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## Erbitux biosimilar

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Supported by a NCI SBIR contract, a biosimilar Erbitux antibody, designated ch225, has been developed over the last three years for the immunotherapy of EGFR+, KRAS mutation negative tumors. In 2011, there were 141,210 new cases of colon and rectal cancers and 49,380 deaths in the USA accounting for the 12.2 billion dollars spent on colorectal cancer treatment alone. In addition, head and neck cancers account for 45,000 additional cases that are eligible for Erbitux treatment. These statistics show that Erbitux is an important treatment modality especially since its therapeutic effects against other tumors such as non-small cell lung cancer has been demonstrated. After extensive analyses of commercial Erbitux, a biosimilar antibody was developed using genetic engineering methods. Our initial studies demonstrated that ch225 has the same primary amino acid sequence, charge distribution, and glycosylation profile as Erbitux required for its biosimilarity. In addition, the potency of ch225 against EGFR positive and negative cell lines and PK/PD studies closely matched commercial Erbitux batches both in vitro and in vivo. Based upon these results, extensive cloning methods were used to develop a high yielding sub-clone in serum free medium which produces over 1 mg/ml of antibody stable out to 35 generations. A growth supplement was also identified which increased its productivity enabling the accumulation of  $4 \times 10^7$  cells/ml with over 98% viability. In conclusion, despite numerous difficulties encountered during the course of this work, a biosimilar Erbitux has been produced and readied for cGMP and clinical trials.

## Biography

Alan L Epstein received his BA degree from Wesleyan University, Middletown, CT and his MD/PhD degrees from the Medical Scientist Training Program at Stanford University School of Medicine under the tutelage of the late Henry Kaplan. He is currently Professor of Pathology at the USC Keck School of Medicine since 1984 and has over 160 publications and 30 patents in the field of tumor cell biology and cancer immunotherapy. He is expert in the development of novel cancer cell lines, monoclonal antibodies, antibody fusion proteins, and immunodiagnostics useful for the treatment and diagnosis of lymphomas and solid tumors.

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