

Phase II PREDICT-ILD Imaging Study Commences in Interstitial Lung Disease

London, UK, 10 September 2024, Serac Healthcare Limited (“Serac Healthcare” or “the Company”), a clinical radiopharmaceutical company developing innovative molecular imaging technologies, and the University of Exeter today announce that the first patient has been scanned with a novel molecular SPECT imaging agent ^{99m}Tc-maraciclalide in a Phase II study titled ‘Prospective Evaluation of Interstitial Lung Disease progression with quantitative CT (PREDICT-ILD)’.

The primary objective of the ongoing main study is to evaluate the efficacy of quantitative computed tomography (CT) for the detection of interstitial lung disease (ILD) progression. A sub-study has now commenced evaluating ^{99m}Tc-maraciclalide as an imaging marker for disease prognostication in a subset of PREDICT-ILD participants. PREDICT-ILD is currently recruiting patients across three NHS sites in the south-west: North Bristol NHS Trust (NBT), Royal United Hospitals (RUH) NHS Foundation Trust and Royal Devon University Healthcare NHS Foundation Trust.

Co-chief investigators on the study, which is being run by the University of Exeter, a world-leading research centre for lung disease, are Professor Chris Scotton, Associate Professor in Respiratory Biomedicine, and Dr Giles Dixon, Senior Clinical Research Fellow, both at the University of Exeter. PREDICT-ILD is majority funded by the Wellcome Trust GW4-CAT HP PhD Programme for Health Professionals.

To assess the primary endpoint in the sub-study examining the feasibility of using ^{99m}Tc-maraciclalide to evaluate disease activity, the uptake of the imaging agent will be compared between participants with idiopathic pulmonary fibrosis (IPF) and non-IPF fibrosing-ILD and age, sex and ethnicity matched healthy controls. Secondary endpoints include the evaluation of the ability of ^{99m}Tc-maraciclalide to identify $\alpha_v\beta_3$ activity and to predict disease progression in participants with fibrosing ILD. Sixty-nine participants will be recruited in total, 15 of these in the sub-study.

Interstitial lung diseases are a heterogeneous group of over 200 irreversible conditions with varying degrees of inflammation that, without treatment, lead to scarring (fibrosis) of the lining of the lungs. It affects more than 150,000 people in the UK, with an incidence of 2,000-4,000 and causes significant morbidity and mortality. It is estimated that lung scarring results in 1% of deaths in the UK. ILD progression is unpredictable, making prognostication challenging and creating barriers to effective drug development. Therapies are available that can slow disease progression in some patients, however current limitations in diagnosis mean that determining the most suitable treatment is challenging, and prescribing the wrong treatment can make the condition worse. For example, certain medications are known to be effective at treating inflammation (which can be a feature of this disease) but can be detrimental in patients with fibrotic disease. Understanding the mechanisms that drive the progression of ILD is an urgent research priority.

David Hail, Chief Executive of Serac Healthcare commented:

“The distinction between ILD conditions which are characterised by scarring and inflammation is crucial as this determines the appropriate treatment. A molecular imaging marker with the potential to differentiate between early-stage inflammation and the fibrosis it causes could have a significant impact on improving patient outcomes, as well as the development of new therapies. We are looking

forward to working with the University of Exeter to evaluate maraciclalide’s potential in this new indication.”

Professor Michael Gibbons, Senior Investigator Fellow, NIHR Exeter Biomedical Research Centre, Consultant Respiratory Physician, Royal Devon University Healthcare NHS Trust, and Clinical Lead on the study said:

“Being able to detect disease progression sooner and thereby enabling earlier access to disease modifying treatments to appropriate patients would represent a step change in the treatment of this incurable condition. We are excited to be working with Serac Healthcare to evaluate whether maraciclalide could play a part to bring precision medicine to this patient population.”

The sub-study is being facilitated by the Nuclear Medicine Department at the RUH, Bath and is supported by specialist radiologists Dr David Little and Dr Jonathan Rodrigues and specialist ILD physicians Dr Shaney Barratt and Professor Michael Gibbons. The study is also supported by the University of Exeter’s EPSRC Hub for Quantitative Modelling in Healthcare under the guidance of Professor Krasimira Tsaneva-Atanasova. Dr Michael Gibbons is also a Senior Investigator Fellow at the [NIHR Exeter Biomedical Research Centre](#).

-ENDS-

^{99m}Tc-maraciclalide is for investigational use only and is not approved by the FDA or UK and European regulatory authorities.

For more information, please contact:

David Hail, Chief Executive Officer

+44 (0)208 948 0000
info@seraclifesciences.com
www.serachealthcare.com

Francetta Carr, Communications

+44 (0)7711 010 820
francettacarr@seraclifesciences.com

University of Exeter Press Office

+44 (0)1392 722405 or 722062
pressoffice@exeter.ac.uk

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 to accelerate diagnosis, improve monitoring and enable earlier and more effective treatment decisions. Serac Healthcare is using these targeted technologies to underpin personalised medicine in two primary indications: endometriosis and inflammatory arthritis; a pilot study is also underway in interstitial lung disease. Serac Healthcare is a wholly owned subsidiary of Serac Life Sciences Limited.

About ^{99m}Tc-maraciclalide

^{99m}Tc-maraciclalide is a radio-labelled tracer which binds with high affinity to $\alpha_v\beta_3$ integrin, a cell-adhesion molecule which is up-regulated on activated vascular endothelial cells, activated

macrophages and osteoclasts. Maraciclatiside has already been shown to successfully image inflammation in patients with rheumatoid arthritis. In a Phase II study (INIRA), maraciclatiside uptake in the inflamed synovium of hand and wrist joints of 50 patients was highly correlated with power Doppler ultrasound images (PDUS).

Details on the PREDICT-ILD study can be found at www.clinicaltrials.gov: NCT05609201

About the University of Exeter

The University of Exeter is a Russell Group university that combines world-class research with high levels of student satisfaction. Exeter has over 30,000 students and sits within the Top 15 universities in The Complete University Guide 2025, and tenth in the world in the Times Higher Education (THE) Impact Rankings. In the 2021 Research Excellence Framework (REF), more than 99% of our research were rated as being of international quality, and our world-leading research impact has grown by 72% since 2014, more than any other Russell Group university.

www.exeter.ac.uk