17 June 2024

Cizzle Biotechnology Holdings plc

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

Update on Strategic Licensing and Partnership Memorandum of Understanding for North America

And

Extension of Research Agreement with the University of York to conduct Clinical Evaluation with Leading US Cancer Centre.

Cizzle Biotechnology, the UK based diagnostics developer, is pleased to announce that as a result of its early collaboration with its planned strategic and exclusive licensing partner in the USA, Cizzle Bio Inc ("BIO"), its proprietary test for the CIZ1B biomarker has been selected as part of a major study being conducted at a leading cancer centre in the USA.

In addition, the Company's continuing assay development and clinical evaluation of CIZ1B, which is is highly associated with early-stage lung cancer, is underpinned by renewal of a research and development contract with the University of York. Subject to local ethical approvals, a new phase of work will provide clinical results on patients suspected to have early stage lung cancer arising from CT scanning in the US cancer centre. The new research agreement with the University of York will run until July 2025.

Following the Company's signing of a Memorandum of Understanding ("MoU") with BIO, as announced on 2 April 2024, the Company received the initial non-refundable upfront fee of US$100,000 and expects a binding legal agreement to be completed within the envisaged 120 day period from signing the MoU, with a further US$300,000 payment to Cizzle on signing the binding agreement. The Company has been working closely with BIO's US management team to determine a timetable with key milestones for bringing the company's CIZ1B biomarker test to market. Further details on BIO's plans are outlined below. Details of the first hospital locations, clinical trials and initial deployment sites are confidential at this time, but will be announced in due course.

Key Highlights

- Cizzle received an up-front payment of US$100,000 as a non-refundable fee to grant BIO an exclusive negotiating period of 120 days from the signing of the MoU on 1 April 2024.
- It is anticipated that the binding agreement, together with an initial royalty payment of US$300,000, will be completed within this 120 day period and will grant BIO an exclusive licence to develop and market clinical diagnostic assays based on the CIZ1B biomarker to facilitate the early detection of lung cancer in North America.
- Minimum advance royalty payments of US$2.3 million, as part of the 10% royalty to be paid on gross revenues minus taxes, are due over a period of 30 months following signing of a binding agreement.
- On completion of the binding agreement, Cizzle will own 10% of BIO for no cash consideration.
- Cizzle has been selected by a major cancer centre in the US to evaluate CIZ1B testing as part of an important clinical study, to confirm whether lung nodules identified by CT scanning are positive for the CIZ1B biomarker.
- BIO expects to register its first US CLIA (Clinical Laboratory Improvement Amendments) accredited lab with the FDA (US Food and Drug Administration) for the CIZ1B LDT test in September 2024
- BIO plan to achieve CLIA Certification for the LDT test in November 2024, with insurer reimbursement code achievement and full product launch April 2025.

Further Information

Lung cancer remains the biggest cause of cancer deaths worldwide, with nearly 5000 people losing their lives daily to the disease. Other than the ability of pathologists to confirm the presence of cancer, the current gold standard for detection remains CT scanning, which produces a high rate of false positive results. To reduce premature cancer deaths, improve survival rates and increase quality of life a simple blood test that can facilitate early cancer detection is needed.

As part of the Company's global licensing strategy, and stated aims to deploy its first commercial tests in the USA, the partnership with BIO is already achieving significant results. The decision of a large cancer centre to select Cizzle's CIZ1B biomarker as part of its clinical evaluation is a major endorsement of the Company's technology. With clear milestones established to roll out the commercial test by 2025, the Company is poised to help address the current low uptake in cancer testing, in relation to the US Preventive Services Task Force's target of screening 14.2 million at-risk adults.

With guaranteed royalties over a 30-month period, a potential upside in value through the company's 10% ownership of BIO, Cizzle will accelerate the development, regulatory approval and launch of its biomarker diagnostic tests in North America. This will be followed by, and will enable, similar strategies elsewhere in the world.

Allan Syms, Executive Chairman of Cizzle Biotechnology, said:

"After years of research at the University of York and further investment and development by Cizzle, the Company is now at an exciting inflection point. The partnership with BIO in North America has opened doors to work with major cancer centres, brings clarity to route and time of first product launch and generates guaranteed revenue streams going forward. This is an exciting time for Cizzle Biotechnology and I look forward to completing the binding agreement with BIO and providing more details on the significant clinical trial programme with top hospitals in the territory, in due course."

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About Cizzle Biotechnology

Cizzle is developing a blood test for the early detection of lung cancer. The Company is a spin- out from the University of York, founded in 2006, around the work of Professor Coverley and colleagues. Its proof-of-concept prototype test is based on the ability to detect a stable plasma biomarker, a variant of CIZ1 known as CIZ1B. CIZ1 is a naturally occurring cell nuclear protein involved in DNA replication, and the targeted CIZ1B variant is 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 Cizzle Bio Inc

Cizzle Bio Inc, a company registered in Texas USA, has been created by a group of high-net-worth individuals with a passion to improve cancer patient survival. 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. BIO is led by Bill Behnke, who has been pioneering Cizzle Biotechnology's marketing activities in the USA and is an accomplished entrepreneur and performance-driven senior executive with an extensive background of success in funding and building healthcare businesses through direct sales, marketing, sales management, and business development. He is heavily engaged in charitable work for cancer, and served a nine-year tenure on the national board of the Leukemia and Lymphoma Society. He currently serves on the boards of the ASCO Foundation's Conquer Cancer; the AYA Cancer Foundation; The Wheeler Group; Children's Shelter of San Antonio; South Texas Blood and Tissue Center; and the Leukemia and Lymphoma Society.