

Clinical Data Recap

Peer reviewed phase 1 trial

OSS, Netherlands — In August of 2017, Clinical Cancer Research published a report on the positive outcome of Glycostem’s NK-killer cells phase I clinical trial, which was carried out at Radboud University Center in the Netherlands.

Ten elderly and fragile AML patients were treated in the dose escalating trial, the primary endpoint of which was safety. The goal was achieved with no exhibited side effects; not even at the highest levels of infusion.

Importantly, the treated patients’ duration of survival significantly exceeded the expected duration of survival in the general patient population. The trial results built on Glycostem’s already considerable developmental momentum as the company moves on to the next clinical stage.

Troels Jordansen, Glycostem’s CEO, stated, “We were very fortunate to have worked with Radboud’s incredibly skilful clinical staff to realise this ‘first in human’ data in AML patients. The very positive outcome, as to overall safety of the product, was expected. The greatest advantage with NK-cells is that they only attack cancerous cells.” He added, “But the strong indication of efficacy took us and many others by surprise. We were, of course, delighted with the outcome and are very driven as we move on to the pivotal clinical trials. We firmly believe we will make a huge difference in the lives of AML patients,” Jordansen concluded.

Glycostem has achieved Orphan Drug Status from EMA and FDA. For AML applications, the next clinical trial will be pivotal. This will be the final clinical trial before expected conditional product approval in 2021.

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Outcome and Indications:

- oNKord® is a safe treatment - no dose limiting toxicities or Graft-versus-Host Disease observed in the study
- 5 out of 10 patients survived
- Oldest surviving patient is 60 months (5 years) from date of treatment
- 1-year survival = 80%
- Median survival = 22 months
- Median follow-up = 48 months (based on 5 surviving patients)
- oNKord® cells show in vivo survival, expansion and further maturation
- oNKord® cells home to the bone marrow and target leukaemia cells
- oNKord® resulted in strong reduction of residual disease as well as
- Prolonged Progression Free Survival and Overall Survival as compared to historical data

About Glycostem

Netherlands-based Glycostem Therapeutics BV, a clinical stage biotech company focused on developing off-the shelf allogeneic cellular immunotherapy using Natural Killer (NK) cells to treat several types of cancer. NK-cells are the body's first line of defence because of the innate ability of NK-cells to rapidly and accurately identify and destroy cells under stress, such as cancer or virally-infected cells.

Glycostem's lead product, oNKord®, is produced in a closed system in Glycostem's state-of-the-art production facility in The Netherlands, from which the product can be distributed globally. The platform technology includes ex vivo expansion of a high number of pure and highly activated NK-cells for clinical applications. oNKord® successfully concluded phase I clinical trial (elderly and fragile AML patients), providing solid safety data and strong indication of clinical activity, including response on MRD. Glycostem expects to obtain GMP certification by the end of 2018 and is planning to enter pivotal clinical trial in Q1 2019.

Thanks to the six patent families, longstanding technical expertise and resources, as well as 'Orphan Drug Designation', Glycostem has secured a leadership position in the global NK-cell market."

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