

BIOCAPTIVA Provides Update and Remains on Track to Transform the Liquid Biopsy Market for Cancer Management

- *BIOCAPTIVA aims to significantly enhance the potential of liquid biopsy, bringing significant benefit to the diagnosis and management of patients with cancer*
- *BIOCAPTIVA's BioCaptor, the world's leading cell free DNA capture device, offers significant cfDNA yield improvements over conventional blood draw*

Edinburgh, UK – January 5 2022 – BIOCAPTIVA Ltd (“BIOCAPTIVA”), a company developing the BioCaptor, a revolutionary cell free DNA (cfDNA) capture device, which has the potential to transform liquid biopsy testing for cancer management, provides an update on the company’s progress since spinning out of the University of Edinburgh in April 2021.

The company’s BioCaptor technology, developed from the research led by Board members Tim Aitman and Mark Bradley, has seen a number of important technical advances in the last nine months. These have led to highly significant and clinically relevant improvements in capture efficiency, in terms of both the quality and quantity of cfDNA that the BioCaptor is able to collect. The pre-clinical version of the BioCaptor was, on average, able to collect 345ng of cfDNA per yield, significantly higher than quantities of cfDNA recovered from a conventional venous blood draw, which can be as much as 100 times less. The latest developments for the clinical version of the BioCaptor indicate a further significant enhancement in yield over the pre-clinical device.

Lower quantities of cfDNA obtained from a blood draw often require amplification and ultradeep sequencing for liquid biopsy testing, decreasing assay sensitivity and accuracy and limiting the type and stage of cancers that are amenable to existing liquid biopsy testing.

The improved ability to capture high quality and quantity cfDNA by the BioCaptor will help realise the full potential of liquid biopsy and expand the number of patients who can benefit from this approach to cancer management. The BioCaptor has the potential to enable earlier and more accurate diagnosis of cancers, without the need for invasive physical biopsy of the tumour. This will enhance clinical data collection and the ability to diagnose and monitor patients during or post treatment, to track remission and to help direct therapy.

Alongside the technical improvements that have been made to the device, significant progress in manufacturing has also been made. Furthermore, BIOCAPTIVA has amassed considerable preclinical data, including trialing the technology in pigs, which provide a model which closely resembles humans. These data demonstrate the BioCaptor’s safety in relation to liver and kidney function, blood biochemistry and haemocompatibility.

BIOCAPTIVA plans to begin the first in human trials with the BioCaptor in 2022. Ahead of this key milestone, the company has entered into a partnership with Mi3 Medical Intelligence, an expert medical device design, development and manufacturing company. The partnership seeks to develop the technology to manufacture the BioCaptor at a commercially viable scale to the required manufacturing standards.

Jeremy Wheeler, CEO of BIOCAPTIVA, said “The company is now well positioned to advance the BioCaptor into first in human trials in 2022. With strong additions to the team and Board since April, we are proud to have made significant technical advancements, a pre-submission to the FDA for the BioCaptor and made progress with the design of the first clinical trial for the device, including



identification of our first clinical trial site. I look forward to reporting on the advancements made by the company in 2022 as we look to validate this exciting technology in man.”

Frank Armstrong, Chair of the Board, added “Dramatically increasing the quantity and quality of cell-free DNA (cfDNA) available for liquid biopsy testing can empower cancer diagnostics and research capabilities, far beyond what is currently possible. We are about to enter an exciting chapter with the start of clinical trials, which will address a huge unmet need, enabling more precise and enhanced clinical decisions for a wide spectrum of cancer patients.”

About BIOCAPTIVA

BIOCAPTIVA is developing the BioCaptor, a revolutionary medical device which has the potential to transform liquid biopsy testing for cancer management, by improving early diagnosis and monitoring of disease and enhancing clinical trial data of cancer patients. The BioCaptor captures up to 100x more cell free DNA (cfDNA) than a venous blood draw, yielding cfDNA in high quality and quantity for testing, addressing the major challenge of liquid biopsy in cancer management. This will potentially allow the testing of a far greater number of cancer types and stages in a much wider range of patients.

BIOCAPTIVA was founded in 2021 when it spun out from the University of Edinburgh. BIOCAPTIVA is based in Edinburgh and backed by Archangels and Scottish Enterprise.

For more information, please visit www.biocaptiva.com

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