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Oxford BioDynamics Plc

Peer-reviewed study results confirm and expand validation of Oxford BioDynamics' EpiSwitch® CiRT blood test for checkpoint inhibitor immunotherapies

- *Publication in high-impact journal Cancers describes the development and validation of OBD's EpiSwitch CiRT blood test for predicting individual cancer patient's therapeutic response to checkpoint inhibitor immunotherapies*
- *Results of the peer-reviewed studies document the expanded validation of CiRT to five widely used checkpoint inhibitors across 280 patients and 14+ broad oncological indications*
- *The first-in-class liquid biopsy test demonstrated high accuracy (85%), sensitivity (93%), specificity (82%) to aid physicians in identifying responders*
- *CiRT continues to post record monthly orders in the US and is available to physicians at* mycirt.com

Oxford, UK - 15 May, 2023 - Oxford BioDynamics, Plc (AIM: OBD, the Company), a biotechnology company developing precision medicine tests based on the EpiSwitch® 3D genomics platform, announces the publication in the journal *Cancers* of an expanded validation supporting the use of its EpiSwitch CiRT (Checkpoint inhibitor Response Test) test across the majority of widely used anti-PD-1/L1 checkpoint inhibitor monotherapies.

OBD's EpiSwitch CiRTis a first-of-its-kind blood test that predicts an individual cancer patient's therapeutic response to immune checkpoint inhibitors (ICIs), providing unique benefits for physicians in treatment planning and navigating complex decisions [1]. Despite pre-screening with currently approved tests, such as tumor PD-L1 expression, typically only 1 in 5 patients see an overall anti-cancer benefit to costly ICIs for most cancers, and many face one or more adverse events [2].

In this peer-reviewed study, prospective clinical trials representing 280 treatments with ICIs were used to develop, verify and validate a predictive assay comprising the eight 3D genomic biomarkers used in CiRT. The blood-based biomarker assay achieved high accuracy (85%), sensitivity (93%), specificity (82%), and NPV (97% *negative predictive value*) across 14+ broad oncological indications, including melanoma, head and neck, lung, pancreas, prostate, liver, colon and breast cancer [3].

The work builds on an earlier study published as a preprint in *medRxiv* [4]. The validation results were extended to a total of 280 samples, using an additional collection exclusively from an observational trial [3]. All of the observational samples were evaluated with the EpiSwitch predictive biomarkers against a clinical response assessment (using standard *RECIST 1.1* guidelines) performed for the same cycle of treatment as the sample collection. Together, all the results expand CiRT utility to five of the most widely used checkpoint inhibitor therapies: *Pembrolizumab, Atezolizumab, Durvalumab, Nivolumab* and *Avelumab*.

The study demonstrates strong biomarker potential for systemic readouts for the most challenging patient stratification problems - prediction of response to cancer treatments. With these published results, the power of liquid biopsy, as harnessed by the EpiSwitch 3D genomic platform, opens real possibilities in personalized patient care, patient management and medical practice.

The publication, titled "*Development and validation of blood-based predictive biomarkers for response to PD-1/PD-L1 checkpoint inhibitors: evidence of a universal systemic core of 3D immunogenetic profiling across multiple oncological indications,*" [3] is available online in *Cancers* here.

The study also shares important insights into the biological relationship between 3D genomic architecture, exosome signaling and biological mechanisms underlying systemic flow of epigenetic synchronization that links a blood-based readout of 3D genomic biomarkers with features of the tumor microenvironment.

The publication was a collaboration between OBD, Mount Miriam Cancer Hospital (MMCH) and Island Hospital, Malaysia, and the University of East Anglia, and was partly supported by one of two concurrent awards granted to OBD by the Foundation for the National Institutes of Health (FNIH) Partnership for Accelerating Cancer Therapies (PACT) 2021 [5] & 2023 award [6]). PACT is a collaboration between the US National Institutes of Health (NIH) National Cancer Institute (NCI), US Food and Drug Administration (US-FDA), and 12 leading pharmaceutical companies.

Launched in February 2022, the CiRT blood test continues to gain traction in the US, posting record monthly orders in March [7] and April 2023. EpiSwitch CiRT was launched in the US in February 2022 and made available in the UK in June 2022. A unique CPT PLA reimbursement code for the test has been available for use by US payors since October 2022.

Dr Alexandre Akoulitchev, Chief Scientific Officer of Oxford BioDynamics, said: *"This study publication is an important validation of the expanded use of CiRT to five widely used checkpoint inhibitors, demonstrating the potential for this test to help more cancer patients.*

"Personalised liquid biopsy tests promise to change the future of medical practice. Most of those technologies remain in the development stage. With the EpiSwitch CiRT test, we are delighted to have already brought it to physicians and their patients without delay. We are also determined to bring with it changes in medical practice, to the mutual benefits of patients' and doctors' communities."

Dr Joseph Menetski, Senior Vice President and Chief Translational Sciences Officer of the FNIH, said: *"The Foundation for the NIH is pleased to see the results from Oxford BioDynamics' PACT Novel Biomarker Award. It brings the field a more accurate and deployable test for predicting responses to immune-oncology interventions. By developing tools for personalized care like CiRT, we can connect patients to the right treatment for them and truly build bridges to innovative new therapies."*

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References

[1] Oxford BioDynamics Plc. (2022). *EpiSwitch CiRT.* https://www.mycirt.com
[2] Zhao, B.; Zhao, H.; Zhao, J. (2020). Efficacy of PD-1/PD-L1 blockade monotherapy in clinical trials, *Therapeutic Advances in Medical Oncology*, Vol. 12. https://doi.org/10.1177/1758835920937612
[3] Hunter, E., et al. (2023). *Development and validation of blood-based predictive biomarkers for response to PD-1/PD-L1 checkpoint inhibitors: evidence of a universal systemic core of 3D immunogenetic profiling across multiple oncological indications,* Cancers 15(10), 2696. https://www.mdpi.com/2072-6694/15/10/2696
[4] Hunter, E., et al. (2021). *Development and validation of blood-based predictive biomarkers for response to PD-(L)-1 checkpoint inhibitors: evidence of a universal systemic core of 3D immunogenetic profiling across multiple oncological indications.* MedRxiv, 2021.12.21.21268094. https://doi.org/10.1101/2021.12.21.21268094
[5] Oxford BioDynamics Plc. (2021). *Oxford BioDynamics awarded US FNIH Grant to apply EpiSwitch® Immune Health test for improved prediction of patient response to Immune Checkpoint Inhibitor (ICI) cancer therapies.* https://otp.tools.investis.com/clients/uk/oxford_biodynamics_plc/rns/regulatory-story.aspx?cid=2040&newsid=1503717
[6] Oxford BioDynamics Plc. (2023). *Oxford Biodynamics granted US Foundation of NIH PACT Award for prognosis of cancer patients with IO-triggered Hyper-Progressive Disease.* *https://otp.tools.investis.com/clients/uk/oxford_biodynamics_plc/rns/regulatory-story.aspx?cid=2040&newsid=1684666*
[7] Oxford BioDynamics Plc. (2023). *Business update - plan to launch Prostate Screening EpiSwitch® test by end of 2023; sales progress for flagship EpiSwitch® CiRT.* https://otp.tools.investis.com/clients/uk/oxford_biodynamics_plc/rns/regulatory-story.aspx?cid=2040&newsid=1679474

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About Oxford BioDynamics Plc
Oxford BioDynamics Plc (AIM: OBD) is a global biotechnology company, advancing personalized healthcare by developing and commercializing precision medicine tests for life-changing diseases.

Its flagship product is EpiSwitch® CiRT (Checkpoint Inhibitor Response Test) for cancer, a predictive immune response profile for immuno-oncology (IO) checkpoint inhibitor treatments, launched in February 2022.

In March 2021, the Company launched its first commercial prognostic test, EpiSwitch® CST (Covid Severity Test) and the first commercially available microarray kit for high-resolution 3D genome profiling and biomarker discovery, EpiSwitch® Explorer Array Kit.

The Company has developed a proprietary 3D genomic biomarker platform, EpiSwitch®, which can build molecular diagnostic classifiers for prediction of response to therapy, patient prognosis, disease diagnosis and subtyping, and residual disease monitoring in a wide range of indications.

Oxford BioDynamics has participated in more than 40 partnerships with big pharma and leading institutions including Pfizer, EMD Serono, Genentech, Roche, Biogen, Mayo Clinic, Massachusetts General Hospital and Mitsubishi Tanabe Pharma.

The Company has created a valuable technology portfolio, including biomarker arrays, molecular diagnostic tests, bioinformatic tools for 3D genomics and an expertly curated 3D genome knowledgebase comprising hundreds of millions of data points from over 10,000 samples in more than 30 human diseases.

OBD is headquartered in Oxford, UK and is listed on AIM of the London Stock Exchange. It also has a commercial office in Gaithersburg, MD, USA and a reference laboratory in Penang, Malaysia.

For more information, please visit the Company's website, www.oxfordbiodynamics.com, or follow OBD on Twitter (@OxBioDynamics) and LinkedIn.

About EpiSwitch®
The 3D configuration of the genome plays a crucial role in gene regulation. By mapping this architecture and identifying abnormal configurations, EpiSwitch® can be used to diagnose patients or determine how individuals might respond to a disease or treatment.

Built on over 10 years of research, EpiSwitch® is Oxford Biodynamics' award-winning, proprietary platform that enables screening, evaluation, validation and monitoring of 3D genomic biomarkers. The technology is fully developed, based on testing of over 10,000 samples in 30 disease areas, and reduced to practice.

In addition to stratifying patients with respect to anticipated clinical outcomes, EpiSwitch® data offer insights into systems biology and the physiological manifestation of disease that are beyond the scope of other molecular modalities. The technology has performed well in academic medical research settings and has been validated through its integration in biomarker discovery and clinical development with big pharma.

About the Partnership for Accelerating Cancer Therapies
The Partnership for Accelerating Cancer Therapies, or PACT, is a five-year project meant to support research that seeks to identify, develop and validate robust biomarkers - standardized biological markers of disease and treatment response - to advance new immunotherapy treatments that harness the immune system to attack cancer. PACT is overseen by the Foundation for the National Institutes of Health. The pharmaceutical companies participating that have made this grant award possible are: AbbVie, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene Corporation, Genentech, Gilead, GlaxoSmithKline, Janssen/Johnson & Johnson, Novartis, and Pfizer.

About The Foundation for the National Institutes of Health
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