

Curriculum Vitae

Name: Qinhua Cindy Ru

Affiliation: EVP, Chief Scientific Officer, CARsgen Therapeutics

Short Biography (maximum of 400 words):

Near 20 years profound global leadership in Oncology Clinical Research, Regulatory Filing, Product Launch, and Business Development at the prestigious pharmaceutical companies such as Merck, Novartis, Pfizer, innovative biotech Exelixis, well-established Asian pharmaceutical company Sihuan, and cell therapy start-up CARsgen. Holding in-depth knowledge and practical leadership skills to strategically manage cross functions and efficiently deliver the results and bet the company objectives in widespread areas, including but not limited to, Pharmaceutical Quality/CMC, Nonclinical Pharmacology and Toxicology, Global Clinical Development (early to late phase, innovative & generic), Global Regulatory Submission (NDA/BLA/aNDA), Global Commercial and Product Launch, Global Business Development (Licensing In/Out, Mergers and Acquisitions), and Asset Life Cycle Management.

Leading and being major contributor for multiple oncology global regulatory submissions, including one BLA, one NDA, two MAAs, and three INDs. Proactively planned and attended numerous TC/F2F meetings (i.e. post-IND, End of Phase 2, pre-BLA, pre-MAA, post-BLA orientation, etc) with FDA, EMA, and managed numerous response and interactions to address the inquiries from ROW regulatory agencies (i.e. SWISS MEDIC, Health Canada, Australia TGA, Japan PMDA/MHLW, China FDA, etc)

Speech Summary at ATC 2017

Speech Title: Fill the Gap to Share the Success

Speech Summary (200-400 words)

Chimeric antigen receptor (CAR) T cell therapy has been celebrated worldwide as regulatory approvable and commercial achievable gene therapy following Novartis received the first ever FDA approval for a CAR-T cell therapy, Kymriah, for pediatric acute lymphoblastic leukemia and acquisition of Kite Pharmaceutical by Gilead at \$11.9 B before the PUDFA date for KTE-C19, also known as axicabtagene ciloleucel in late Number this year. In this presentation, a comprehensive overview of the clinical trials performed so far worldwide and analyze parameters such as targeted antigen and indication, CAR molecular design, CAR T cell manufacturing, anti-tumor activities, and related toxicities will be provided.