

Lion the first beneficiary of NCI's trial resumption



[Jacob Plieth](#)

The suspension of 13 cell therapy studies at the US National Cancer Institute in April cast uncertainty on their corporate partners, but less than three months later, and with little fanfare, five have resumed patient enrolment.

This is good news for Lion Biotechnologies, as the five include all three of the tumour-infiltrating lymphocyte studies that are subject to a co-operative R&D agreement it has with the NCI. Four trials for which Kite Pharma has a separate CRADA remain suspended, but should reopen within three months, an NCI spokesperson told *EP Vantage*.

This means that the suspensions look to have been less serious than had been suspected at the time. [In April the NIH said](#) the move was due to follow-up from an earlier finding of serious problems with sterile manufacturing processes, and concerned an NCI cell therapy lab as well as a facility at the National Institute of Mental Health.

Of course, because CRADAs are arm's-length arrangements that do not involve a formal licence with a corporate entity, Kite and Lion were able to shrug the suspensions off. Nevertheless, Kite stock was hit amid confusion over disclosure of the halts as well as underwhelming data presented at the AACR meeting ([AACR – Mage-A3 double-whammy hits Kite, April 17, 2016](#)).

Lion said the suspensions did not affect its own manufacturing capabilities for tumour-infiltrating lymphocyte (TIL) therapy, as these relied on agreements with Lonza and WuXi AppTec. However, this only told half the story since the suspension concerned the lab of Dr Steven Rosenberg and included the TIL project Lion had accessed under its CRADA.

This now becomes academic, as all three of Dr Rosenberg's TIL trials reopened for patient enrolment on June 17, said Shannon Hatch, an NCI spokesperson. "We expect the remaining eight trials to reopen for enrolment within three months," she added.

NCI cell therapy studies suspended in April 2016, now enrolling again

Detail	Company affiliation	Principal investigator	Trial ID
TILs + IL-2 alone or after Keytruda in 170 melanoma pts	CRADA with Lion Biotechnologies	Dr Steven Rosenberg	NCT02621021
Use of TILs in 85 NSCLC pts	CRADA with Lion Biotechnologies	Dr James Yang	NCT02133196
Use of TILs in 64 metastatic melanoma pts	CRADA with Lion Biotechnologies	Dr Steven Rosenberg	NCT01993719
Use of TILs in 290 pts with various solid tumours	None	Dr Steven Rosenberg	NCT01174121
Use of TILs in 57 pts with metastatic ocular or uveal melanoma	None	Dr Udai Kammula	NCT01814046

Lion investors might see this as another line drawn under various simmering problems. The company recently [raised \\$100m in a private placement](#), and [replaced its previous chief executive](#), Elma Hawkins, with Maria Fardis.

Meanwhile, Kite's focus remains on filing its lead CAR-T asset, KTE-C19, with the US FDA. Irrespective of the ongoing suspension of the NCI's Mage-A3 engineered TCR project, Kite's own studies of this asset are to begin

under an IND to be filed later this year.

The other two NCI projects to which Kite has access under a CRADA – a CAR against EGFRvIII and an engineered TCR targeting NY-ESO-1 – also remain suspended for now. Kite has had problems with these, and recently [downgraded them both to preclinical status](#), citing the need for “additional engineering”.

If the NCI’s studies do resume within three months this will not solve such issues, but it should at least remove some of the negative sentiment.

NCI cell therapy studies still suspended as at 4 July 2016

Detail	Company affiliation	Principal investigator	Trial ID
Engineered TCRs vs Mage-A3 in 16 HLA-DP0401-positive pts with various cancers	CRADA with Kite Pharma	Dr Steven Rosenberg	NCT02111850
Engineered TCRs vs Mage-A3 in 3 HLA-A01-positive pts with various cancers	CRADA with Kite Pharma	Dr Steven Rosenberg	NCT02153905
Engineered TCRs vs NY-ESO-1 in 7pts with various solid tumours	CRADA with Kite Pharma	Dr Steven Rosenberg	NCT01967823
CAR-T vs EGFRvIII in 18 malignant glioma pts	CRADA with Kite Pharma	Dr Steven Rosenberg	NCT01454596
CAR-T vs mesothelin in 15 pts with various cancers	None	Dr Steven Rosenberg	NCT01583686
Engineered TCRs vs human thyroglobulin in 68 thyroid cancer pts	None	Dr James Yang	NCT02390739
Use of TILs in 29 pts with HPV-associated cancers	None	Dr Steven Rosenberg	NCT01585428*
TILs cultured with pharmacologic inhibitor of AktKT in metastatic melanoma	None	Dr Steven Rosenberg	NCT02489266**

*Note: *marked as active, not recruiting; **study withdrawn prior to enrolment.*

Selected NCI cell therapy studies still suspended for unrelated reasons

Detail	Company affiliation	Principal investigator	Trial ID
CAR-T vs BCMA in 14 multiple myeloma pts	None*	Dr James Kochenderfer	NCT02215967
Donor-derived anti-CD19 allo CAR-T in 42 pts with B-cell malignancies	None	Dr James Kochenderfer	NCT01087294

*Note: *Dr Kochenderfer is primary investigator in a separate anti-BCMA CAR-T study of Bluebird Bio's bb2121.*

The tables in this story were updated on July 6. To contact the writer of this story email [Jacob Plieth](mailto:jacobp@epvantage.com) in London at jacobp@epvantage.com or follow [@JacobPlieth](https://twitter.com/JacobPlieth) on Twitter

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