5.5bn^[v] of hospitalisation costs to healthcare systems, and further indirect costs through patient treatment and follow up.

An effective oral preventative therapy for cancer immunotherapy-induced CRS has the potential to significantly reduce direct costs in the healthcare system and improve patient access to these therapeutics, potentially including access to these therapies outside of specialist centres, while further augmenting wider market uptake.

Poolbeg recently announced promising in vivo results for POLB 001 in addressing cancer immunotherapy-induced CRS, where CRS clinical symptoms were significantly improved by administration of POLB 001. Dose dependent reductions were seen in all serum proinflammatory cytokines measured.

Jeremy Skillington, Chief Executive Officer, Poolbeg Pharma plc said: "Rare and Orphan disease medicines fit Poolbeg's efficient capital model particularly well. Clinical development is typically more cost efficient and the market opportunity remains high because of the high unmet medical need. There is also a very active M&A

market opportunity remains high because of the high unmet medical need. There is also a very active M&A market in this sector which Amryt took advantage of. We see this strategic approach as highly complementary to our existing programmes. The former Amryt team that have joined Poolbeg have an exceptional track record, have hit the ground running and are aligned with our vision of rapidly generating revenues and creating value for shareholders."

Enquiries

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About Poolbeg Pharma

Poolbeg Pharma plc is committed to the development and commercialisation of innovative medicines targeting diseases with a high unmet medical need. Its model focusses upon developing its exciting clinical assets and commercialising approved and marketed drugs to fund the development of its robust pipeline of innovative products, thereby driving significant value creation.

Poolbeg is led by an experienced leadership team with a history of delivering significant shareholder value. The team has been strengthened by the appointment of three former members of the Amryt Pharma plc leadership team, with the intention of repeating Amryt's success and generating near term revenues.

Poolbeg's clinical programmes target large addressable markets including cancer immunotherapy-induced CRS, infectious disease, and metabolic conditions such as obesity with the development of an oral GLP-1R agonist. It uses a cost-effective development philosophy to generate high quality human data to support partnering and further development. Its AI-led infectious disease programmes analyse unique data from human challenge trials to identify clinically relevant drug targets and treatments, leading to faster development and greater commercial appeal.

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.

[i] Grand View Research. CAR T-Cell Therapy Market Analysis 2023-2030; Bispecific Antibodies Market Size, Share & Trends Analysis Report.

[ii] Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023.

[iii] Grand View Research. CAR T-Cell Therapy Market Analysis 2023-2030; Bispecific Antibodies Market Size, Share & Trends Analysis Report.

[iv] Average rate from Summary of Product Characteristics (SmPCs) for Yescarta, Tecartus, Abecma, Kymriah, Carvykti, Breyanzi, Elrexfio, Columvi, Epkinly, Tecvayli and Talvey

[v] Adapted from 1. Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023 2. Abramson JS et al. Cytokine release syndrome and neurological event costs in lisocabtagene maraleucel-treated patients in the TRANSCEND NHL 001 trial. Blood Adv. 2021 Mar 23;5(6):1695-1705.

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