To whom it may concern,

19 January 2022

Re: End of Trial justification for the Study LMT-01-02-18

Study Title:	**An open label, single centre study, to evaluate the safety and imaging characteristics of [^{18}F]PI-2620 as PET radioligand for imaging tau deposition in the brains of subjects with amnestic mild cognitive impairment (aMCI) and mild to moderate Alzheimer's Disease (AD) in comparison with non-demented controls**
Study Protocol No.:	**LMT-01-02-18**
IRAS Project ID:	**254854**
REC Reference:	**19/EE/0193**
EudraCT No.:	**2018-003891-11**
MHRA No.:	**51487/0001/001**

Dear Sir or Madam,

Life Molecular Imaging SA, Sponsor of the above-mentioned study, would like to inform you that the trial has been terminated as of today, 19 January 2022.

The study was halted temporarily for an undetermined period as per Substantial Amendment 2 and covering letter to the MHRA (dated 18 December 2020 and submitted 24 December 2020) and to the ethics committee (dated 18 December 2020 and submitted 12 January 2021), due to a number of factors including the COVID-19 pandemic. The COVID situation was not supporting the recruitment of participants and the running of the clinical trial in appropriate conditions. The COVID situation was also impeding the routine production of the study drug, [^{18}F]PI2620, as needed for supply of this study.

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To date, these challenges continue impacting the study and prevent any progress of the study. As a consequence of the uncertain recruitment in the face of COVID, results from this study will not be obtained in a timely manner. Moreover, the inconveniences and risks to the subjects and their caregivers, including travelling to central London, can no longer be justified for this observational study. The Sponsor has therefore decided to close the study and begin study termination activities.

The early termination of this study is explicitly not due to safety concerns or a change in the Sponsor's risk benefit assessment. The sponsor's risk benefit assessment has not changed and will not change due to the early termination of the study.

No [^{18}F]PI-2620-related data has been collected as part of that study. However, clinical development of [^{18}F]PI-2620 is ongoing in other countries and the Sponsor expects that data from other studies will compensate for the data not collected in the above mentioned study.

In total, three non-demented control subjects signed informed consent for the study and initiated screening procedures. These subjects have not been enrolled into the study and have not received [^{18}F]PI-2620. An unavailability of [^{18}F]PI-2620 due to manufacturing issues resulted in a closing of the screening windows for these subjects. The early termination of the study has no impact on the subjects who were included as their participation had already stopped.

We remain at your disposal if you require any further information.

Sincerely yours,

[redacted]

On behalf of the sponsor,

[redacted] MD, PhD

Chief Medical Officer

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