# T-RSV Lycosome Treatment for Diabetic Foot Ulcer

Globally there are more than 40 million adults with Diabetic Foot Ulcers (DFU). 1 in 5 will require amputation due to the development of persistent and progressive infection. After the first amputation, 50% of people will have their other limb amputated within 2 years. The 5-year mortality rate after the first amputation is 68% - second only to lung cancer.

Despite the severity of this disease and its growing prevalence, there are no dedicated therapeutic products available. The only treatment is to administer antibiotics, change the dressing of the ulcer and alleviate physical pressure on the foot.

T-RSV Lycosome, a product developed by Lycotec, is the first of its kind to be able to specifically target DFU regeneration, reduce fibrinogen blood concentration, hence risk of clotting, and improve planter pressure of the patient's affected foot.

## Lycosome - Pharmacokinetics

T-RSV Lycosome is a combinatory product where molecules of *trans*-resveratrol are embedded into clusters of *trans*-lycopene. This embedment, Lycosome, provides protection of the former from the stomach environment by the acid resistant latter molecules. As a result of this, bioavailability of *trans*-resveratrol is significantly increased, fig. 1.

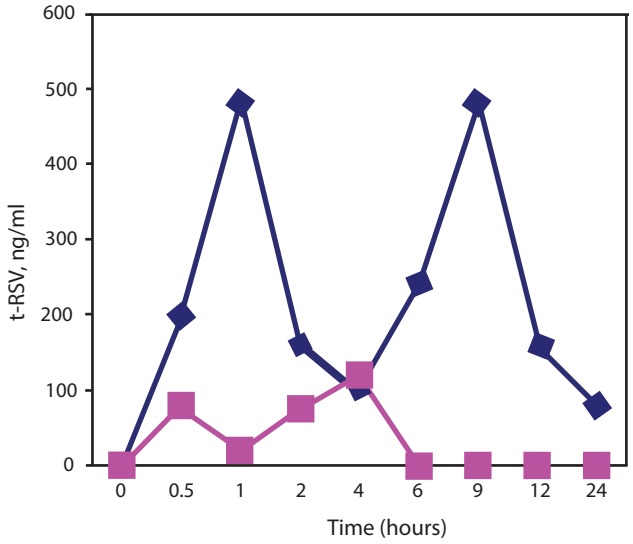


Figure 1. Typical pharmacokinetics of *trans*-resveratrol in the serum of the same volunteer in a cross-over experiment, ingestion dose 100 mg in both cases; purple – control preparation, blue – in Lycosome formulation with 7 mg *trans*-lycopene.

In addition, *trans*-lycopene serves in this formulation not only as a facilitating delivery entity, but also as a bioactive anti-hypoxia molecule, which is important for improvement of peripheral microcirculation and tissue respiration in these patients. Therefore, a combination of bioactive resveratrol and lycopene molecules could provide a synergetic therapeutic effect in DFU patients.

## Clinical Trial Proof-of-concept – Phase IIa

In a clinical examiner-blinded, randomised, controlled two-arm study on 24 patients with DFU, it was demonstrated that administration of T-RSV Lycosomes (100mg *trans*-reservatrol and 7mg *trans*-lycopene) resulted in a significant reduction in the size of the diabetic ulcer, figure 2.

Figure 2. DFU images before and after 60 days of treatment

with T-RSV Lycosome | with control *trans*-resveratrol

Before | 60 days after treatment | Before | 60 days after treatment

Yuriy K. Bashmakov, Samir H. Assaad-Khalil, Myriam Abou Seif, Ruzan Udumyan, Magdy Megallaa, Kamel H. Rohoma, Mohamed Zeitoun, and Ivan M. Petyaev - Clinical Study: Resveratrol Promotes Foot Ulcer Size Reduction in Type 2 Diabetes Patients. Endocrinology (2014), Article ID 816307.

Moreover, there was a significant reduction in fibrinogen plasma level and, ultimately, improvement in the peak planter pressure. In the control group there were no changes in any of these parameters after the same 60 days of intervention.

## Next step

The main objective of Lycotec is to find funding and/or a partner to take T-RSV Lycosome to a Phase IIb clinical trial, with follow-up registratiton of this product as an "Orphan Drug", and/or, or if necessary in parallel, to take it to a clinical Phase III trial.

## Regulatory

All molecules comprising T-RSV Lycosome are safe for humans and do not require FDA or other countries' regulatory body approval for oral avadministration in their therapeutic dose-range.

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