



Curriculum Vitae

Name: Karen Wen

Affiliation: CEO, Mycenax Biotech

Short Biography (maximum of 400 words):

Dr. Karen Wen currently serves as the President of Mycenax Biotech Inc and she is the co-founder of this company. She has 20 years' experience in the biopharmaceutical industry and is well versed in drug development. Prior to founding Mycenax, she worked at Development Center for Biotechnology in Taiwan as research fellow, project leader of biomedical plan and manager of research and development for biodevice pilot plant. Her work experience included cell line evaluation, manufacturing process development, clinical trial design, quality assurance and regulatory compliance. Throughout the ten years, she has successfully led her team to execute two biopharmaceutical programs from bench into clinical stage.

Mycenax, a member of Center Laboratories group which is one of the Taiwan leading biopharmaceutical conglomerate, is positioned as biopharmaceutical company specialized in high quality and cost-competitive biological products development. The pipelines include TuNEX, a biobetter of Etanercept, NDA in TFDA, LusiNEX, a biosimilar of Tocilizumab, for EU IND in 2017, a bionovel in immune-oncology, and a collaborated project in growth factor in bone repairing via this product development platform. In 2020, Mycenax will have 2~4 biosimilars in autoimmune indications launched and two biosimilars in oncology indications are launched through our CDMO to CMO services (contract development and manufacturing services). Two bionovels will be in early clinical phase. In the meantime, Mycenax continue to provide CDMO services with CMC expertise and PIC/S GMP production.

Speech Summary at ATC 2017

Speech Title: From TuNEX to LusiNEX, Biologics development in Taiwan

Speech Summary (200-400 words)

TuNEX is the first biologics developed in Taiwan. It is a TNFR:Fc agonist for rheumatoid arthritis therapy. This product has completed two pivotal phase 3 trials and underwent an extension trial. All showed efficacy and safety. The product profile and results from the trails will be presented.

LusiNEX is the biosimilar product of tocilizumab biosimilar with 2000L scale production, the commercial batch design. It is an anti-IL6 receptor. The product selection purpose is to provide the therapy to the patients who has no therapeutic benefit from TNF pathway. This product is conducted in phase 1 trial in Australia. The product profile and results from the trails will be presented.