

## Step change in oncology diagnostics

**Arquer Diagnostics is developing a series of innovative, non-invasive tests for cancer and recently launched ADXBLADDER, a reliable urine test for bladder cancer.**

Non-invasive cancer diagnostic tests could offer simpler, more reliable and less costly alternatives to current approaches, eliminating the need for invasive tests and improving the patient experience. Arquer Diagnostics is developing and delivering innovative oncology diagnostic products based on the detection of a cancer biomarker, minichromosome maintenance protein 5 (MCM5).

“Our vision is to inspire transformational change in the field of oncology diagnostics by developing and commercializing novel assays, which will support cancer patients, their families and clinicians in their quest for answers,” said Nadia Whittle, CEO of Arquer. “At Arquer, we believe that cancer diagnostics must provide greater certainty, which is why our diagnostic solutions are among the most reliable and accurate on the market.”

Based in Sunderland, UK, the original company (UroSens) was founded by Nick Miller-Jones in 2005. It was relaunched in 2015 as Arquer Diagnostics, backed by £2 million in funding to drive product development and clinical trials. “Our journey has evolved from one man with a vision to a group of professionals delivering paradigm-shifting test technology,” said Whittle. The team at Arquer is supported by internationally recognized clinical advisors and a number of collaborators, including the International Bladder Cancer Group.

In 2017, Arquer raised a further £2.1 million in series B funding led by Longwall Ventures, and launched its first product, **ADXBLADDER**—a simple, fast and reliable urine test for bladder cancer. A pipeline of clinical programs is also under way, aimed at launching a series of new MCM5-based cancer diagnostic tests over the next two years.

### Patented MCM5 antibodies

Arquer’s proprietary diagnostic tests are based on patent-protected intellectual property licensed exclusively from Cancer Research Technology, the development and commercialization arm of Cancer Research UK.

The **ADXBLADDER** urine test detects the presence of MCM5, which is known to be a clear indicator of bladder cancer and has been studied for more than 20 years<sup>1</sup>. MCM5 is a useful marker of bladder cancer because it is expressed by cells throughout the tumor, including tumor cells on the surface of the bladder lining, which are shed into the urine. In healthy individuals MCM5 is found only below the surface of the lining, where new cells are created, and thus rarely makes its way into the urine.

The patented **ADXBLADDER** diagnostic uses two anti-MCM5 mouse monoclonal antibodies to detect the MCM5 antigen in urine sediment. The test can be performed in most hospital laboratories using



The Arquer Diagnostics team.

standard enzyme-linked immunosorbent assay (ELISA) technology, which can deliver a yes or no result within three hours. Importantly, the results are unaffected by the presence of red blood cells, inflammatory cells or bacteria.

### High sensitivity and reliability

The **ADXBLADDER** MCM5 ELISA kit has one of the highest sensitivities and negative predictive values (NPVs) of any urine test for bladder cancer diagnosis. Results from the clinical study that underpinned the product launch were presented at a satellite symposium on 21 October 2017 during the 37th Société Internationale d’Urologie (SIU) meeting in Lisbon, Portugal.

The study was conducted in 577 patients who attended hematuria clinics at a number of centers in the UK between August 2016 and February 2017. Urine samples were collected for the **ADXBLADDER** test before the patients underwent cystoscopy and other routine assessments, including imaging techniques such as ultrasound.

The prevalence of bladder cancer in the study population was 7.96% ( $n = 46$ ), and the **ADXBLADDER** test had an NPV of 97%, which means there was only a 3% chance of a bladder cancer going undetected. The test also achieved a combined sensitivity of 95% in high-risk non-muscle-invasive bladder cancer and muscle-invasive bladder cancer—types of cancer that are likely to spread more quickly and have a poorer prognosis. The overall sensitivity for the **ADXBLADDER** test was 76%, with correct diagnosis of 35 out of 46 cancer-positive cases.

**ADXBLADDER** also performed better than urine cytology in the trial. In a subset of 98 samples, which included 10 cancer-positive samples, cytology

correctly detected only 4 of these cancers, whereas **ADXBLADDER** detected 8.

### Transformational change

Current patient pathways combine different approaches to bladder cancer diagnosis and monitoring, and there is potential for **ADXBLADDER** to be used at various points. For example, **ADXBLADDER** could replace less sensitive urine tests, such as urine cytology, and reduce the need for unnecessary cystoscopies. There is also potential to use **ADXBLADDER** for regular monitoring of patients who have been treated for bladder cancer, and this approach is currently under investigation.

**ADXBLADDER** received its CE Mark on 11 October 2017 and is currently commercialized in the UK, France, Italy and Turkey. It will be released to other European countries and worldwide regions in 2018. “Meanwhile, we are continuing to drive innovation and positive change in cancer diagnostics through the development of additional MCM5 tests,” said Whittle.

Arquer is also open to partnering opportunities. “We maintain a policy of active collaboration with companies, research groups and clinicians, and are interested in opportunities for in-licensing cancer biomarkers or technologies where there is a fit with our current platform and products,” said Whittle.

1. Stoeber, K. et al. *J. Natl. Cancer Inst.* **94**, 1071–1079 (2002).

contact  
Nadia Whittle, CEO  
Arquer Diagnostics  
Sunderland, UK  
Tel: +44 (0)191 516 6765  
Email: info@arquerdx.com