

# International Conference and Exhibition on **Antibodies**

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## Natural autoantibodies as markers of any chronic disease

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The immune system is a natural component of and direct participant in the physiological activity of healthy organisms. The main forms of physiological activity of the immune system are based on the intrinsic abilities of self-identification, self-maintenance, self-regulation, and self-reparation – that is, on recognizing components of the “self”, i.e., natural autoimmunity. The most ancient and homeostatically important function of natural autoimmunity is auto clearance. A multitude of immune functions, including those related to antimicrobial defense, derive from the basic function of auto clearance. Pathological processes of any kind in any organ are usually accompanied by apoptosis/necrosis of the resident cells and accordingly, by increased extracellular concentration of intracellular components. These events induce the secondary rise in production of autoantibodies with appropriate specificity (opsonines), which provides augmentation of clearance by facilitating the efficacy of macrophage-dependent consumption of debris in the affected organ. This phenomenon is sanogenic in nature and adaptive in essence. Therefore, secondary changes in production and serum content of tissue-specific autoantibodies can be considered the universal and earliest detectable marker of any chronic disease. “Magic mirror” of the immune system can reveal secrets of the bodily state. Practical realization of these ideas may help us transit to a new medical paradigm based upon early detection of the “disease-before-disease” and stop or slow development of pathology by implementing very early preventive measures.

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## IP strategies for the biosimilar arena

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Recent events have shown that lessons learned in generics cannot always be transferred to biosimilars. This applies with respect to technical issues, regulatory issues and IP issues. To cope with this situation, biosimilar companies need, inter alia, a thorough understanding of patent filing strategies related to biologics, as well as of counter measures. Further, because biosimilar companies compete with one another also on a technological level, they should consider developing a patent portfolio to protect proprietary technologies. This presentation explains what biosimilar companies should bear in mind to deal with these challenges.

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