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TO 18-00052

Broadly neutralizing antibodies against hepatitis E virus (HEV)

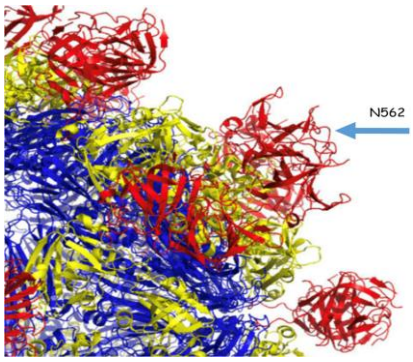
Keywords: HEV, neutralizing antibodies, prophylaxis, therapy, infectious viral particles, acute viral hepatitis, pregnancy, cross-genotype

INVENTION NOVELTY

Scientists of TWINCORE – Centre for Experimental and Clinical Infection Research and Lübeck University identified a novel set of human antibodies specifically binding infectious HEV particles. The newly identified antibodies only bind to non-glycosylated capsid protein, thereby discriminating between capsid protein in infectious particles and non-infectious, secreted capsid protein. Furthermore, several IgGs show cross-genotype binding of capsid proteins of all four main human pathogenic HEV genotypes.

VALUE PROPOSITION

HEV is the most common cause of acute viral hepatitis worldwide. While the majority of infections are asymptomatic, they still pose the risk of chronification and liver failure, resulting in approximately 44,000 deaths every year. Some human populations, especially pregnant women and immunocompromised patients have higher risk to develop severe forms and chronic infections. Pregnant women, particularly in the second or third trimester, are at increased risk of acute liver failure, fetal loss, and mortality of up to 20–25%. Since no specific treatment has been approved to date and an efficient vaccine against HEV has only been approved in China and Pakistan, the newly identified antibodies might be of great value in diagnosis, prophylaxis and treatment of high-risk patient populations.



pORF2 glycosylation site N562 discriminating between infectious and non-infectious HEV particles
Source: Guu et al. PNAS. 2009

TECHNOLOGY DESCRIPTION

Secreted HEV capsid protein (pORF2 dimers) that is glycosylated at position N562 represents the majority of antigen circulating in infected individuals and are believed to serve as a decoy for neutralizing antibodies. The infectious RNA associated particle is assembled in the cytoplasm, and therefore not glycosylated at this position. Constructs representing the non-glycosylated domain of infectious particles were used to screen antigen-specific memory B cells from infected HEV patients. The here presented set of human antibodies only bind to non-glycosylated capsid protein, thereby discriminating between capsid protein in infectious particles and non-infectious, secreted capsid protein. The targeted conformational epitope is highly conserved across viral subtypes resulting in a broad neutralization of the four major human pathogenic HEV genotypes and rat HEV.

COMMERCIAL OPPORTUNITY

The technology is available for co-development or licensing.

DEVELOPMENT STATUS

Neutralizing activity of isolated anti-HEV mAbs has been shown in an *in vitro* assay and a protective effect has been shown in human liver chimeric mice representing an easily accessible HEV infection model.

PATENT SITUATION

International PCT application PCT/EP2023/056552 with priority of March 2022 is pending.

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