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

Completion of PARTNER study

Physiomics plc (AIM: PYC), the oncology consultancy using mathematical models to support the development of cancer treatment regimens and personalised medicine solutions, is pleased to announce the successful completion of its PARTNER study which was funded by a £150k "Connect" award from the National Institute for Health Research ("NIHR") Invention for Innovation ("i4i") programme (originally announced in March 2020).

HIGHLIGHTS

- The NIHR funded PARTNER study builds on work completed under two previous grants
- PARTNER data is being used to support development of a personalised dosing tool for docetaxel in prostate cancer
- Analysis of trial data confirms the ability of the tool to predict levels and timing of episodes of low white blood cell count associated with use of docetaxel
- Trial data further suggests there is potential for the tool to be used to predict the effect of GCSF (granulocyte-colony stimulating factor), a drug commonly used to increase white blood cell count during chemotherapy
- The tool would be highly synergistic with a device that can measure blood cells counts in community or out-patient settings and this will be further explored by Physiomics during the current quarter
- Further work is merited to explore the use of the tool in other settings including haematology and paediatrics

BACKGROUND

The project award, formally titled "Further development of and evidence generation for a precision dosing tool for optimising chemotherapy dosing in advanced prostate cancer" built on work carried out under two previous Innovate UK grants to the Company in 2017 and 2018. Published literature confirms that following the same administered dose, 2-3 fold variations in blood levels of docetaxel have been observed between individuals(1), potentially leading to a significant number of patients receiving either less or more of the drug than intended. Titrating dosing to the level of drug in the blood has been shown to significantly improve patient survival(2) and toxicity(3) in certain chemotherapy treatments. However, such precision-dosing techniques typically require costly additional tests, which restrict their use in clinical practice.

THE PARTNER STUDY

The majority of the i4i award was used to fund "PARTNER", an observational trial run by the Portsmouth Technology Trials Unit ("PTTU"). PTTU is a collaboration between Portsmouth Hospitals University NHS Trust and the University of Portsmouth, specialising in clinical trials in new healthcare technologies. The trial did not directly involve the use of the tool itself, but focused on collecting key data from prostate cancer patients treated with docetaxel to validate our personalised dosing tool, and in particular to:

- Confirm the ability of the tool to predict levels and timing of episodes of low white blood cells ("neutropaenia") associated with the use of chemotherapy and which can lead to serious side effects for patients
- Explore the tool's potential to predict the effect of GCSF, a class of drugs commonly used to counteract neutropaenia associated with chemotherapy

Ethics committee and Health Research Authority (HRA) approval for the study was received in December 2020, however, due to delays caused by the COVID pandemic, the first patient was not recruited until September 2021 and recruitment was therefore extended until September 2022. At the close of the study, 32 patients had been recruited which was fewer than originally targeted, nonetheless, the quality of the data was excellent and, in our view, sufficient for the purposes noted above.

KEY INSIGHTS GAINED

An initial analysis of the data from the PARTNER study has been completed. For each patient, data from their first three-week cycle of docetaxel treatment was used to build a personalised dosing model. This model was then used to predict the same patient's level of neutropenia during their second cycle of treatment and this prediction was compared with actual study data. The model successfully captured both the extent and the timing of neutropaenia and hence could form the basis of a tool to help clinicians make dosing decisions in this disease and, potentially, other cancers where neutropenia is a feature of treatment. This may help clinicians avoid unwanted toxicities and ensure that maximum benefit is obtained by individual patients.

In addition, although the model was not originally designed to capture the effects of GCSF, a modified version of the model was used in the same way described above to predict the levels of neutropenia experienced by patients treated with this drug alongside docetaxel. It was pleasing to note that while predictions were not fully consistent with the observed value, there appeared to be real potential for the model to be used in this alternative setting. This is important as, by contrast with docetaxel which is cheap and available in a generic (non-branded) form, GCSF is an expensive biological product. A model that could inform its use could potentially be of commercial value.

One of the practical challenges of implementing the dosing tool specifically for docetaxel in prostate cancer is the need for patients to come in for 2-3 additional blood tests during their first cycle of treatment to generate the data needed to develop their personalised dosing model. A means of easily conducting these tests at home or in a community setting ("point of care"), might significantly enhance the potential value of the tool.

NEXT STEPS

There are multiple ways in which the results of the PARTNER study can be leveraged:

- Academic dissemination; the insights gained from the PARTNER study will form the basis of several posters and/or publications
- The exploring of solutions for point of care blood testing that could address the limitation noted above. Physiomics has already identified a number of technologies in development that could be the basis for a hardware/ software collaboration
- Exploring other applications of the tool in settings where regular attendance at hospital for additional tests is not an obstacle because it is already required as part of current standard of care or because the use of the drug requires careful monitoring; examples could include:
    - Paediatric applications where it is important to maintain certain cell types within strict limits
    - Patients with haematological malignancies
    - Patients undergoing chemotherapy in combination with radiotherapy

Dr Jim Millen, CEO commented: "*I believe that the PARTNER study, as the culmination of several years of grant funded work, offers a significant opportunity for Physiomics to engage in the emerging personalised dosing space, either alone or in partnership with other complementary technologies. We'll be actively following up the areas noted above and will provide an update to shareholders before the end of Q1 2023.*"

(1) McLeod, H.L et al, 1998. Evaluation of the linearity of docetaxel pharmacokinetics. Cancer chemotherapy and pharmacology, 42(2), pp.155-159.

(2) Fang, Luo, et al. Pharmacokinetically guided algorithm of 5-fluorouracil dosing, a reliable strategy of precision chemotherapy for solid tumors: a meta-analysis. Scientific reports 6 (2016): 25913.

(3) Hénin, Emilie, et al. Revisiting dosing regimen using PK/PD modeling: the MODEL1 phase I/II trial of docetaxel plus epirubicin in metastatic breast cancer patients. Breast cancer research and treatment 156.2 (2016): 331-341.

This announcement is released by Physiomics plc and contains inside information for the purposes of Article 7 of the Market Abuse Regulation (EU) 596/2014 (MAR), and is disclosed in accordance with the Company's obligations under Article 17 of MAR.

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Notes to Editor

About Physiomics

Physiomics plc (AIM: PYC) is an oncology consultancy using mathematical models to support the development of cancer treatment regimens and personalised medicine solutions. The Company's Virtual Tumour™ technology uses computer modelling to predict the effects of cancer drugs and treatments to improve the success rate of drug discovery and development projects while reducing time and cost. The predictive capability of Physiomics' technologies have been confirmed by over 80 projects, involving over 40 targets and 70 drugs, and has worked with clients such as Merck KGaA, Astellas, Merck & Co and Bicycle Therapeutics.

About NIHR

The mission of the NIHR is to improve the health and wealth of the nation through research. We do this by:

- Funding high quality, timely research that benefits the NHS, public health and social care;
- Investing in world-class expertise, facilities and a skilled delivery workforce to translate discoveries into improved treatments and services;
- Partnering with patients, service users, carers and communities, improving the relevance, quality and impact of our research;
- Attracting, training and supporting the best researchers to tackle complex health and social care challenges;
- Collaborating with other public funders, charities and industry to help shape a cohesive and globally competitive research system;
- Funding applied global health research and training to meet the needs of the poorest people in low and middle income countries.

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