Serac Healthcare Announces Successful FDA End of Phase II Meeting for Endometriosis Imaging Agent
- Positive Feedback on Phase III Trial Design -

London, UK, 5 February 2025. Serac Healthcare Limited ("Serac Healthcare" or "the Company"), a clinical radiopharmaceutical company developing an innovative molecular imaging agent, today announced positive feedback from its End of Phase II Meeting with the US Food and Drug Administration (FDA) for the development of ^{99m}Tc-maraciclatide as a diagnostic agent for use with single-photon emission computed tomography (SPECT-CT) for the visualisation and diagnosis of superficial peritoneal endometriosis (SPE) in women aged 16 years of age and older.

Initial Phase II findings indicate that ^{99m}Tc-maraciclatide has potential as a non-invasive test for the detection of SPE. SPE is not well visualised with current non-invasive imaging tools (ultrasound and MRI) and definitive diagnosis requires laparoscopy. The planned Phase III study will compare the findings from women undergoing laparoscopic surgery for endometriosis with imaging using ^{99m}Tc-maraciclatide and SPECT-CT prior to surgery.

The FDA feedback on the Phase III study design follows their review of the Phase II results and builds on the grant of Fast Track Designation to ^{99m}Tc maraciclatide in July 2024 as a diagnostic agent for use with SPECT-CT for the visualisation and diagnosis of SPE in women of 16 years and older.

David Hail, Chief Executive of Serac Healthcare, commented,
"We are delighted with the outcome of our End of Phase II Meeting with the FDA which provides us with a clear development path for maraciclatide. We are looking forward to finalising the Phase III protocol with the FDA."

"Chronic pain, fertility issues and depression are just some of the consequences that one in ten women with endometriosis are living with every day. A non-invasive test, particularly for early-stage disease which cannot easily be visualised by other imaging methods, and which accounts for eighty per cent of diagnoses by laparoscopic surgery, is desperately needed by the 190 million women worldwide suffering from this debilitating condition."

The company is now finalising the protocol and will be working with the FDA to prepare for the start of the Phase III program.

-ENDS-

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

For more information, please contact:

Serac Healthcare Ltd	www.serachealthcare.com
David Hail, Chief Executive Officer	+44 (0)208 948 0000 info@seraclifesciences.com
Francetta Carr, Communications Director	+44 (0)7711 010820 francettacarr@seraclifesciences.com

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 ^{99m}Tc-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) which is known to be critical to the establishment and growth of endometriotic lesions.

About FDA Fast Track Designation

The FDA Fast track is intended to facilitate the development and expedite the review of drugs to treat (or in our case, diagnose) serious conditions and fill an unmet medical need. Criteria include improving the diagnosis of a serious condition where early diagnosis results in an improved outcome.