

End of Trial Declaration (Early Termination)

Investigational Product: FL-101

Protocol Number: FL-101-2001

Protocol Title: “A Two-cohort, Phase 2 Study of FL-101 as Neoadjuvant Therapy in Patients with Surgically Resectable Non-Small Cell Lung Cancer”

EudraCT number: 2020-005602-26

Novartis recently released top line results from its CANOPY-1 trial (a phase III study of pembrolizumab plus platinum-based doublet chemotherapy with or without canakinumab in previously untreated locally advanced or metastatic non-squamous and squamous NSCLC subjects), which did not meet its primary endpoints of OS and PFS in first line NSCLC patients treated with another IL-1beta therapy, canakinumab. These results arrived a few months after the read out of canakinumab’s second line trial CANOPY-2, which also did not succeed.

Such results along with the changing landscape in the neoadjuvant NSCLC space (e.g., CHECKMATE 816) led the Sponsor to receiving feedback from a number of sites/investigators that this trial would be very difficult to conduct without significant changes. Based on such developments, and with regret, Flame Biosciences decided to terminate the FL-101-2001 trial early, with immediate effect.

All study investigator/participating sites have been informed of this early termination (23-Nov-2021).

This early termination is not the result of any safety findings. No patients were recruited into the study, in any country.