# **Oxford BioDynamics Plc**

# Business update - plan to launch Prostate Screening EpiSwitch<sup>®</sup> test by end of 2023; sales progress for flagship EpiSwitch<sup>®</sup> CiRT

- Acceleration of final development and launch of PSE clinical test in both UK and US, for availability in Q4 2023
- Flagship EpiSwitch CiRT (Checkpoint inhibitor Response Test) continuing to gain traction in the US, posting record orders in November and December 2022, and January and March 2023
- Leased US lab space for own CLIA-certified LDT testing facility
- Commenced certification of clinical testing facility within existing Oxford base
- OBD will present both tests in a key note address at the 13<sup>th</sup> World Clinical Biomarker & Companion Diagnostics Europe Summit

**Oxford, UK - 5 April, 2023** - Oxford BioDynamics, Plc (AIM: OBD, "OBD" or the "Company" and, together with its subsidiaries, the "Group"), a biotechnology company developing precision medicine tests based on the EpiSwitch<sup>®</sup> 3D genomics platform, announces updates on its PSE and CiRT tests.

#### Prostate Screening EpiSwitch (PSE)

In order to meet demand and accelerate the delivery of the <u>Prostate Screening EpiSwitch (PSE) blood test</u> as announced by the Company on 6 February 2023, OBD has embarked on standing up clinical testing facilities in both the UK and US.

The Group first discussed PSE in its final results on 24 January 2023. Following the publication of the results involving OBD's technology in the multi-disciplinary NHS PROSTAGRAM study using blood to detect prostate cancer on 6 February 2023, there has been unprecedented levels of interest in and demand for access to the PSE test.

Final product development work on PSE is proceeding well and launch of the test in the US and the UK is now anticipated in the last calendar quarter of 2023. To support the planned launch, the Group has recently leased 7,800 sq ft of lab space in Frederick, Maryland, USA and commenced build-out of a dedicated clinical testing lab in its existing 24,000 sq ft facility in Oxford, UK. The facility in Frederick contains already-configured lab and office space into which the Group will transfer new and existing staff and equipment. In due course, the lab will be accredited by Maryland Dept of Health under the Clinical Laboratory Improvements Act (CLIA). The new Oxford, UK lab facility will offer the PSE test in an ISO15189 clinical laboratory.

#### EpiSwitch CiRT

OBD's EpiSwitch CiRT the first-of-its-kind blood test which predicts an individual patient's therapeutic response to checkpoint inhibitor immunotherapy, continues to gain traction in the US, posting record monthly orders in March 2023. EpiSwitch CiRT was launched in the US in February 2022 and made available to 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, meaning that the test can be paid for by health insurers.

The Group's sales and market access team has continued to generate positive growth in orders from US physicians. Uptake of the test is growing, through both new and repeat orders. It took 9 months from launch for the first 100 CiRT tests to be ordered; the 200-test milestone was achieved after just 4 more months with March 2023 setting another new record.

CiRT tests are processed by the Group's partner laboratory, Next Molecular Analytics, with typical turn-around-times of 3-4 days. Reimbursements from payors are being received at rates in the range anticipated by the Group, with several payors now routinely reimbursing in as little as 2-3 weeks from claim submission.

"It is encouraging to see OBD's EpiSwitch<sup>®</sup> CiRT being ordered and utilized more and more as early-adopter oncologists understand the power of knowing a patient's likely response to checkpoint inhibitor therapy in the continuum of their care," said **Dr Jon Burrows, OBD's Chief Executive Officer.**"The overwhelming response to the success of our PSE test in the clinical research assay in the PROSTAGRAM study has enforced the need for the Group to make every effort to bring this test to market as soon as practically possible."

#### References

[1] Feb RNS re:PSE

[2] Pchejetski, D., et al. (2023). Circulating Chromosome Conformation Signatures Significantly Enhance PSA Positive Predicting Value and Overall Accuracy for Prostate Cancer Detection. Cancers, 15(3), 821. <u>http://dx.doi.org/10.3390/cancers15030821</u>

[3] Oxford BioDynamics Plc. (2022). EpiSwitch CiRT. https://www.mycirt.com

[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.

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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 <u>EpiSwitch® CiRT</u> (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, <u>EpiSwitch® CST</u> (Covid Severity Test) and the first commercially available microarray kit for high-resolution 3D genome profiling and biomarker discovery, <u>EpiSwitch® Explorer Array Kit</u>.

The Company has developed a proprietary 3D genomic biomarker platform, EpiSwitch<sup>®</sup>, 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, <u>www.oxfordbiodynamics.com</u>, or follow on <u>Twitter</u> or <u>LinkedIn</u>.

#### 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<sup>®</sup> 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 outcome, EpiSwitch<sup>®</sup> 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.

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