BioTeZ established a novel therapeutic drug monitoring assay for Evolocumab and PCSK9

The first PCSK9 Inhibitors reach the market and BioTeZ just completed the development project for the therapeutic drug and antigen monitoring assay. The *recoveryELISA*® (RPE) allows the simultaneous quantification of the free PCSK9 and the free Evolocumab in one ELISA assay.

Proprotein convertase subtilisin/kexin type 9 (PCSK9) has medical importance since it directly interferes with the lipoprotein particles (LDL) homeostasis. PCSK9 binds to the lipoprotein particles receptor (LDLR) which transports fat molecules within the extracellular fluid. Agents which block PCSK9 can decrease the LDL particle concentrations in the blood (**Figure 1)** and thereby prevent cardiovascular disease.

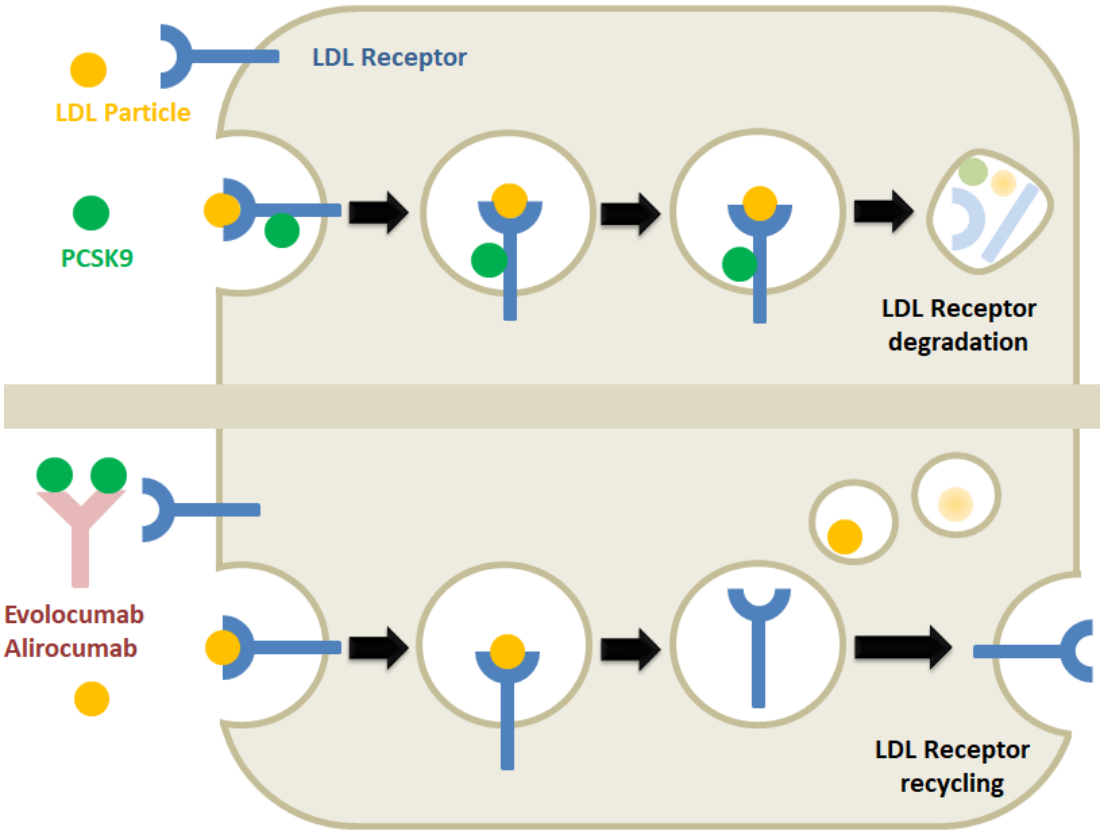

Figure 1: Mechanism of PCSK9 inhibitors Evolocumab or Alirocumab reduce LDL particle in patients suffering from residual cardiovascular disease

The first therapeutic monoclonal antibodies against PCSK9 Evolocumab and Alirocumab were approved by the U.S. Food and Drug Administration in 2015 for lowering LDL-particle concentrations when statins and other drugs were not sufficiently effective or poorly tolerated.

For Evolocumab two different dosing regimes are suggested 140 mg every two weeks or 420 mg once per month. By definition Therapeutic Drug Monitoring (TDM) is the clinical practice of measuring specific drugs to maintain a constant concentration in a patient's bloodstream, thereby optimizing individual dosage regimes (1).

“The *recovery*ELISA® RPE is the only method that simultaneously quantifies the free PCSK9, the PCSK9 neutralization rate and the free available therapeutic antibody Evolocumab in human serum samples during Evolocumab therapy. “With our new *recovery*ELISA® RPE we support TDM studies and can contribute for a truly personalized dose finding strategy” explains Uwe Ahnert (CEO of BioTeZ).

A pilot study enrolled Evolocumab naïve patients suffering from residual cardiovascular disease, treated for the first time with Evolocumab and followed for the next two injections. Serum samples were tested with the recoveryELISA© RPE to quantify free PCSK9 and free Evolocumab simultaneously and compared these results with the lipid profile.

“We are glad to demonstrate the ability of the recoveryELISA© PCSK9 & Evolocumab for this important application in a clinical setting. Currently, we evaluate the data and we will start soon with writing up a publication on our findings” says Dr. Janko Brand (senior Scientist at BioTeZ).

Product specifications: The working range for PCSK9 is 0.04 - 0.35 µg/mL and Evolocumab 0.2- 24.0 µg/mL. Please use the serum samples at dilution of 1:10. Keep in mind that BioTeZ has also totalPCSK9 ELISA® (BTPCSK9-001) on stock for the quantification of PCSK9.

About BioTeZ: BioTeZ is a 1992 founded Biotech Company, developing and producing ELISA kits, protease activity kits, antibodies, diagnostics and oligonucleotides. BioTeZ has longstanding experience in the development of biochemical test procedures for research institutes, hospitals and laboratories worldwide. BioTeZ hold all relevant patents on the recoveryELISA© and the technology was previously established for Omalizumab/IgE (2), Infliximab/TNFα (3), Adalimumab/TNFα (4) and customized for clients involved in early biological development projects from the pharmaceutical industry.

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