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 ("UK MAR"). Upon the publication of this announcement this inside information is now considered to be within the public domain.

6 May 2022

## **Cizzle Biotechnology Holdings Plc**

("Cizzle Biotechnology" or the "Company")

## Strategic Alliance to develop and market early lung cancer detection in USA

"Caring for Lives and Saving Lives through Early Detection"

Cizzle Biotechnology, the UK based diagnostics developer, is pleased to announce that it has signed a heads of terms to partner with CorePath Laboratories ("CorePath"), a full service cancer reference laboratory, to develop and offer its proprietary early-stage lung cancer test throughout the USA.

#### **Highlights**

- Heads of terms signed with CorePath Laboratories, USA, covering an intended strategic alliance to develop and offer the Company's CIZ1B based early-stage lung cancer test in the USA
- CorePath is a Clinical Laboratory Improvement Amendments ("CLIA") and College of American Pathologists ("CAP") accredited laboratory
- CorePath intends to develop and offer a clinical laboratory test throughout the USA using the Company's proprietary technology
- Proposed 15% royalty and royalty sharing arrangements for the Company over all offering of products and services using CIZ1B via CorePath in the USA
- Initial pilots planned

# **Background**

Lung cancer is by far the leading cause of cancer death in the USA, making up almost 25% of all cancer deaths. Each year, more people die of lung cancer than of colon, breast, and prostate cancers combined.

The American Cancer Society's estimates for lung cancer in the United States for 2022 are:

- About 236,740 new cases of lung cancer (117,910 in men and 118,830 in women) annually\*
- About 130,180 deaths from lung cancer (68,820 in men and 61,360 in women) every year\*
- Currently, there are no simple specific blood tests to detect lung cancer early when targeted
  interventions can improve timely access to cancer care and save lives. Yet it is estimated that
  about eight million Americans qualify as high risk for lung cancer and are recommended to
  receive annual screening with low-dose CT scans and if half of these high risk individuals were
  screened, over 12,000 lung cancer deaths could be prevented\*\*

#### **Further Information**

The heads of terms entered into by the Company with CorePath envisages the parties entering into a full commercial agreement in due course combining CorePath's proven expertise and knowledge in providing premier pathology services and consultants for patients, oncologists, clinicians, academic affiliates and biopharma companies across the USA, with the Company's proprietary biomarker for early-stage lung cancer detection. It is intended that Cizzle Biotechnology will benefit from future revenues via a 15% royalty on the direct offering of all products and services using its proprietary CIZ1B technology and from shared royalties from future third party revenues generated jointly by CorePath and the Company.

CorePath is a specialist oncology reference laboratory bringing together leading clinicians, scientists, academic affiliates and state of the art facilities and will be responsible for all activities in the USA including development, clinical trials and test validation for clinical use

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

"Lung cancer is the leading cause of cancer deaths in the USA and a major health problem globally. This is because for many, detection of lung cancer only happens when it has become symptomatic and therefore more advanced, meaning 5-year survival rates are poor. The Company's CIZ1B biomarker to detect early-stage lung cancer could represent a major breakthrough and we now have the opportunity to bring the benefits of this test to such an important market. We are delighted to be partnering with CorePath Laboratories who bring the expert knowledge and market reach to help develop our biomarker into a certified test that can be made available to patients and healthcare providers throughout the USA."

## Commenting, Dr Aamir Ehsan, CEO and Medical Director of CorePath, said:

"As a board-certified hematopathologist and molecular geneticist; diagnosing cancer on a daily basis is hurting when cancer has already metastasized in patients. While efforts are underway to find actional genetic mutations to target treatment and improve survival; early detection and intervention are key to patients' long-term survival and cure. The agreement with Cizzle Biotechnology represents a significant opportunity to provide early and cost-effective lung cancer detection via a simple and quick blood test which will result in significant cost savings downstream, avoiding expensive treatment, hospital admissions and ultimately saving lives."

### **Enquiries:**

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#### **Notes to Editors:**

## **About Cizzle Biotechnology**

Cizzle Biotechnology is developing a blood test for the early detection of lung cancer. Cizzle Biotechnology 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 <a href="https://cizzlebiotechnology.com">https://cizzlebiotechnology.com</a>

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

#### **About CorePath Laboratories**

Founded and headquartered in San Antonio, Texas as one of the few international laboratories with the ability to offer immunohistochemistry, cancer cytogenetics, molecular genetics and multicolour flow cytometry services at one location. CorePath brings academic expertise, compassion and state of the art technology to help physicians help their patients and achieve the most accurate time-sensitive results for early treatment.

Together, they are a highly specialised team with a shared passion: "Caring for Lives."

CorePath provides an extensive range of haematopathology services to healthcare providers across the USA and internationally. They work closely with the biopharma industry through a seasoned project management team with relevant scientific and therapeutic expertise in cancer drug study needs. Their team of board-certified pathologists are subspecialised in different areas of oncology to precisely diagnose cancers using cutting edge technology. Customers include ICON, Alexion, Covance, Ventana (Roche) and Becton Dickenson

For more information, please see https://www.corepath.us/

#### References

- \* https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html
- \*\*Cheung LC, Katki HA, Chaturvedi AK, Jemal A, Berg CD. Preventing Lung Cancer Mortality by Computed Tomography Screening: The Effect of Risk-Based Versus U.S. Preventive Services Task Force Eligibility Criteria, 2005–2015. *Annals of Internal Medicine*. 2018; 168(3):229-32. doi:10.7326/M17-2067.