

8th January 2025

Physiomics plc
("Physiomics" or the "Company")

Clinical Trial Approval

Physiomics plc (AIM: PYC), a leading mathematical modelling, data science and biostatistics company supporting the development of new therapeutics and personalised medicine solutions, is delighted to announce that the Innovate UK Funded project called PREDICT-ONC has now received both regulatory and ethical approval.

The Company's personalised dosing software has been developed primarily with grant funding from UK bodies, including £68,000 from Innovate UK (March 2018), £150,000 from the National Institute for Health and Care Research to fund the PARTNER study (March 2020) and more recently £137,376 from Innovate UK and The Office for Life Sciences to fund the PREDICT-ONC study (announced in November 2023).

The software was initially developed to support clinicians make cancer chemotherapy (docetaxel) dosing decisions, helping to optimise dosing for individual patients to improve patient outcomes. However, as a result of the PARTNER study (completed in January 2023), a second utility was observed, in that the software could be used to support the dosing of an expensive biological drug G-CSF. This drug is routinely used in many countries to counteract the toxic effect chemotherapy has on patient's white blood cells - a condition known as neutropenia.

The aim of this latest Innovate UK funded grant, "Precision Risk Evaluation and G-CSF Dosing for Chemotherapy-Induced Neutropenia Tool", known as PREDICT-ONC ("Project"), is to further develop and evaluate the software's ability to predict G-CSF dosing. The Project, being run in partnership with Beyond Blood Diagnostics Limited ("Beyond Blood Diagnostics") and Blackpool Teaching Hospitals NHS Foundation Trust ("Blackpool Teaching Hospitals") will recruit breast cancer patients undergoing standard of care G-CSF treatment onto an observational clinical trial in order to predict and measure the effect treatment has on neutropenia. The data resulting from this trial will support the refinement and evaluation of the software.

Although, due to reasons outside of our control, the approval for the PREDICT-ONC observational trial has been somewhat delayed from the initial target of summer 2024, the project team believes that recruitment can start imminently and the overall impact on completion timelines will be kept to the minimum (projected for Oct-Dec 2025).

Dr Peter Sargent, CEO, commented: *"Physiomics and our partners are thrilled to have now obtained approval to proceed with the PREDICT-ONC observational trial. We had initially planned to start this trial last summer, but due to delays in the approval process that were out of our hands, approval has only now been obtained. However, due to the hard work of the project team, including recruitment of a research nurse and proactive identification of potential patients, we predict that these delays will have minimal impact on the overall timelines and final readout of the project. We at Physiomics are excited to start receiving the data generated from this trial, so we can continue development of our Personalised Dosing Software".*

Enquiries:**Physiomics plc**

Dr Peter Sargent, CEO

+44 (0)1235 841575

Hybridan LLP (Broker)

Claire Louise Noyce

+44 (0) 203 764 2341

Strand Hanson Ltd (NOMAD)

James Dance & James Bellman

+44 (0)20 7409 3494

Notes to Editor**About Physiomics**

Physiomics plc combines expertise across Modelling & Simulation, Biostatistics, Data Science and Bioinformatics, together with deep biology expertise, to help biotech and pharma companies streamline their drug development journeys. Our approach is to help derive insight from all relevant and often disparate data in order to de-risk decision making and optimise research design across discovery, pre-clinical and clinical studies. Through use of cutting-edge computational tools, bespoke models and our proprietary Virtual Tumour technology, the Physiomics team has informed the development of over 100 commercial projects, with over 125 targets and drugs modelled. Clients include Merck KGaA, Astellas, Bicycle Therapeutics, Numab Therapeutics & CRUK.

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