Lycotec

GAL – new treatment of chronic and persistent forms of Chlamydia infection

Chronic and persistent forms of Chlamydia pneumonia or Chlamydia trachomatis infections are widespread and associated with the development of atherosclerosis and cardiovascular diseases for the former, or for the latter, with asymptomatic pathologies in the reproductive system, which are one of the main causes of infertility.

Traditional antibiotics are efficient only against acute Chlamydia infections and unable to treat their chronic persistent forms.

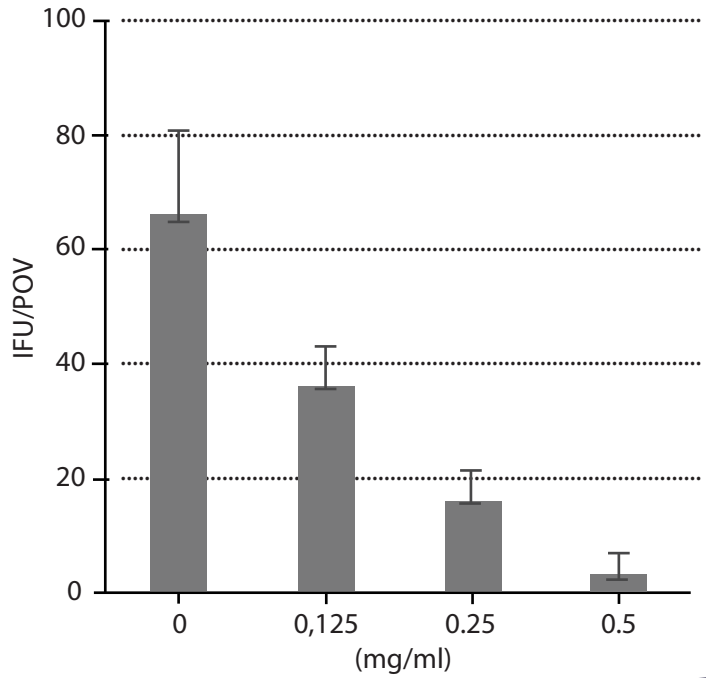
GAL is the first pharmaceutical candidate developed to inhibit formation of elementary bodies, the infectious forms of these bacteria. This molecule does not target these bacteria directly, but stimulates the formation of Lipid Droplets, LDs, which provide an accumulation of intracellular molecular oxygen in the host cells, which is toxic to the Chlamydia.

GAL is a composite product based on a combination of a prime molecule, *trans*-lycopene, stimulating formation of LDs, and two chaperones facilitating lycopene delivery and efficacy in the infectious inflammatory environment.

The Prime

trans-Lycopene is representative of a new class of molecules, which can stimulate formation of LDs, leading to accumulation of intracellular O_2 and suppression of anaerobic Chlamydia infection (fig. 1).

Figure 1. Dose-dependent inhibition of Chl. trachomatis growth at 42 hpi in B10.MLM by *trans*-Lycopene; IFU/FOV – average Inclusion Forming Units per Field of view (n = 20)



1st chaperone – scaffolding

Since lycopene isomers are highly hydrophobic, they can be transported in the circulation only by lipoproteins. If their assembly, which predominately happens in enterocytes and the liver, is impaired, then the concentration of these molecules in the blood and in other organs will be reduced, therefore having poor bioavailability in middle-aged and older persons, and in those who have fatty liver or metabolic syndrome. To overcome this problem, a chaperone molecule was added into the formulation to work as scaffolding to facilitate incorporation of the *trans*-lycopene into newly assembling lipoproteins.

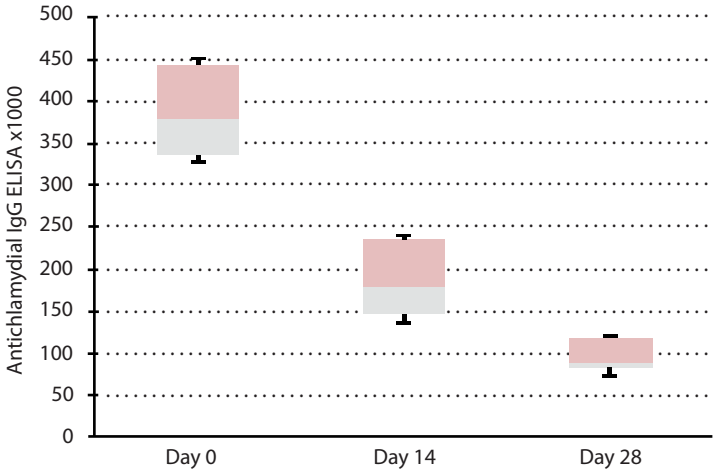
2nd chaperone – recovery cofactor

An on-going inflammatory environment, even on a sub-clinical level, which typically happens in patients with chronic persistent infections, can accelerate lycopene oxidation and decomposition. Therefore, to extend the life of these molecules to be efficient under these conditions, it was beneficial to add a second chaperone molecule, which could facilitate a reverse conversion of their oxidised form back to the intact structure.

Pharmacodynamics

In a randomised open-label clinical study on 36 patients positive on the presence of the specific anti-Chlamydia pneumonia IgG, it was demonstrated that administration for 4 weeks of GAL, containing 7mg of *trans*-Lycopene, led to a reduction of these antibodies to an undetectable level, fig. 2.

Figure 2. Effect of 4 weeks of GAL administration on the serum level of specific anti-Chlamydia pneumonia IgG



Naylia A. Zigangirova, Elena Y. Morgunova, Elena D. Fedina, Natalia V. Shevyagina, Tatiana G. Borovaya, Vladimir G. Zhukhovitsky, Nigel H. Kyle, and Ivan M. Petyaev - Lycopene Inhibits Propagation of Chlamydia Infection. Scientifica (2017), Article ID 1478625.

Next Step

The main objective of Lycotec is to find funding and/or a partner to take GAL to a larger double-blind clinical trial programme to assess further its impact on both chronic persistent *Chlamydia pneumonia and Chlamydia trachomatis infections.*

Regulatory

All molecules comprising GAL are safe for humans, and do not require FDA or other countries' regulatory body approval for oral administration in their therapeutic dose-range.