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Cizzle Biotechnology Holdings PLC
18 July 2024

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

Manufacturing Agreement with BBI Solutions

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 a strategic agreement with BBI Solutions ("BBI"), the world's largest independent producer of immunodiagnostic reagents, to supply its first order of commercial propriety monoclonal antibodies. This collaboration is a significant milestone in Cizzle's mission to commercialise its cost-effective biomarker test for early-stage lung cancer detection.

This initial order of CIZ1B commercial propriety monoclonal antibodies from BBI is crucial for advancing the clinical evaluation process, marking a vital step towards bringing the test to market. These antibodies will be manufactured at BBI's ISO 13485-certified facilities and are expected to support up to 5000 assays for detecting the CIZ1B biomarker, which is strongly associated with early-stage lung cancer.

The antibodies produced will be used in a clinical evaluation of patients with suspicious indeterminant (undiagnosed) lung nodules for lung cancer with a major cancer centre in the USA. This evaluation is ahead of the planned rollout of commercial tests by the Company's intended licensing partner in the USA, Cizzle Bio Inc ("BIO"). Additionally, this partnership supports the development of a point of care ("POC") assay and the Company's broader plans to explore the utility of CIZ1B for detecting other cancers.

Key Highlights:

- Partnership with BBI Solutions: BBI will manufacture commercial CIZ1B monoclonal antibodies.
- Certified Manufacturing: Production in ISO 13485-certified facilities ensures adherence to stringent quality standards.
- Sufficient Initial Supply: The first batch will support up to 5000 blood tests for the CIZ1B biomarker.
- Supporting Clinical Evaluation: The antibodies will facilitate clinical evaluations with a major US cancer centre, critical for confirming the presence of lung cancer in patients with indeterminate lung nodules identified by CT scans.

Commercialization and Regulatory Strategy

The antibodies being produced will support Cizzle's ongoing commercialisation and regulatory strategy, including:

- US CLIA accreditation: As announced on 17 June 2024, BIO aims 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.
- CLIA certification and product launch: BIO plan to achieve CLIA certification for the LDT in November 2024, with an anticipated product launch and insurer reimbursement code achievement by April 2025.
- Point of Care ("POC") development: Plans include developing a POC test for use in pharmacies, doctors' offices, and by healthcare providers.
- Expanded research: Continued R&D at the University of York to explore the utility of CIZ1B in detecting other cancers.

It is essential that reagents, including the Company's monoclonal antibodies, meet strict regulatory requirements. The ISO standards (International Organization for Standardization) provide a platform to bring globally accepted standards together and in the case of medical devices, which includes in vitro diagnostics, ISO 13485 is the Quality Management System applicable to the regulatory requirements for a business operating in the medical device sector*. BBI will be producing the Company's antibodies within their ISO13485 certified facilities for custom manufacture of antibodies.

*PUB100422_preview.pdf (iso.org)

Further Information

With nearly 5000 lives lost daily to lung cancer, largely due to the lack of a simple early detection test, Cizzle is dedicated to bringing its proprietary CIZ1B test to market as quickly as possible. This partnership with BBI is a pivotal step in providing reliable clinical results and developing a user-friendly point-of-care test.

The supply of the new commercial monoclonal antibodies will be used to provide clinical results on patients suspected to have early-stage lung cancer arising from CT scanning in the US cancer centre, developing a simple finger prick point of care test for the CIZ1B biomarker and continuing Cizzle's work to determine the utility of the test for other cancers.

In addition, the Company's ongoing assay development and clinical evaluations are supported by Cizzle's renewed research and development contract with the University of York, announced on 17 June 2024. Subject to local ethical approvals, the new phase of work will provide clinical results on patients with suspected early-stage lung cancer arising from CT scanning at a leading US cancer centre.

Allan Syms, Executive Chairman of Cizzle Biotechnology, said: *"We are making significant progress in bringing the company's CIZ1B test to market. CIZ1B is highly associated with early-stage lung cancer and after extensive and dedicated research at the University of York, we are now at a point where the test will be made available to clinicians and patients to help in the drive to detect cancer early and as a result save lives. A key step in making the test commercial is to partner with a trusted global manufacturer with the skills, experience and first-class quality-assured facilities to produce reliable, robust and reproducible antibodies. Hence we are delighted to be partnering with BBI solutions to make our first batch of antibodies for use in clinical evaluations and trials, before rolling out the test across North America and importantly investigating whether CIZ1B is relevant in detection other cancers. I believe this is an inflection point in the Company's development and now through working with BBI we have the capability to accelerate growth by being able to produce our essential antibodies at scale."*

Mario Gualano, CEO of BBI, added: *"We are excited to partner with Cizzle Biotechnology in their mission to bring an innovative*

lung cancer detection test to market. Our expertise in producing high-quality immunodiagnostic reagents will ensure that Cizzle's CIZ1B monoclonal antibodies meet the highest standards. We are proud to contribute to a project that has the potential to significantly improve early cancer detection and patient outcomes globally."

Enquiries

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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 Cizzle Bio

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.

About BBI

BBI Solutions stands at the forefront of the global immunodiagnostic reagents industry, leveraging over 5 decades of expertise in In Vitro Diagnostics (IVD). The company specializes in high-quality raw materials and custom development solutions, supporting lateral flow test development and manufacturing. The company's ISO 13485 certification underscores its adherence to the highest global standards, ensuring superior performance and compliance.

Annually, BBI's reagents play a pivotal role in 400 million lateral flow tests and are a trusted component in 5 billion blood glucose test strips -showcasing the company's significant contribution to global health and solidifying its reputation as an industry leader.

With a focus on quality and customization, combined with a robust pipeline of recombinant products, BBI Solutions continues to meet the evolving demands of the market. Providing precise, cutting-edge solutions, guaranteeing its partners' assays achieve market prominence and contribute to transformative patient outcomes.

For more information visit BBI Solutions | Lateral Flow, Reagents and POCT

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