STUDY SUMMARY

Title	Thymosin alpha 1 plus maintenance therapy with the Standard of Care (SoC) chemotherapy plus cisplatin (or carboplatin) in patients with metastatic Non-Small Cell Lung Cancer (NSCLC), EGFR wild type
Code	SCI-Ta1-NSCLC-CHEMO P2-001
EudraCT n.	2015-005605-36
Sponsor	SciClone Pharmaceutical
PI coordinator	Prof. Paolo Marchetti. Sant'Andrea Hospital, Rome

Primary Objective

To evaluate the activity/efficacy in terms of PFS of Thymosin alpha 1 in patients with metastatic, non-small cell lung cancer (NSCLC), EFGR wild type, taking SoC chemotherapy as compared to SoC alone.

Inclusion Criteria	✓ Age 18 years or older ✓ Histological or cytological confirmation of NSCLC EGRF wild type (either from initial diagnosis of NSCLC or subsequent biopsy). Only patients with available tissue samples will be enrolled ✓ Locally advanced or metastatic NSCLC, not amenable to curative surgery or radiotherapy ✓ Measurable disease by Response Evaluation Criteria in Solid Tumours (RECIST) in a lesion not previously irradiated or non-measurable disease ✓ Eastern Cooperative Oncology Group - performance status (ECOG-PS) 0-2 ✓ Absolute neutrophil count (ANC) > 1.5 x 10^9/liter (L) and platelets > 100 x 10^9/L ✓ Bilirubin level either normal or <1.5 x ULN ✓ AST (SGOT) and ALT (SGPT) <2.5 x ULN (≤ 5 x ULN if liver metastases are present) ✓ Serum creatinine <1.5 x ULN ✓ Effective contraception for both, male and female pts, if the risk of conception exists ✓ Recovery from all acute toxicities of prior therapies ✓ Provision of written informed consent

Exclusion Criteria	✓ Prior therapy with Thymosin alpha-1 ✓ Newly diagnosed central nervous system (CNS) metastases that have not yet been treated with surgery and/or radiation. Pts with previously diagnosed and treated CNS metastases or spinal cord compression may be considered if they have evidence of clinically stable disease (SD) (no steroid therapy or steroid dose being tapered) for at least 28 days ✓ Pregnancy or suspected pregnancy ✓ Any unresolved chronic toxicity from previous anticancer therapy that, in the opinion of the investigator, makes it inappropriate for the patient to be enrolled in the study ✓ Known severe hypersensitivity to study drugor any of the excipients of this product ✓ Other co-existing malignancies or malignancies diagnosed within the last 5 years with the exception of basal cell carcinoma or cervical cancer in situ ✓ Any evidence of clinically active interstitial lung disease (ILD) (patients with chronic, stable, radiographic changes who are asymptomatic or patients with uncomplicated progressive lymphangiticcarcinomatosis need not be excluded) ✓ As judged by the investigator, any evidence of severe or uncontrolled systemic disease (e.g., unstable or uncompensated respiratory, cardiac, hepatic or renal disease) ✓ As judged by the investigator, any inflammatory changes of the surface of the eye ✓ Evidence of any other significant clinical disorder or laboratory finding that makes it undesirable for the patient to participate in the study

Drug Formulation:	Thymosin alpha 1 is contained, stored, and dispensed from individual tamper-proof glass vials with 1.6 mg Thymosin alpha 1 as a lyophilized cake containing 5% mannitol, buffered with phosphate to pH 6.4-7.3.Vials are reconstituted with 1 mL of supplied diluent (sterile water for injection), prior to subcutaneous (SC) administration.
Dose and Mode of Administration:	**Approximately 140 patients:** Arm A: 70 patients will receive Thymosin alpha 1 in 1mL SC injection five time a week (first four months); then two

	time a week for eight months. SoC chemotherapy and cisplatin (or carboplatin) for twelve months. Arm B: 70 patients (control group) will receive SoC chemotherapy and cisplatin (or carboplatin) for twelve months.
Duration of Treatment:	12 months

Efficacy Endpoints:	**Primary endpoint** Time to progression free survival (PFS) **Secondary endpoint(s):** • time to Overall Survival (OS); • Quality of Life (QoL); • organ failure free days; • biomarkers of immunity and inflammation.
Safety Endpoints:	Adverse events, serious adverse events (SAEs),vital signs, electrocardiograms (ECGs) and laboratory parameters

Start date: February, 1st 2017

End Date: October 1st, 2017

Reasons for discontinuation

Lack of recruitment. Since October 1st, only 4 patients was enrolled into the study (3 in Sant'Andrea Hospital and 1 in Albano Laziale Hospital) ; 3 of them in control group and 1 in IMP (Thymosin alpha1) group.

Rome, December 1st 2018

Carlo Tomino (study coordinator)