^{99m}Tc-maraciclatide Granted FDA Fast Track Designation for the Visualization of Inflammation in Interstitial Lung Disease

London, UK, 12 Feb, 2026. Serac Healthcare Limited, a clinical radiopharmaceutical company developing an innovative molecular imaging agent, announced today that the US Food and Drug Administration (FDA) has granted Fast Track Designation to ^{99m}Tc-maraciclatide as a diagnostic SPECT-CT agent for the "visualization of inflammation in the lungs of patients with known and suspected interstitial lung disease (ILD)."

Fast track is a process designed 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.

ILD is a life-threatening condition encompassing over 200 disorders affecting lung function, characterized by progressive inflammation, fibrosis, and reduced quality of life. Accurate, early differentiation between inflammation and fibrosis is critical to guiding treatment decisions, predicting disease outcomes, and monitoring therapy response, yet this is currently very difficult or impossible to assess.

The benefits of Fast Track designation, which are intended to reduce the time to approval in the US and enable faster access for patients, include:

- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met
- More frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials
- Rolling Review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed.

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

"The FDA's Fast Track designation of maraciclatide signals the imperative for improved ILD diagnosis, assessment, and monitoring. ILD symptoms are non-specific and often present late in disease progression, making early detection extremely difficult. While symptom management therapies are available, including powerful anti-inflammatory agents, inappropriate administration can prove more detrimental than beneficial. A non-invasive imaging solution capable of distinguishing inflammation and fibrosis predominant ILD has the potential to meaningfully advance early diagnosis, change the treatment paradigm and improve patient outcomes."

About ^{99m}Tc-maraciclatide

^{99m}Tc-maraciclatide is a radio-labelled tracer which binds with high affinity to $\alpha_v\beta_3$ integrin, a cell-adhesion molecule which is up-regulated in vascular endothelial cells during angiogenesis, a key biological process that occurs during inflammation.

Phase II preliminary data from the PRospective Evaluation of Interstitial Lung Disease progression with quantitative CT (PREDICT-ILD)' trial have demonstrated that visualisation of inflammation in people with fibrotic-ILD could be feasible with ^{99m}Tc-maraciclatide. Further clinical results will be published later this year.

-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	+44 (0)20 8948 0000 info@seraclifesciences.com
Francetta Carr, Communications	+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 precision medicine in the fields of endometriosis, inflammatory arthritis and interstitial lung disease, 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 Fast Track designation

https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

About Interstitial Lung Disease

Interstitial lung disease (ILD) encompasses over 200 disorders affecting lung function, characterized by progressive inflammation, fibrosis, and reduced quality of life. With an estimated 650,000 cases in the United States and a life expectancy of three to five years for patients with the most severe forms, ILD represents a significant unmet medical need.

Current treatment efficacy hinges on the balance between inflammation and fibrosis. While anti-inflammatory therapies can be effective when inflammation predominates, they offer limited benefit, and can be detrimental, once fibrosis is established. Compounding this challenge, ILD symptoms are nonspecific and often present late in disease progression, making early detection difficult. Accurate, early differentiation between inflammation and fibrosis is critical to guiding treatment decisions, predicting disease outcomes, and monitoring therapy response.

Further details on the PREDICT-ILD study, including a poster presented at the European Respiratory Society congress in Sept 2025, can be found here: https://www.serachealthcare.com/wp-content/uploads/2025/09/9_29_25-SHC-PR-PREDICT-ERS-FINAL.pdf

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 a key biological process that occurs during inflammation. Clinical trials in a range of conditions in which angiogenesis plays a key role have shown the agent to perform as expected and be well tolerated:

- Preliminary results from an ongoing Phase II study (PREDICT) have shown that ^{99m}Tc-maraciclatide reveals increased activity in patients with interstitial lung disease (ILD) compared to healthy controls.
- In a Phase II trial (DETECT), maraciclatide has demonstrated a high correlation between locations of uptake identified on SPECT-CT and laparoscopy across all types of endometriotic lesions, including superficial peritoneal endometriosis, which is not well visualised with existing non-invasive imaging techniques.
- In a Phase II study (INIRA), maraciclatide uptake in the inflamed synovium of hand and wrist joints of 50 patients with rheumatoid arthritis was highly correlated with power Doppler ultrasound images (PDUS).