

Tekmira

Around the time of the Ebola outbreak, before the first cases were confirmed/made public, came this announcement:

VANCOUVER, Jan. 14, 2014 GLOBE NEWSWIRE -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, today announced that it **has dosed** the first subject in a Phase I human clinical trial of TKM-Ebola, an anti-Ebola viral therapeutic that is being developed under a **US\$140 million contract** with the **U.S. Department of Defense**.

Nice money if you can get it! Since Anthrax, if your project has got anything to do with the non-existent threat of bioterrorism, then there's a bottomless pit of public money to support it.

Dr. Mark J. Murray, Tekmira's President and CEO: *Building upon our **compelling preclinical results**, the Phase I data generated will guide our determination of the appropriate dose of this drug for the potential use as a medical countermeasure against this lethal hemorrhagic fever virus. We remain on track to have data from this trial available in the second half of this year.*

Four things:

1. The trial was conducted in Sierra Leone
2. The compelling *preclinical* results claimed 100% efficacy in non-human primates - using the Zaire version of Ebola known as Kikwit-95 to infect macaques.
3. The data never did become available. Including details of how the trial subjects were tested or *tolerability* (adverse effects).
4. Tekmira experienced a huge stockmarket surge due to the drug x DoD deal.

Following the outbreak 2014, Tekmira tweaked their RNAi drug to target the Guinea version of Ebola, but the trial was unceremoniously halted due to a lack of efficacy.

Peter Horby, Oxford, study head (June 2015): *It is a great tribute to the team in Sierra Leone that the trial has been run so efficiently and that we now have substantial experience on the use of TKM-Ebola-Guinea in patients with Ebola. While the trial has reached a statistical endpoint, final conclusions on the efficacy and tolerability of the drug must await full analysis of the data.*

So what does *statistical endpoint* mean exactly? Hope you don't mean the subjects met a statistical endpoint ...

The drug has not demonstrated an overall therapeutic benefit. But we need time to look at all the data to interpret that in the context of the patient mix and other variables. Final conclusions on

efficacy and **tolerability** must await full analysis.

That analysis is still *must awaiting* publication.

Then there's this: Tekmira's TKM-Ebola (subsequent) trials in Guinea started .. with financial and **other support** from British NGO Wellcome Trust.

Hmm. So we've got Andersen, Garry, Holmes, Rambaut, Oxford (Horby - head of the RECOVERY trial coordinated by Farrar that killed-off Hydroxy by overdosing the trial patients), Springer Nature (Stefan Von Holtzbrinck - his father was publisher for the Nazis), and Wellcome Trust (Farrar).

All thereabouts in the Ebola 14 outbreak. If the plot gets any thicker we could stand a spoon up in it.

Finally, in 2015, the Tekmira/Wellcome/US Dept Defense drug trial was cancelled when it came to a *statistical endpoint*. Had a great ride on the stockmarket before that though if you were a shrewd investor. Tekmira dropped all interest in researching Ebola from 2015 on.

You could call this a strange set of coincidences, but Dr. Cyril Broderick, Liberian scientist didn't:

DoD gave a contract worth \$140 million dollars to Tekmira .. to conduct Ebola research. This research work involved injecting and infusing healthy humans with the deadly Ebola virus. The DoD is listed as a collaborator in a 'First in Human Ebola clinical trial' (NCT02041715), which started in January 2014 shortly before an Ebola epidemic was declared in West Africa in March.

I'm not sure that's true. I know it was a rumour going around. The Jan 2014 event was a Phase 1 trial. It had already been pre-clinically trialed on macaques in a biosafety-level-4 biocontainment at the US Army Medical Research Institute of Infectious Disease. Lancet published a paper on it:

Lancet/Tekmira, *Post exposure protection of nonhuman primates against a lethal Ebola virus challenge with RNA interference:*

The monkeys were then placed in primate jackets, returned to their cages, and tethered. After 7 days, the animals were inoculated intramuscularly with a target dose .. of ZEBOV (Kikwit strain)

I wonder if people haven't got this trial confused with what happened in Sierra Leone.

I'm not easily shocked but i would be if they were injecting and infusing healthy humans with the deadly Ebola virus. Surely Tekmira was only testing tolerability. Details of the trial are scant though.

It is also odd why Tekmira would go to Sierra Leone to test an Ebola drug - if it's only about tolerability. Remembering the first trial was at least a month before the outbreak was known, and Sierra Leone had never had an Ebola outbreak.

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