

To:

Subject:

## SECOMBIT

"Sequential Combo Immuno and Target therapy (SECOMBIT) study"

*"A three arms prospective, randomized phase II study to evaluate the best sequential approach with combo immunotherapy (ipilimumab/nivolumab) and combo target therapy (LGX818/MEK162) in patients with metastatic melanoma and BRAF mutation"*

<b>Protocol Code:</b>	SECOMBIT
<b>EudraCT number:</b>	2014-004842-92
<b>Phase:</b>	II
<b>Sponsor:</b>	Fondazione Melanoma (ONLUS) c/o Istituto Tumori Napoli - Fondazione "G. Pascale" Via Mariano Semmola 80131 Naples, Italy
<b>Coordinating Investigator:</b>	Dr. Paolo Antonio Ascierto

Naples, 29 October 2021

This supplement contains the following items:

1. Original protocol v. 1.0 dated 15 October 2015, final protocol v. 10.0 dated 03 May 2021, summary of changes of intermediate versions,
2. Final statistical analysis plan v. 1.0 dated 22 October 2021.

Faithfully

Dr. Paolo A. Ascierto

