10 August 2023

Cizzle Biotechnology Holdings Plc

("Cizzle Biotechnology" or the "Company")

Expansion of Research Agreement with the University of York for Cancer Diagnosis and Therapy and Update on Progress to Launch CIZ1B Biomarker Early Stage Lung Cancer Test

Cizzle Biotechnology, the UK based diagnostics developer, is pleased to announce an expansion of its current research programme with the University of York to develop its CIZ1B biomarker technology for early stage cancer diagnosis, and other potential applications in cancer therapy. This follows significant progress in isolating additional new and specific monoclonal antibodies to the CIZ1B biomarker and incorporating these into a new high-throughput clinical diagnostic immunoassay platform. The recent developments meet key milestones to begin commercial clinical trials. The Company is now engaged in clinical trials design to support the validation and accreditation of the CIZ1B test prior to commercial launch.

Highlights

- Successful development of additional specific monoclonal antibodies for CIZ1B Biomarker
- Application to a new high-throughput immunoassay platform.
- Significant expansion of current research and development agreement with the University of York, to allow continued access to state of the art facilities and world-leading scientists.
- All intellectual property rights arising from the work to be owned by the Company

Cizzle Biotechnology and the University of York have benefited from a long-standing close relationship since the Company was spun out from the University in 2006. That collaboration has continued since the Company was admitted to trading on the London Stock Exchange and currently has a funded programme until 25 September 2024. During this period the team at the University of York under the direction of Professor Dawn Coverley has successfully isolated and validated an additional panel of specific monoclonal antibodies for the CIZ1B biomarker, which is highly associated with early stage lung cancer.

A key milestone for the Company was to take the proof of concept test for CIZ1B and develop an accredited and commercially viable assay that could be used in a laboratory to test for early stage lung cancer. A common first approach to achieve this, known as an enzyme-linked immunosorbent assay (ELISA), involves a multistep process of analysing multiple blood samples in either manual or robotic handling systems. A major breakthrough by the team at the University of York has significantly improved on this traditional approach using alternative high-throughput assay formats for CIZ1B, that will now be used as the basis for a commercial product.

The next steps are to finalise standard production and operating protocols and to commence clinical trials that should lead to an accredited Laboratory Developed (LDT) test for launch initially in the USA. The Company will then extend that to other key markets and will extend its use through regulatory approval with the FDA in the USA, the EMA for a CE mark in Europe, the MHRA in the UK for UKCA approval, and with the appropriate regulatory groups elsewhere in the world including China.

Cizzle Biotechnology will continue to own all intellectual property rights and, through its further funding of research programmes at the University of York, aims to create new solutions for early cancer diagnostics and develop new therapeutic tools.

Commenting, Allan Syms, Executive Chairman of Cizzle Biotechnology, said: "The University of York has been the home of the Company's research and development from its inception. Under the expert and insightful leadership of Professor Coverley, the laboratory team have made excellent progress in developing our test for the CIZ1B Biomarker to be used for detecting lung cancer at its earliest stage. This provides a much-needed solution to early diagnosis, which can save lives. The latest exciting developments have met important milestones and so I am delighted to expand our investment with the University, which continues to provide support to the Company from the leading-edge research and state of the art laboratories. This new agreement aligns will an exciting phase of the Company's plans to achieve regulatory approval and bring our early detection tests for lung cancer to market."

Enquiries:

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About the Company

Cizzle Biotechnology 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 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.