



5 Aug 2021

RE: Premature closure of study MT_3724_NHL_001

To whom it may concern and engaged in the conduct of study MT-3724_NHL_001, titled “Safety, Pharmacodynamics, and Efficacy of MT-3724 for the Treatment of Patients with Relapsed or Refractory DLBCL”:

On 19 March 2021, the FDA placed all MT-3724 IND clinical study protocols on a full hold and requested additional information. Due to the significant time needed to address the FDA requests, MTEM closed the conduct of study MT-3724_NHL_001 in all countries. No MT-3724_NHL_001 subjects were receiving treatment with MT-3724 at the time of the decision to close the study.

Study MT-3724_NHL_001 was planned to be completed in four parts. Parts 1 and 2¹, considered to be a Phase 1/1b of the study, were completed at the time of study closure and a full clinical study report (CSR) was prepared. Part 3 was ongoing at the time of study closure (aborted study) and only an abbreviated CSR will be prepared aligned with ICH E3 and including a full description of safety. Part 4 of the study was never initiated and no clinical study report will be prepared for this part.

Digitally signed by 


Date: 2021.08.05 09:14:55
-04'00'

Vice President, Regulatory Affairs
Molecular Templates, Inc.

¹ Protocol title for Part 1 and 2: Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of Multiple Dose Regimens of MT-3724 for the Treatment of Patients with Relapsed non-Hodgkin’s B-Cell Lymphoma and B-Cell Chronic Lymphocytic Leukemia