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Oxford BioDynamics
("**OBD**" or the "**Company**" and, together with its subsidiaries, the "**Group**")

EpiSwitch® Prostate Screening (PSE) Blood Test to be used in correlative studies of NCI Trial for Prospective Monitoring of Biochemically Recurrent Prostate Cancer

- FDA registered trial (NCT05588128) organized and sponsored by the National Cancer Institute (NCI), part of the US National Institutes of Health
- Patients will be monitored over 5 years with regular blood collections and prostate specific membrane antigen (PSMA) PET scans
- EpiSwitch® Prostate Screening (PSE) test to be used in correlative studies of the clinical trial to investigate early markers of prostate cancer progression

Oxford, UK - 6 June 2024 - Oxford BioDynamics, Plc (AIM: OBD, the Company), a biotechnology company developing precision medicine tests based on the EpiSwitch® 3D genomics platform, announces that its EpiSwitch® Prostate Screening (PSE) test will be utilized in correlative studies of a clinical trial,NCT05588128, organized and sponsored by the National Cancer Institute (NCI) of the National Institutes of Health, (Bethesda, MD, USA), to regularly monitor prostate cancer in patients with biochemically recurrent disease.

Prostate cancer is the most common malignancy and the second leading cause of cancer-related deaths in American men. Each year in the US up to 50,000 men whose early-stage cancer was treated, e.g. via definitive radiation or surgery, unfortunately experience biochemical recurrence (BCR). At this biochemically recurrent stage however, standard imaging techniques, such as computed tomography (CT) and Tc99 bone scan, are often unable to detect the disease.

One goal of the NCI clinical trial is to identify techniques, tools, and biomarkers which can predict outcomes in patients with BCR. As part of this clinical trial, NCI will follow ~250 patients with biochemically recurrent prostate cancer for up to five years monitoring changes on prostate specific membrane antigen (PSMA) PET imaging, collecting blood samples every three months, as well as conducting annual or biannual bone or CT scans of the chest, abdomen, and pelvis. The EpiSwitch® PSE test is one such tool being evaluated and is being utilized in correlative studies under this clinical trial to investigate early markers of prostate cancer progression.

"OBD's novel blood-based PSE test will be investigated while monitoring patients in our prospective five-year trial with PSMA-PET recurrent prostate cancer," said **Dr Ravi Madan, M.D., the trial lead.** *"The multi-institutional PROSTAGRAM trial by OBD, Imperial College London, the University of East Anglia, and Imperial College NHS Trust, highlighted the potential role of the PSE test in supporting us in reaching the objectives of our new trial - to help us explore the complex dynamics of recurrent prostate cancer and investigate how best to monitor it using all available tools."*

OBD and NCI are collaborating on the evaluation of samples and data collected from NCI's clinical trial using the EpiSwitch® PSE test under a material transfer agreement (MTA).

"We are delighted that we have been chosen to be part of this important and far-reaching NCI trial," said **Thomas Guiel, COO, OBD.***"This natural history study will allow all parties to study the evolution of recurrent prostate cancer and validate new tools for managing patient care. We are pleased at how quickly the utility of the PSE test has been recognized by prestigious research organisations such as the NCI, with an eye to expanding the application of our test into cancer monitoring applications."*

For Patients Interested in Enrolling in NCT05588128:

For more information on this clinical trial, please call NCI's toll-free number 1-800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615), visit the website https://trials.cancer.gov, and/or email NCIMO_referrals@mail.nih.gov .

References

1. *Chromatin conformation changes in peripheral blood can detect prostate cancer and stratify disease risk groups.* Alshaker *H, Mills R, Hunter E, Salter M, Ramadass A, Skinner BM, Westra W, Green J, Akoulitchev A, Winkler M, Pchejetski D. J Transl Med. 2021 Jan 28;19(1):46. doi: 10.1186/s12967-021-02710-y.*

2. *Circulating Chromosome Conformation Signatures Significantly Enhance PSA Positive Predicting Value and Overall Accuracy for Prostate Cancer Detection.Pchejetski D, Hunter E, Dezfouli M, Salter M, Powell R, Green J, Naithani T, Koutsothanasi C, Alshaker H, Jaipuria J, Connor MJ, Eldred-Evans D, Fiorentino F, Ahmed H, Akoulitchev A, Winkler M. Cancers (Basel). 2023 Jan 29;15(3):821. doi: 10.3390/cancers15030821.*

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For further details please contact:

Oxford BioDynamics Plc +44 (0)1865 518910
Jon Burrows, CEO
Paul Stockdale, CFO

Shore Capital +44 (0)20 7408 4090
(Nominated Adviser and Broker to OBD)
Stephane Auton
Lucy Bowden

WG Partners +44 (0)20 3705 9330
(Joint Broker to OBD)
David Wilson / Claes Spång /
Sateesh Nadarajah / Erland Sternby

Instinctif Partners Tel: +44 (0)20 7457 2020
(Media / Analyst enquiries for OBD) OxfordBioDynamics@instinctif.com
Melanie Toyne-Sewell / Katie Duffell

Notes for Editors

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.

It has two commercially available products: the EpiSwitch® PSE (EpiSwitch Prostate Screening test) and EpiSwitch® CiRT (Checkpoint Inhibitor Response Test) blood tests. PSE is a blood test that boosts the predictive accuracy of a PSA test from 55% to 94% when testing the presence or absence of prostate cancer, launched in the US and UK in September 2023. CiRT is a predictive immune response profile for immuno-oncology (IO) checkpoint inhibitor treatments, launched in February 2022.

The Company's product portfolio is based on a proprietary 3D genomic biomarker platform, EpiSwitch®, which can build molecular diagnostic classifiers for the prediction of response to therapy, patient prognosis, disease diagnosis and subtyping, and residual disease monitoring, in a wide range of indications, including oncology, neurology, inflammation, hepatology and animal health.

In March 2021, the Company launched the first commercially available microarray kit for high-resolution 3D genome profiling and biomarker discovery, EpiSwitch® Explorer Array Kit which is available for purchase by the life science research community.

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 15,000 samples in more than 30 human diseases.

OBD's group headquarters and research, product development and UK clinical laboratories are in Oxford, UK. It also has a commercial office in Gaithersburg and a clinical laboratory in Frederick, MD, USA, and a reference laboratory in Penang, Malaysia.

The company is listed on the London Stock Exchange's AIM, with ticker OBD. For more information, please visit the Company's website, www.oxfordbiodynamics.com, or follow OBD onTwitter (@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 15,000 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.

EpiSwitch® Prostate Screening test (PSE)

The current PSA blood screening test is only 55% accurate and is considered as unreliable by many doctors, including the UK NHS[1]. The EpiSwitch® PSE test is the culmination of nearly ten years of collaboration between OBD, Imperial College London, University of East Anglia, Imperial College NHS Trust, and the UK's leading prostate cancer experts. The results of this multi-disciplinary PROSTAGRAM study were published in the peer-reviewed publication, *Cancers*[2] in February 2023.
The PSE test combines the PSA score with five additional proprietary epigenetic biomarkers, to predict, with 94% accuracy, the presence (or absence) of prostate cancer.[2] Those with a PSE result showing low likelihood of cancer can be placed on active surveillance and retested later without being referred for an invasive and often destructive biopsy. Meanwhile, a high likelihood result would necessitate referral to a Urologist for further investigation.

As well as very high accuracy, PSE has a high specificity, 97% (PSA: 53%), and sensitivity, 86% (PSA: 64%), as well as high positive, 93% (PSA: 25%), and high negative, 95% (PSA: 86%), predictive values to assess the risk of prostate cancer in men.[2] The PSE test has been validated as a laboratory developed test (LDT) in OBD's CLIA-certified testing laboratory in Frederick, Maryland.

For more information on OBD's PSE test, please visit: www.94percent.com.

References

1. *Chromatin conformation changes in peripheral blood can detect prostate cancer and stratify disease risk groups. J Transl Med. 2021 Jan 28;19(1):46. Alshaker H, Mills R, Hunter E, Salter M, Ramadass A, Skinner BM, Westra W, Green J, Akoulitchev A, Winkler M, Pchejetski D.*
2. *NHS Health A to Z. Prostate cancer: PSA testing (2021). https://www.nhs.uk/conditions/prostate-cancer/psa-testing*

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