

9 September 2024

Cizzle Biotechnology Holdings plc

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

Collaboration with Moffitt Cancer Center to evaluate patients with suspected lung cancer

Cizzle Biotechnology, the UK based diagnostics company focused on developing a cost-effective biomarker test to help detect early-stage lung cancer, is pleased to announce that it has been selected by the Moffitt Cancer Center ("Moffitt"), the number one cancer hospital in Florida and the Southeast USA, to test patients with suspicious lung nodules in a clinical evaluation using the Company's proprietary CIZ1B biomarker assay.

With multiple sites and over 7000 employees, Moffitt is the only US National Cancer Institute-designated 'Comprehensive Cancer Center' based in Florida. They have developed a comprehensive lung cancer screening programme that is among the best in the United States, which has resulted in them being named a Screening Center of Excellence by the [GO2 Foundation for Lung Cancer](#).

Highlights

- Collaboration with Moffitt Cancer Center, a leading dedicated cancer centre in the USA
- First time suspected lung cancer patients will be tested for the CIZ1B Biomarker as part of a major clinical evaluation
- Study follows US national guidelines
- Cizzle selected after scientific review by Moffitt and as a result of the Company's partnership in the USA with Cizzle Bio Inc
- First use of new monoclonal antibodies to be delivered shortly by Cizzle's strategic commercial manufacturing partner, BBI Solutions
- Blood samples from US patients will be analysed at the University of York
- More clinical collaborations planned by Cizzle BIO in the USA
- Will help validate use of CIZ1B for early lung cancer detection

As part of Moffitt's Phase 2 programme, "Using Biomarkers for Diagnosis, Risk Stratification of Post-treatment Recurrence and Long Term Survival of Lung Cancer", a large observational prospective study in patients with suspicious indeterminate (undiagnosed) lung nodules seen in the Lung Cancer Early Detection (LEAD) Center Lung Nodule Clinic, led by its Director Dr. Lary Robinson, the Company will for the first time be analyzing patient blood samples to determine biomarker accuracy in predicting whether or not a nodule is likely to be cancer. The study follows US nationally recommended guidelines and will be using the first batch of the Company's new commercial monoclonal antibody, to provide new sensitivity and specificity data of the CIZ1B biomarker blood test in the diagnosis of early-stage lung cancer in people with indeterminate lung nodules. The blood sample tests for CIZ1B will be conducted in Professor Dawn Coverley's laboratory at the University of York.

The collaboration with Moffitt arises from the progress being made, and extensive network being generated, by the Company's US licensing partner Cizzle Bio Inc ("BIO"). The Company expects to shortly complete its formal licensing agreement with BIO following the signing of a MOU with them on 2 April 2024, which was extended until 30 September 2024. Since signing the MOU, BIO have been establishing clinical partnerships across the USA as part of a planned expansion to make the CIZ1B biomarker test available throughout North America. BIO expect to announce further clinical evaluations with additional major cancer centers and clinics this year, to be conducted in their growing network of laboratories accredited by the College of American Pathology Pathologists (CAP) with Clinical Laboratory Improvement Amendments (CLIA) certification. On signing of the full agreement with BIO a further US 300,000 advance royalty fee will be paid to the Company.

Further Information

More people die from lung cancer than any other cancer, and every day nearly 5000 people lose the battle to survive. This is due, in large part, to the unmet clinical need for a simple blood test that can detect lung cancer at an early-stage. While both the USA and UK are rolling out screening programmes based on low dose CT scanning, uptake has been poor and still too many people present with suspicious lung nodules that are not cancer, leading to unnecessary stress, avoidable radiation, high costs and consumption of valuable clinician time. The identification of the CIZ1B biomarker and its association with early-stage lung cancer offers an opportunity to add a valuable tool in the clinician's armoury to improved cancer detection rates and ultimately save lives. The Company remains focused on bringing its proprietary test for CIZ1B to market at the earliest opportunity. Bringing the test initially to the USA provides an important platform to then enter new markets and meet the demand for a cost-effective biomarker test globally.

Allan Syms, Executive Chairman of Cizzle Biotechnology, said:

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ready's announcement of the collaboration with the Moffitt Cancer Center marks a major inflection point in the Company's development, and delivery of our proprietary CIZ1B biomarker test to market, by enabling patients in a major cancer clinic with suspicious lung nodules to be tested for the presence of the biomarker. Having transitioned from the development phase into full commercial manufacture of the Company's CIZ1B monoclonal antibody and in establishing a guaranteed royalty bearing licence with our US partners Cizzle BIO, we are now able to forge new links with doctors, hospitals and major cancer clinics, initially in North America and then to make the test available elsewhere in the world.

"The collaboration with Moffitt is significant given their leading position as one of the largest dedicated cancer centers in the USA and already demonstrates the benefit of our new relationship with our US partners Cizzle BIO. This will be the first-time patients with suspicious lung nodules, will, as part of their clinical assessment provide blood samples in a prospective study to test for the CIZ1B biomarker. The results could benefit patients by helping reduce false positives associated with CT screening and provide a valuable tool in helping clinicians identify at risk patients that may have early-stage lung cancer."

Dr. Lary Robinson, Director of the Lung Cancer Early Detection (LEAD) Center Lung Nodule Clinic at Moffitt Cancer Center, said:

"The only current, proven way to find lung cancer early is with low-dose screening chest CT scans for individuals considered high risk. But, unfortunately, we have only been able to get 6% of people at risk to obtain this scan. However, even with chest CT scans, at least 25% of patients will be found to have a lung nodule. The majority of these are false positive results, that nevertheless require careful evaluation, often invasive tests, and long-term follow-up."

"Development of a reliable, highly accurate blood biomarker for discovery of early-stage lung cancer would be a tremendous advancement and would be far easier to implement in the routine clinical setting. There are three scenarios where a highly accurate blood test would be of potential benefit: 1. Aid in the determination of whether an indeterminant lung nodule found on CT scan is cancer; 2. Use as a primary blood screening test for lung cancer; 3. Use for periodic long-term surveillance for recurrent lung cancer or second primary lung cancer for patients who have had curative lung cancer treatment. I am hopeful that the CIZ1B biomarker will prove to be that much-desired lung cancer diagnostic test."

Bill Behnke, Chairman and CEO of Cizzle Bio Inc, commented:

"The team at Cizzle Bio is grateful for the positive reception we have received in the short 7 months we have been in the market. Early detection is crucial in saving lives and we find it quite inspiring to watch the healthcare community welcome us with strong interest in the CIZ1B test that will have a positive impact on so many lives."

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About Cizzle Biotechnology

Cizzle is developing a blood test to help in the early detection of lung cancer. The Company was spun out from the University of York, in 2006, around the work of Professor Coverley and colleagues and was admitted to the Standard segment of the main market of the London Stock Exchange in May 2021. Its test is based on the ability to detect a stable plasma biomarker, a variant of CIZ1 known as CIZ1B. Normal CIZ1 is a naturally occurring cell nuclear protein involved in DNA replication, and the targeted CIZ1B variant has been shown to be highly correlated with early-stage lung cancer. For more information, please see <https://cizzlebiotechnology.com>

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

About Moffitt Cancer Center

[Moffitt](#) is dedicated to one lifesaving mission: to contribute to the prevention and cure of cancer. The Tampa-based facility is one of only 57 [National Cancer Institute-designated Comprehensive Cancer Centers](#) a distinction that recognizes Moffitt's scientific excellence, multidisciplinary research, and robust training and education. Moffitt's expert nursing staff is recognized by the American Nurses Credentialing Center with Magnet® status, its highest distinction. For more information, visit [MOFFITT.org](#), and follow the momentum on [Facebook](#), [Twitter](#), [Instagram](#) and [YouTube](#).

About Cizzle Bio

Cizzle Bio, Inc. stands at the forefront of biotechnological innovation, dedicated to revolutionizing the detection of lung cancer through groundbreaking diagnostic tools. We are driven by a commitment to improve early cancer detection and enhance patient outcomes. With a passion to improve cancer patient survival and recognising that one of the main causes of poor survival rates for certain cancers, and in particular lung cancer, is because diagnosis is often when the disease is at an advanced state, there is an unmet need for a simple blood test that can be used to detect cancer early. As a result of the strategic importance of the USA, Cizzle and BIO have entered into a MOU which will shortly become an exclusive licensing agreement for the CIZ1B biomarker in the USA and Canada. BIO has already made significant progress in adding a Chief Medical Officer to its experienced healthcare management team and in forging links with large physician groups, hospitals and major cancer centers across the USA.

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You can find more about Cizzle BIO at [Early Lung Cancer Detection | Innovative CIZ1B Biomarker Blood Test | Cizzle Bio, Inc.](#)

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