



NEW HOPE FOR WOMEN WITH SUSPECTED ENDOMETRIAL CANCER AS INNOVATIVE URINE TEST RULES OUT DISEASE IN UP TO 99% OF CASES

New research adds to wealth of existing data for ADX portfolio of cancer diagnostics

Sunderland, United Kingdom, 03 February, 2021 – For the first time, a simple, innovative test which uses patented technology to detect the cancer biomarker MCM5 (Minichromosome Maintenance Complex Component 5) in the urine, could help gynaecologists rule out endometrial cancer in as little as three hours. New research recently published in the journal *BMC Cancer* shows that **ADXYNAE** could have an important role in the diagnostic pathway for women suspected of having the disease, reducing the need for painful, invasive procedures.¹

This new data for **ADXYNAE** is the latest to highlight the effectiveness of the non-invasive **ADX** portfolio of diagnostic tests developed by UK-based Arquer Diagnostics. The study, which enrolled a total of 125 patients from Saint Mary's Hospital – part of the Manchester University NHS Foundation Trust (MFT) – showed that **ADXYNAE** can accurately detect the presence of an endometrial tumour with a sensitivity of 87.8%. While this study enrolled patients already known to have endometrial cancer, in a prospective population this sensitivity would generate a 99.3-99.5% Negative Predictive Value (NPV)¹, reinforcing that **ADXYNAE** could be a valuable rule-out test for the disease.

Around 9,400 women are diagnosed with endometrial cancer, also known as uterine or womb cancer, in the UK each year. This makes it the fourth most common cancer in women in the UK - and the sixth most common globally - and the incidence and prevalence continue to rise each year.^{2,3} Over the past decade in the UK, uterine cancer incidence rates increased by 13%, in part fuelled by factors including increased rates of obesity, poor lifestyles and increased glycaemic load.³ Unfortunately, because of a lack of diagnostic options, over 11 million invasive and painful tests are conducted globally each year, with just 3-5% resulting in a cancer diagnosis.

Professor Richard Edmondson, professor of gynaecological oncology at The University of Manchester, consultant at Saint Mary's Hospital, and lead investigator of the new research, said: *"Endometrial cancer, which affects the lining of the womb, is the most common gynaecological cancer in the UK. Although many women are diagnosed at an early stage when treatment is successful, unfortunately, due to a variety of reasons, such as issues with diagnostic procedures or women presenting too late, some are still diagnosed at a late stage.*

"Diagnosis usually involves taking a biopsy from the lining of the womb which can be uncomfortable and even painful on some occasions. Many thousands of these tests are carried out in the UK each year. But most women who undergo a biopsy will be found not to have a cancer.

"ADXYNAE is a non-invasive test which has the potential to rule out cancer with high accuracy. We hope that further clinical trials, including a pre-regulatory trial in the US, will show that ADXYNAE, which can be carried out quickly and easily in NHS hospitals, will reduce the number of women needing these further procedures to confirm a diagnosis and provide faster reassurance for those who do not have cancer," he added.



Nadia Whittle, Chief Executive Officer of Arquer Diagnostics, said: *“We know that there is a significant need to develop non-invasive and accurate diagnostic tests for endometrial cancer. At Arquer, we are proud to be able to build on the work we have been doing in bladder cancer to bring a new diagnostic option to women suspected of endometrial cancer. In initial studies, our **ADXGYNAE** test is quick, painless and could rule out cancer with 99% accuracy and this should be validated by our ongoing studies currently being conducted. We are excited to continue with further clinical trials of **ADXGYNAE** in both the USA and Europe to bring this new diagnostic option to the Endometrial Cancer Pathway as quickly as possible.”*

Arquer Diagnostics’ first product currently marketed and available in clinical practice is **ADXBLADDER**. In rigorous clinical trials, **ADXBLADDER** has shown that it can rule out the presence of bladder cancer with an NPV of 99% in newly diagnosed patients and those undergoing routine monitoring, without the need for invasive and unnecessary procedures.⁴⁻⁵

Arquer Diagnostics has conducted a large number of clinical trials of MCM5 at over 20 centres in countries including the UK, Italy, Spain, France and the Netherlands, which demonstrate the science behind its technology.

To access the full research paper, please click [here](#).

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NOTES TO EDITORS:

For further information on Arquer Diagnostics please click [here](#).

To arrange interviews or for further press information please contact The Difference Collective at arquer.comms@thedifferencecollective.com

About ADXBLADDER and ADXGYNAE

- **ADXBLADDER** and **ADXGYNAE** are game-changing tests which use patented technology to detect the biomarker protein MCM5 (Minichromosome Maintenance Complex Component 5) in the urine which is present when cells grow uncontrollably.
- Normal, healthy cells ‘switch off’ and stop growing. These cells, such as those lining the endometrial wall or the bladder are shed into secretions, but do not contain MCM5. However, cells which continue to grow and cause cancer do contain MCM5.
- If the tests cannot detect MCM5 in the urine it is highly likely that cancer is not present. If urologists and oncologists do suspect cancer, they can then investigate further, using cystoscopy for bladder and tissue biopsy for endometrial.
- **ADXGYNAE**, currently in the clinical trial phase, is a highly accurate, simple, fast and painless urine testing kit which can rule out endometrial cancer with up to 99% accuracy.¹
- The test takes just 2.5 hours once in the lab and urologists will typically get the results back in a number of days.



About Endometrial Cancer (Womb or Uterine cancer)

- Each year in the UK around 9,400 women are diagnosed with endometrial cancer and this is projected to continue to rise. This makes it the fourth most common cancer in women in the UK - and the sixth most common globally - and the incidence and prevalence continues to rise each year.^{2,3}
- There are around 2,300 uterine cancer deaths in the UK every year and 89.5% of women diagnosed with uterine cancer survive their disease for one year. Approximately 75.6% of women survive their disease for five years or more.²

About Arquer

- Arquer Diagnostics is a UK-based company committed to manufacturing and marketing innovative, non-invasive cancer tests for diagnosis and monitoring, whose tests are supported by highly regarded experts at leading international organisations
- The Endometrial cancer clinical development programme is supported by European and US medical advisory boards.

About [Manchester University NHS Foundation Trust \(MFT\)](#)

- Manchester University NHS Foundation Trust is one of the largest NHS Trusts in the country and a leading provider of specialist healthcare services. Its nine hospitals are home to hundreds of world class clinicians and academic staff committed to finding patients the best care and treatments.

REFERENCES

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