Session 3: Characterization of active pharmaceutical ingredients

Pharmacological Characterization of New Active Pharmaceutical Ingredients

Priv.-Doz. Dr. Thomas M. Zollner and Prof. Dr. Khusru Asadullah
Bayer Schering Pharma AG
Target Discovery
Müllerstr. 178
D-13342 Berlin

Development of new active dermatics today is rather challenging. The new compound will hit a market with a plethora of active compounds which have been successfully used partially over decades with quite success. This is especially the case for glucocorticosteroids which are broadly used in many patients and different indications and systemic side effects as observed earlier are rather uncommon, at least with low – medium potent compounds. Market needs has to be understood early on in project work and preclinical research has to address these needs. Preclinical research is obliged to implement an improved disease and compound understanding, develop screening and disease models that reflect these novel developments and are especially suited for chronic diseases and therapeutic settings and finally address potential side effects early on.

In dermatological research, the understanding of cytokine networks in acute vs. chronic skin diseases led to the in house development of several models of chronic T cell mediated skin diseases (e.g. Schneider C et al. J Invest Dermatol 2009; Röse L et al., submitted). The aim to further reduce attrition rates due to lack of efficiency fuelled the implementation of humanized xenotransplantation models as late-stage, confirmatory models (e.g. Igney F. et al. Trends Pharmacol Sci 2006). To further profile novel compounds against competitors, optimized models for relevant side effects are essential at latest for development candidates. These models should address the needs of the patients, e.g. for compounds interacting with the glucocorticoid receptor the typical potential systemic (e.g. growth retardation, interference with the HPA axis, hyperglycemia) and topical (e.g. skin atrophy) undesired effects.

Taken together, characterization of novel pharmaceutical ingredients starts with a continuous improvement of our understanding of diseases and pharmacological concepts, the understanding of our patients' needs and will finally translate this into projects for desired new drug discovery projects, with the need of thorough characterization of potential development candidates and their competitors in a plethora of state of the art efficacy and side effects models.