ARQUER DIAGNOSTICS' ADXBLADDER BECOMES FIRST BLADDER CANCER URINE TEST TO UNDERGO RIGOROUS CLINICAL TRIALS IN USA

First patients recruited for bladder cancer recurrence monitoring study

Sunderland, United Kingdom, Tuesday 27th July 2021 – ADXBLADDER has become the first new generation urinary biomarker test for bladder cancer to undergo rigorous clinical trials in the USA in decades. The innovative and highly accurate test, developed by UK company Arquer Diagnostics, is already approved for use across Europe.

ADXBLADDER is now being evaluated in a bladder cancer recurrence monitoring study in the US. With results of the study expected by the end of 2021, Arquer Diagnostics hopes to make a 510(k) premarket submission to the US Food and Drug Administration (FDA) to gain clearance from the organisation for **ADX**BLADDER to be commercialised in the US.

This would make **ADX**BLADDER – an MCM5 ELISA (enzyme-linked immunosorbent assay) Test – the first new generation urinary biomarker test for bladder cancer to be approved by the FDA in almost two decades.

Dr Jacqui Stockley, Chief Scientific Officer at Arquer Diagnostics, says: "We believe that many urologists have been disappointed over the past 20 years by diagnostic urinary biomarker technologies aimed at helping solve problems with the bladder cancer pathway failing to deliver on their promises.

"That is why at Arquer, we are determined to ensure our products have been tested in a comprehensive clinical trial programme to break that cycle and ensure that urologists can be confident in the robustness of our tests and the scientific rigour of the studies behind them. We have already carried out three large studies and we are delighted this latest US trial is now underway."

ADXBLADDER is the first of its kind using patented technology to detect the cancer biomarker MCM5 (Minichromosome Maintenance Complex Component 5) in the urine. All cancer cells – in every cancer type – are continually dividing (replicating) so contain MCM5, and these cells are shed into the urine when a tumour is present in the bladder. An important feature of **ADX**BLADDER is that the test is not influenced by infections or inflammation as bacteria do not contain MCM5 and inflammatory cells cannot replicate so do not express the MCM5 protein.

This latest study will evaluate the performance of **ADX**BLADDER to help in the monitoring of cancer recurrence in non-muscle invasive bladder cancer (NMIBC) patients. Arquer has engaged the CUSP Group LLC, a Uro-Oncology Trial Management Organisation, to execute and manage this bladder cancer biomarker study being conducted at 13 large urology practices across the USA. KCI/WSU (Karmanos Cancer Institute/Wayne State University), a National Cancer Institute Comprehensive Cancer Center, is providing data abstraction, curation and analytical support.

Data published last year in the Journal of Urology from a clinical trial involving 1,431 patients at 21 European centres showed that **ADX**BLADDER can rule out bladder cancer with a negative-predictive value (NPV) of 99%.[1,2,3] This reinforces rigorous clinical trial results investigating the urinary biomarker protein MCM5 which show that **ADX**BLADDER can exclude the presence of high-risk bladder cancer with an NPV of 98.9% in newly diagnosed patients.[1-3] The test has also been shown to detect twice as many tumours as cytology in recurrence monitoring.[2]

The European Association of Urology (EAU) has called for changes to be made to the bladder cancer diagnosis pathway following the COVID-19 pandemic, with adapted guidelines to prioritise patients with high-risk tumours to undergo cystoscopy, while recommending that patients with low-risk or intermediate-risk tumours who remain asymptomatic have their cystoscopies deferred by six months. Acknowledging that some diagnoses will be missed, it has called for "timely action and innovation" to end "this game of probability".[4]

The study objectives are to establish the sensitivity (primary objective), specificity and Negative Predictive Value (NPV) of **ADX**BLADDER in the detection of bladder cancer recurrence in patients with a previous diagnosis of NMIBC (a positive diagnosis by pathological examination of clinically removed tissue, either initial or recurrent disease, within the previous 24 months), compared with diagnosis obtained by cystoscopy (and biopsy/TURBT of suspect lesions where clinically indicated). It will also compare the sensitivity, specificity, NPV and Positive Predictive Value (PPV) results for **ADX**BLADDER with those of urine cytology.

Chief Investigator of the study, Dr Ashish Kamat, Professor of Urologic Oncology (Surgery) and Cancer Research at M.D. Anderson Cancer Center, Houston, Texas, says: "Clinical trials have demonstrated that **ADX**BLADDER is a highly accurate test which can help to rule out the presence of bladder cancer quickly and painlessly. It is fantastic to see Arquer Diagnostics continuing to invest in robust studies and, if this leads to FDA approval, it will be an incredibly useful new tool for us to safely and accurately diagnose and monitor our patients."

Dr Neal Shore, Medical Director for the Carolina Urologic Research Centre, co-PI for the study and founding member of CUSP Group LLC, says: "Enhancing physician and patient ability to accurately evaluate for recurrent bladder cancer, through the simplicity of a voided urine specimen, will improve both the diagnosis and management for bladder cancer patients. The CUSP Group LLC are very pleased to expeditiously facilitate this important trial."

The American Cancer Society estimates that this year in the US there will be approximately 83,730 new cases of bladder cancer (about 64,280 in men and 19,450 in women) and it will cause around 17,200 deaths (12,260 men and 4,940 women).[5]

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NOTES TO EDITORS:

Full background documents on **ADX**BLADDER, bladder cancer and Arquer Diagnostics are available on request along with details of case studies.

For further press information please contact The Difference Collective
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For further information on Arquer Diagnostics please visit https://arquerdx.com/

About Arquer

- Arquer Diagnostics is a UK-based company committed to manufacturing and marketing innovative, non-invasive cancer tests for diagnosis and monitoring.
- Arquer's approach and tests are supported by highly regarded experts at leading international organisations: University Hospital Southampton and Sunderland Royal Hospital in the UK; Pitié Salpêtrière University Hospital and Hôpital Edouard Herriot, Lyon in France; University Hospital Fundació Puigvert in Spain; Radboud University Medical Centre, Nijmegen in The Netherlands; as well as Ospedale Molinette, Turin, and Universita'Policlinico Milano, in Italy.

References:

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