





Imaging with 99mTc-Maraciclatide Correlates with Identification of Early-Stage Endometriosis by Laparoscopic Surgery

London, UK, 15 March 2024. Serac Healthcare Limited ("Serac Healthcare" or "the Company"), a clinical radiopharmaceutical company developing an innovative molecular imaging agent, and the Nuffield Department of Women's and Reproductive Health at the University of Oxford announce that preliminary data has been presented from the "Detecting Endometriosis expressed integrins using technetium-99m" (DETECT) imaging study, indicating that ^{99m}Tc-maraciclatide is capable of imaging superficial peritoneal endometriosis, the earliest stage of the disease. The data was presented today by Dr Tatjana Gibbons, an investigator on the study from the University of Oxford, in an oral presentation at the Society for Reproductive Investigation (SRI) annual meeting taking place from 12-16 March 2024 in Vancouver, Canada.

The presentation summarised the preliminary findings from patients with known or suspected endometriosis who were imaged with a SPECT-CT camera and subsequently underwent planned laparoscopic surgery, a key-hole surgical procedure to establish the presence, absence and location of endometriotic lesions. The imaging findings were compared to the surgical and histology reports and indicate that ^{99m}Tc-maraciclatide holds potential as a non-invasive test for early-stage endometriosis.

Specifically, these preliminary findings demonstrate that ^{99m}Tc-maraciclatide has the potential to:

- Visualise superficial peritoneal endometriosis which is found in the thin peritoneum lining which covers the abdomen and pelvis, and currently can only be identified accurately by surgery. This subtype accounts for c. 80% of all endometriosis diagnoses. In the patients in this study ^{99m}Tc-maraciclatide correctly identified superficial peritoneal endometriosis in those who went on to have this early-stage endometriosis confirmed by laparoscopy
- Highlight areas of activity in patients with deep endometriosis (often found on the organs e.g., bladder, bowel, rectum, ovaries) and endometrioma (cysts which are commonly found in the ovaries)

The presentation also outlined a case study on one patient with superficial peritoneal endometriosis which had not been identified by ultrasound, but which had been visualised with ^{99m}Tc-maraciclatide and later confirmed by laparoscopic surgery.

The ongoing study which will recruit 20-25 patients in total is being led by Professor Christian Becker, Co-Director of the Endometriosis CaRe Centre in Oxford, together with Professor Krina Zondervan, Head of Department at the Nuffield Department of Women's and Reproductive Health, University of Oxford. It is anticipated that the study will complete later this year.

 99m Tc-maraciclatide is a radio-labelled tracer which binds with high affinity to the cell adhesion protein $\alpha_v\beta_3$ integrin and images angiogenesis (new blood vessel formation) which is known to be critical to the establishment and growth of endometriotic lesions.

David Hail, Chief Executive Officer of Serac Healthcare, said:

"These promising initial findings indicate that there is real potential for maraciclatide as a novel non-invasive method of diagnosing early-stage endometriosis. The ability to visualise the early stage of this disease is particularly significant as it cannot be seen by other imaging modalities, which contributes to the almost nine year average delay to secure a diagnosis. We are hugely encouraged by these results and look forward to continuing this work with the world-leading specialists from Oxford University."

Professor Christian Becker, Co-Director of the Endometriosis CaRe Centre in Oxford added: "Endometriosis is a common disease affecting many millions of women worldwide with pain and infertility. The current delay in diagnosis results in prolonged suffering and uncertainty. Therefore, a novel imaging tool to assist healthcare professionals in identifying or ruling out the disease is urgently needed."

Professor Krina Zondervan, Head of Department at the Nuffield Department of Women's and Reproductive Health, University of Oxford added:

"Superficial peritoneal endometriosis is the most prevalent form of the disease. It often affects younger women for whom earlier diagnosis could enable intervention at an earlier stage, with the potential to significantly change outcomes and improve prospects. At the Endometriosis CaRe Centre at the University of Oxford our studies focus on identifying novel genetic, diagnostic and therapeutic targets for endometriosis. We are delighted about the early results of the DETECT study and are looking forward to recruiting more patients to consolidate the data."

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Maraciclatide is for investigational use only and is not approved by the FDA or UK and European regulatory authorities.

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Notes to Editors

About Serac Healthcare Ltd

Serac Healthcare is a clinical radiopharmaceutical company with deep expertise in discovering, developing and commercialising innovative molecular imaging technologies. Using these targeted technologies to underpin personalised medicine in the fields of endometriosis and inflammatory arthritis, Serac Healthcare is focused on bringing to market effective tools to accelerate diagnosis, and to deliver earlier and more effective treatment decisions. Serac Healthcare Ltd is a wholly owned subsidiary of Serac Life Sciences Limited.

About Nuffield Department of Women's & Reproductive Health

The Nuffield Department of Women's & Reproductive Health (NDWRH) at the University of Oxford is a pioneering institution with a rich legacy dating back to 1937; and stands as a vanguard of excellence in perinatal research and clinical practice.

Our vision is clear: a world where everyone enjoys high-quality, evidence-based women's and reproductive healthcare. Through cutting-edge research and transformative teaching, we're committed to elevating the standard and accessibility of women's healthcare worldwide.

For further information about NDWRH and its ground breaking initiatives, please visit https://www.wrh.ox.ac.uk

About 99mTc-maraciclatide

 99m Tc-maraciclatide is a radio-labelled tracer which binds with high affinity to the cell adhesion protein $\alpha_{v}\beta_{3}$ integrin and images angiogenesis (new blood vessel formation). Clinical trials in a range of conditions, including breast cancer, bone metastases and rheumatoid arthritis, in which angiogenesis plays a key role, have shown the agent to perform as expected and be well tolerated. Angiogenesis is also known to be critical to the establishment and growth of endometriotic lesions.

About endometriosis

Endometriosis is a common inflammatory disease that affects up to one in 10 women of childbearing age, about 190 million women worldwide. Endometriosis occurs when tissue similar to the lining of the uterus is found outside the uterus, predominantly in the pelvis, but sometimes also elsewhere in the body, e.g. lungs. The presence of this ectopic endometrial tissue can lead to inflammation and distortion of normal anatomy, which can cause significant pain and infertility. The diagnostic journey in those with endometriosis typically results in numerous visits to physicians and hospitals, along with multiple scans.

About the DETECT study

The study is jointly sponsored by the Oxford Endometriosis CaRe Centre and the Nuffield Department of Women's and Reproductive Health, Oxford University, and funded by Serac Healthcare Ltd who are providing the experimental imaging marker ^{99m}Tc-maraciclatide. Further details are available on ClinicalTrials.gov <u>here.</u>

About the Society for Reproductive Investigation Meeting: www.sri-online.org/meetings-calendar/2024