

Media Release



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Okairos announces initiation of Phase I/II clinical trial for potential first-in-class hepatitis C vaccine

Basel, Switzerland – 14 March 2012 – Okairos today announced the initiation of a Phase I/II clinical trial evaluating its vaccine against the hepatitis C virus (HCV). This is the first multi-center, double blinded, randomized, placebo-controlled trial of a vaccine to prevent HCV infection, and represents a major milestone in the collaboration between Okairos and the National Institute of Allergy and Infectious Diseases (NIAID), which is part of the US National Institutes of Health (NIH). The NIH-funded trial will be conducted by co-principal investigators from Johns Hopkins University and the University of California San Francisco (UCSF).

The trial follows promising Phase I results that were recently [published in Science Translational Medicine](#), showing that the vaccine had a good safety profile, was well tolerated, and that it stimulated a highly potent T-cell response in healthy volunteers. This Phase I/II trial will provide the opportunity to demonstrate the potential effectiveness of such an approach in protecting against chronic HCV infection, the leading cause of liver cancer.ⁱ

Dr Riccardo Cortese, Chief Executive Officer of Okairos, said: “This news represents many years of work in developing our technology platform and proving its utility in early clinical studies in HCV and other areas. We are very pleased to be part of this productive collaboration and look forward to initiating additional clinical programs from our platform in the near future.”

The trial will enroll 350 subjects and will begin with an interim Phase I analysis of safety and immunogenicity data in a subset of them. The primary endpoints of the overall study will measure the incidence of chronic HCV infection, as well as the safety and tolerability of the vaccine.

Dr Alfredo Nicosia, Chief Scientific Officer of Okairos, explained: “The history of vaccine research has primarily focused on stimulating antibody responses. We’ve unlocked the door to stimulating robust T-cell responses and will leverage this technology to combat important diseases such as HCV, respiratory syncytial virus (RSV) and influenza.”

About hepatitis C virus (HCV)

Three per cent of the global population carries HCV, which affects the liver cells and is the leading cause of liver transplants in the US. Around 170 million people have the chronic form of the disease, which may lead to cirrhosis, liver failure, hepatocellular carcinoma and ultimately death. In the US and Western Europe around 150,000 new cases occur annually.ⁱⁱ Extensive variations of the virus present

major challenges to the development of a vaccine - there is currently no vaccine for the prevention (prophylactic vaccine) of HCV infection.

About Okairos' HCV vaccine

Extensive preclinical experiments and studies of the interaction of the virus with the human immune system have highlighted the importance of T-cells in counteracting HCV. Okairos' HCV vaccine is based on a technology platform that uses proprietary, chimpanzee-derived adenovirus vectors to stimulate a robust T-cell response against selected antigens. Okairos' research has shown that it is able to stimulate robust T-cell responses that provide strong protection in preclinical non-human primate challenge models.

About Okairos

Okairos is a clinical-stage biopharmaceutical company, developing genetic vaccines for major infectious diseases - including malaria, hepatitis C, influenza, respiratory syncytial virus and cancer - using a novel proprietary technology. The company is headquartered in Basel, Switzerland and has laboratories in Rome and Naples, Italy.

Okairos' technology platform is centered on the development of new, potent adenovirus vectors to generate a pipeline of T-cell vaccines against a range of infectious diseases for which there is currently no effective vaccine. The company is also pursuing therapeutic vaccines to treat cancer.

The company's investors include BioMedInvest, Boehringer Ingelheim Venture Fund, LSP, Novartis Venture Funds and Versant Ventures.

For more information, visit www.okairos.com

References

ⁱ www.cdc.gov/hepatitis/C/cFAQ.htm

ⁱⁱ www.who.int/csr/disease/hepatitis/Hepc.pdf

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