

NewLink's pancreatic cancer candidate fails to Impress



[Madeleine Armstrong](#)

The phase III failure of NewLink Genetics' algenpantucel-L is not only a blow to the company, it also dashes hopes of getting a new pancreatic cancer therapy approved any time soon. Of the four pivotal trials in the disease that were due to read out this year, three have already fizzled out (see tables below).

The final study set for results in 2016 also involves algenpantucel-L, so is not looking too hopeful either. While other companies continue to try their luck in pancreatic cancer, NewLink's focus will shift to its IDO inhibitors indoximod and GDC-0919 - members of a new immuno-oncology class that is seeing increasing interest.

However, on a call to discuss the latest results, the company did not commit to dropping the HyperAcute cellular immunotherapy platform on which algenpantucel-L is based, instead saying it was evaluating its future. An announcement is expected in "weeks rather than months", according to its chief financial officer, Jack Henneman.

It seems likely that the platform will be wound down after algenpantucel-L's disastrous performance in Impress, which would also mean the end of NewLink's other HyperAcute programmes including its phase III non-small cell lung cancer vaccine tergenpumatumucel-L and phase II melanoma therapy dorgenmeltucel-L.

Shifting landscape

Earlier this year there was optimism in the pancreatic cancer space, with 10 phase III studies under way involving eight agents ([Pancreatic cancer 2016: this time it's \(getting\) personal](#), February 5, 2016).

But since then, two of these assets - Incyte's Jakafi and Immunomedics' Y-90 clivatuzumab - are no longer in development for pancreatic cancer after failing interim analyses. Algenpantucel-L now looks set to join them, unless it can pull off a positive result in the ongoing Pillar study, which has a primary completion date of December 2016.

Recent pancreatic cancer phase III setbacks				
Project	Company	Study	Status	Trial ID
Jakafi	Incyte	Janus-1	Discontinued Feb 2016	NCT02119663
Jakafi	Incyte	Janus-2	Discontinued Feb 2016	NCT02117479
Y-90 clivatuzumab	Immunomedics	Pancrit-1	Discontinued March 2016	NCT01956812
Algenpantucel-L	NewLink Genetics	Impress	Failed	NCT01072981

And a win in Pillar seems unlikely. In the Impress study algenpantucel-L did not achieve its primary goal of improving overall survival. In fact, median survival was longer in the placebo group, at 30.4 months, than in the treatment group, at 27.3 months. NewLink's stock opened down 33% today.

Algenpantucel-L is no doubt facing a downgrade now - it had been forecast to become the biggest-selling pancreatic cancer drug by 2022, according to *EvaluatePharma* sellside consensus.

There are several other agents in phase III, but most are not set to report results until 2017. Next up should be Gilead's momelotinib, but hopes are not high as it is a Jak inhibitor like Jakafi.

Past failures do not seem to be putting companies off the pancreatic cancer space, however. Recent entrants into pivotal trials include Halozyme's PEGPH20, which is being investigated in combination with Celgene's Abraxane and gemcitabine in previously untreated metastatic pancreatic cancer patients whose tumours have high levels of hyaluronan.

Meanwhile, AB Science has told *EP Vantage* that it has started a new European phase III study with its lead compound, Masican, in combination with gemcitabine, although this is not yet listed on clinicaltrials.gov.

Ongoing late-stage trials in pancreatic cancer				
Project	Company	Study	Trial ID	Primary completion
<i>Phase III</i>				
Momelotinib	Gilead Sciences	-	NCT02101021	July 2016
Algenpantucel-L	NewLink Genetics	Pillar	NCT01956812	Dec 2016
Glufosfamide	Eleison	-	NCT01954992	May 2017
Nanoplatin/NC-6004	Orient/Nanocarrier	-	NCT02043288	Jun 2017
Lynparza	AstraZeneca	Polo	NCT02184195	Oct 2017
PEGPH20	Halozyme	Halo-301	NCT02715804	Oct 2018
Gemcitabine +/- Masican	AB Science	-	N/A	Unknown
<i>Phase II/III</i>				
Imbruvica	AbbVie/J&J	Resolve	NCT02436668	Mar 2018

To contact the writer of this story email Madeleine Armstrong in London at madeleinea@epvantage.com or follow [@medtech_ma](https://twitter.com/medtech_ma) on Twitter

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Evaluate HQ
[44-\(0\)20-7377-0800](tel:44-020-7377-0800)

Evaluate Americas
[+1-617-573-9450](tel:+1-617-573-9450)

Evaluate APAC
[+81-\(0\)80-1164-4754](tel:+81-080-1164-4754)

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