

Note to File 3

Official Title: A Phase III, Open label, Randomized, Multi-center Study of the Effects of Leukocyte Interleukin, Injection [Multikine] Plus Standard of Care (Surgery + Radiotherapy or Surgery + Concurrent Chemoradiotherapy) in Subjects with Advanced Primary Squamous Cell Carcinoma of the Oral Cavity / Soft Palate Versus Standard of Care Only

NCT Number: NCT01265849

Date: 28 March 2021

March 28, 2021

CEL-SCI Clinical Study CS001P3

Note To File #3

The current SAP does not address survival measured from the date of first documented progression.

For those patients with documented progression at any time on study, the following additional tables and figures will be generated.

The following tables and figures will be added to the SAP:

Tables:

- Cox PH measured from first documented progression: ITT, TCI C
- Cox PH measured from first documented progression: ITT, TCI E
- Cox PH measured from first documented progression: eITT, TCI C
- Cox PH measured from first documented progression: eITT, TCI E
- Cox PH measured from first documented progression: ePP, TCI C
- Cox PH measured from first documented progression: ePP, TCI E

The Cox PH models will each contain terms for Stage, Location, Geographic Region, and Treatment with the same referent terms per covariate. The same treatment comparisons will be performed (Multikine + CIZ + SOC vs. SOC and Multikine + CIZ + SOC vs. Multikine + SOC) as for the other Cox PH analyses.

Figures:

- K-M Survival measured from first documented progression: ITT, TCI C
- K-M Survival measured from first documented progression: ITT, TCI E
- K-M Survival measured from first documented progression: eITT, TCI C
- K-M Survival measured from first documented progression: eITT, TCI E
- K-M Survival measured from first documented progression: ePP, TCI C
- K-M Survival measured from first documented progression: ePP, TCI E

These tables and figures are considered to be prospective in that the SDTM databases have not been finalized and none of the above analyses have been performed.

Signatures:

Yaping Cai

Yaping Cai
30 Mar 2021 17:04:059+0000

REASON: I approve this document

5847fe6f-1cee-4c47-ac55-feff592129f2

Yaping Cai

ICON plc

Phil Lavin

Phil Lavin
30 Mar 2021 17:36:055+0000

REASON: I approve this document as author.

81797106-ad47-4969-9923-72071d5c68a9

Philip Lavin PhD, FASA, FRAPS
Lavin Consulting LLC
(CEL-SCI Statistical Consultant)

Eyal Talor

Eyal Talor
30 Mar 2021 16:41:005+0000

REASON: I approve this document

5a7c1b19-989b-4b38-8dd9-45225e5fa404

Eyal Talor PhD

CEL-SCI Corp

John Cipriano

John Cipriano
30 Mar 2021 16:48:042+0000

REASON: I approve this document

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John Cipriano

CEL-SCI Corp