Oxford BioDynamics

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

Oxford Biodynamics to present on its line of EpiSwitch® products for companion diagnostics in cancer immunotherapy at the 14th World Summit for Clinical Biomarkers and Companion Diagnostics in Boston, MA.

Oxford, UK - 25 July 2024- Oxford BioDynamics, Plc (AIM: OBD, the Company) a precision clinical diagnostics company bringing specific and sensitive tests to the practice of medicine based on the EpiSwitch® 3D genomics platform [1], announces its key-note presentation at the 14th World Summit for Clinical Biomarkers and Companion Diagnostics, taking place on 3-6 September 2024 in Boston, MA, USA.

Oxford BioDynamics will discuss the diagnostic, predictive and prognostic power of the EpiSwitch® platform as companion assays in a keynote presentation. The Company will cover:

- **EpiSwitch CiRT**, a highly accurate (85%) Immune-Oncology (IO) response test available today, predicts a patient's response to immune checkpoint inhibitor therapy, giving physicians a powerful tool for patient care management.

- PROWES (Prospective Real-World Evidence Study); an application of CiRT in an IRB-approved Registry Study currently enrolling up to 2,500 patients across up to a dozen oncology institutions, evaluating CiRT performance and demonstrating the clinical utility of the test.

- EpiSwitch® CiRT has been submitted to the New York State Department of Health Clinical Laboratory Evaluation Program (CLEP) for approval.

- **EpiSwitch® HiRT**, a prognostic test for IO-triggered Hyperprogressive Disease, is a new test being validated by OBD to address this most detrimental and life-threatening side effect of immunotherapy.

- Application of a **novel multiplexed Agilent® array platform** to deliver EpiSwitch® assays for early diagnosis and prevention of immune related adverse events (irAEs) which affect up to 70% of treated patients involving cutaneous, musculoskeletal, gastrointestinal, renal, nervous system, endocrine, hematologic and lung toxicities.

Oxford BioDynamics will present a keynote address at the 14th Annual World Summit for Clinical Biomarkers and Companion Diagnostics, a flagship meeting which takes place on September 3-6, 2024 in Boston, MA. OBD will discuss its products and pipelines of clinical assays aimed at enhancing the benefits of, and navigating the complexities of utilizing immunotherapy, by addressing low response rates and predicting side effects - from the life-threatening Hyper-Progressive Disease (manifested in c. 12% of treated patients) to the normally-anticipated immune related adverse events (affecting c. 70% of treated patients).

The EpiSwitch® Checkpoint Inhibitor Response Test (CiRT) is a first-in-class, blood-based, accurate predictor of response to immune checkpoint inhibitors (ICIs)[2-4]. The test is commercially available through clinical diagnostic labs in both the US and UK.

Today, EpiSwitch® CiRT is the focus of an observational registry study in US: PROWES is a national IRB-approved study of the concordance of CiRT response prediction to the clinically observed response rate. It will further document the clinical application and utility of the assay for the treatment of multiple oncological indications. PROWES is projected to onboard up to dozen oncology institutions and enroll up to 2,500 patients. The study is being run under commercial terms through the CLIA labs in the US.

Dr Kashyap Patel, Oncologist and CEO at Carolina Blood and Cancer Care Associates said *"Episwitch CiRT is the*

unique blood-based test that enables oncologists to identify patients with advanced cancer likely to respond to Immunotherapy. This is truly an unmet need and will likely improve outcomes, reduce toxicities and with prospective HEOR studies will establish cost improvements too.

OBD has recently applied for a New York Department of Health Clinical Laboratory Evaluation Program (CLEP) New York State (NYS) CLIA license and, working with its partner lab NeXT Molecular Analytics, has submitted EpiSwitch® CiRT for NYS DOH CLEP approval. NYS CLEP requires that both the lab and the assay performed meet the high standards expected for the care and management of medically vulnerable populations

The EpiSwitch® HiRT (Hyper-Immune Response Test), a unique prognostic blood test developed with support from the Partnership for Accelerating Cancer Therapies (PACT, USA), will demonstrate the application of EpiSwitch as an important companion for patient management. The test accurately predicts individuals who are most likely to exhibit IO-triggered Hyper-Progressive Disease (HPD), a response to immunotherapy which triggers life-threatening, disease-accelerating side effects. An average of 12% of ICI-treated patients exhibit HPD[5].

OBD will also introduce the EpiSwitch Data Knowledgebase, a database of greater than 1 billion data points and a suite of proprietary AI algorithms for *in silico* modelling of biomarkers and assays. Application of the knowledgebase will facilitate development of a multiplex assay for the early diagnosis of irAEs. OBD has already pioneered the application of its EpiSwitch platform and microarrays manufactured by Agilent Technologies, Inc to develop a multi-choice/multiplex array for the early diagnosis of multiple canine cancers (the EpiSwitch SCB test)[6]. Using a similar approach and test design, OBD will develop a multiplex Agilent array-based assay for prediction of the most prevalent side effects in immunotherapy: cutaneous toxicity (inflammatory dermatitis), musculoskeletal toxicities (inflammatory arthritis), gastrointestinal toxicities (hepatitis), renal toxicities nephritis), nervous system toxicity (peripheral neuropathy), endocrine toxicities (hypophysis and primary hypothyroidism), hematologic toxicities (haemolytic anemia) and lung toxicities (pneumonitis).

These new efforts follow on the successful development of prognostic and predictive biomarkers for prevention of rheumatoid arthritis in collaboration with Prof. Andrew Cope, Kings College, (APIPPRA trial)[7]. The EpiSwitch platform went beyond the boundaries of disease diagnosis with samples from the APIPPRA trial to prospectively identify patients who will respond, if treated prophylactically, in the presymptomatic stage of rheumatoid arthritis treatment with Abatacept thus minimizing or eliminating irAEs.

Dr Alexandre Akoulitchev, CSO at OBD said: *"Immunotherapy is bringing a revolution into the field of oncology. Today, as the field has matured and the real-world data provides us with better guidance on treatment utility, there is a strong consensus emerging in the application of immunotherapy that we need to do a better job on selecting biomarkers and developing strong assays. The highest priority questions lie with biomarker selection and the need for: 1) robust and accurate predictive biomarkers to help identify potential responders among the majority of non-responders; 2) prognostic biomarkers to identify patients most likely to suffer IO-triggered Hyper-Progressive Disease and protect them from harm, 3) diagnostic and prognostic biomarkers to help correctly identify and manage the multitude of irAEs. The value of such biomarker insights is recognized today by our industry partners, clinical oncology clients and government programmes, such as the Cancer Immunotherapy Response Research Platform (CIRRP) call from the Office for Life Sciences, UK. Without good biomarkers, the impact of side-effects and socio-economic aspects of the expensive immunotherapy treatments will outweigh the great benefits from the high efficacy that these new treatments can offer to the sub-group of responsive patients. EpiSwitch biomarkers have the potential to make a real difference in oncological practice. Early real-world evidence from today's US practice already attests to that".*

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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 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 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.

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