

Note to File 4

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: 30 March 2021

March 30, 2021

CEL-SCI Clinical Study CS001P3

Note To File #4

The current SAP Section 7.2 states the following censoring rule. For the ITT population analysis for TCI E, all randomized subjects will be included based on any follow-up post-randomization through study exit. To include all subject follow-up, we will drop this censoring rule.

Condition	Date of Censoring
Randomized and not treated	Date randomized

Signatures:

Yaping Cai

Yaping Cai
30 Mar 2021 18:22:035+0000

REASON: I approve this document
5847fe6f-1cee-4c47-ac55-feff592129f2

Yaping Cai
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REASON: I approve this document
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Phil Lavin

Phil Lavin
30 Mar 2021 18:37:054+0000

REASON: I have reviewed this document and have no comments that require addressing.
81797106-ad47-4969-9923-72071d5c68a9

Philip Lavin PhD, FASA, FRAPS
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John Cipriano

John Cipriano
30 Mar 2021 18:25:027+0000

REASON: I approve this document
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John Cipriano
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