

***THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE PURPOSES OF ARTICLE 7 OF EU REGULATION 596/2014 (WHICH FORMS PART OF DOMESTIC UK LAW PURSUANT TO THE EUROPEAN UNION (WITHDRAWAL) ACT 2018 ("EUWA")) ("UK MAR")***

24 March 2025

**Cizzle Biotechnology Holdings plc**

("Cizzle", "Cizzle Biotechnology", or the "Company")

**First COLA and CLIA Accredited Laboratory in USA confirmed**

**Update on Launch of CIZ1B Biomarker Assay**

Cizzle Biotechnology, the UK based diagnostics developer of early cancer tests, is pleased to announce that its licensing partner Cizzle Bio Inc ("BIO" or "Cizzle Bio") has appointed iGenomeDX, a specialist clinical diagnostics laboratory to launch the Company's first commercial CIZ1B biomarker test in the USA. iGenomeDX is a Commission on Office Laboratory Accreditation ("COLA") accredited and Clinical Laboratory Improvement Amendments ("CLIA") certified clinical laboratory and has been establishing operating and quality systems ahead of offering the test to clinicians for the first time.

**Key Highlights**

- iGenomeDX appointed by BIO as first clinical diagnostics laboratory to offer commercial CIZ1B biomarker testing.
- This follows successful collaboration and support between Cizzle, iGenomeDX and BIO to complete an operational and quality systems programme designed to meet the exacting standards required in iGenomeDX's COLA accredited, CLIA certified laboratory, designated to validate CIZ1b as a laboratory developed test for commercial use ahead of the launch of the CIZ1B biomarker test.

**Background**

On 21 October 2024 the Company announced an exclusive licensing and partnership agreement with BIO for its proprietary CIZ1B biomarker test to help detect early-stage lung cancer, throughout the USA and Canada. The Company has since received payments of US 400,000 due from initial exclusivity fees and advanced royalties as part of guaranteed payments totalling US 2.4 million over the period ending April 2027. The Company has now extended that agreement, as announced on 16 December 2024, to cover the 14 Sovereign States of the Caribbean and the Cayman Islands ("Caribbean") triggering early payments totalling US 250,000 in July 2025 and US 250,000 in September 2025.

The appointment of iGenomeDX by BIO, a specialist clinical diagnostics laboratory, is the next step in the Company's plan to achieve commercial sales later this year by providing an accredited facility to launch the CIZ1B biomarker test. The accreditation process involved an evaluation of a laboratory's operations, including its testing procedures, quality control, personnel qualifications, and compliance with regulatory requirements. Labs that achieve COLA accreditation demonstrate a commitment to maintaining high standards of accuracy, reliability, and patient safety in diagnostic testing to ensure they meet CLIA standards and can legally operate.

The successful completion of the operational and quality systems programme is necessary for launching a cost-effective and scalable version of the CIZ1B biomarker assay with rigorous quality control requirements to meet expected reproducibility and sensitivity. This will demonstrate the test is commercially scalable and can be rolled out as a global solution to help reduce premature cancer deaths and improve survival rates and

can be rolled out as a global solution to help reduce premature cancer deaths and improve survival rates and quality of life for cancer patients.

**Commenting, Allan Syms, Executive Chairman of Cizzle Biotechnology, said:**

*"I am delighted to announce the positive progress being made by our partners Cizzle Bio who have appointed the first of their COLA and CLIA accredited clinical diagnostics laboratories to bring our CIZ1B Biomarker test for early-stage lung cancer to market. In the short time since we began our exclusive licensing partnership with Cizzle Bio, they have initiated multiple ongoing partnerships with several National Cancer Institute (NCI) designated cancer centres throughout the United States, with the goal of enhancing early detection capabilities for lung cancer. They have strengthened their leadership team with industry and clinical expertise and in creating the launchpad for our CIZ1B biomarker test. In collaboration with Cizzle Bio we continue to work closely with iGenomeDX's exceptional leadership and technical team to ensure a seamless transition of technology into the clinic. We look forward to sharing updates on their first commercially available tests in the near future."*

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**About Cizzle Biotechnology**

Based on the pioneering work of Professor Coverley and colleagues, on a naturally occurring variant of the cell nuclear protein CIZ1, the CIZ1B biomarker is highly associated with the presence of early-stage cancer. The company has developed CIZ1B into a non-invasive, cost-effective blood test to help in the early detection of lung cancer and has now entered commercial royalty-bearing arrangements to license its proprietary technology, and into collaborations with centres of excellence in cancer care. Cizzle was admitted to the Standard segment of the main market of the London Stock Exchange in May 2021.

For more information, please see <https://cizzlebiotechnology.com>

You can also follow the Company through its twitter account @CizzlePlc and on LinkedIn.

**About Cizzle Bio**

Cizzle Bio Inc, a company registered in Texas USA, stands at the forefront of biotechnological innovation, dedicated to revolutionizing the detection of lung cancer through groundbreaking diagnostic tools. With exclusive rights to detect the CIZ1B Biomarker in the USA and Canada, we are driven by a commitment to improve early cancer detection and enhance patient outcomes.

For more information, please see <https://cizzlebio.com>

**About iGenomeDX**

iGenomeDx is a COLA accredited and CLIA certified clinical diagnostics company based in San Antonio, Texas meeting U.S. federal standards that ensures quality and reliability in laboratory testing for human specimens. Their mission is to enhance physician decision-making, improve patient care, and reduce healthcare costs by providing reliable genetic testing services. iGenomeDx offers pharmacogenomic tests to help physicians personalize medication choices and dosages based on an individual's genetic makeup, as well as molecular diagnostics for infectious diseases such as respiratory, urinary tract, wound, and nail infections. They also provide therapeutic drug monitoring to assess medication adherence.

For more information, please see <https://igenomedx.com>

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