CHEMICAL & BIOMOLECULAR ENGINEERING

Center for Biomanufacturing Science & Technology

CBST SEMINAR

Tuesday, October 8, 2019

366 Colburn Lab

10:00 a.m.

"Developing Biologics for a Global Population"

While success rates for the development of new drug candidates are improving, they are still disappointingly low, and require a decade or more to complete. The industry learns from failure, but it is imperative that we collectively learn more quickly, efficiently, and use this learning to enhance our ability to predict from the often complex and expensive experimental approaches used in drug development. Better, more systematic and integrated approaches are needed to speed learning across the entire drug development and commercialization space. The discovery, development, and manufacture of biologics is ripe for disruption by approaches that use predictive tools to deliver superior biologics faster, and at a lower cost.

An example of this process is the development of broadly neutralizing antibodies (bNAb) against HIV-1 which have been derived from patients who have shown resistance to multiple HIV-1 viral strains. These antibodies may prove useful as therapeutics if their cost of manufacture and stability characteristics can be made suitable for geographically diverse populations. We applied in silico tools to engineer anti-HIV bNAbs to increase manufacturability and stability. Evaluation of the engineered bNAb molecules was conducted by high throughput screening using a series of tools to evaluate both conformational and colloidal stability, parameters related to manufacturability and long-term storage. The results of the high throughput analysis demonstrate that anti-HIV bNAbs can be substantially improved without significantly impacting virus neutralization.

Improvements in conformational and colloidal stability also had an unexpected effect on their PK profiles showing increased half-lives for the optimized antibodies. Along with improvements in reducing the cost of production, increasing the half-life of a mAb can further reduce the overall cost of biologics and improve dosing regimens, an important factor to help keep patients on drug.

The results described here can be extended to other important antibody therapeutics to increase accessibility across all populations in the world.

Bruce Kerwin

Vice President Drug Product Design

Just Biotherapeutics

Dr. Kerwin is responsible for all aspects of Drug Product Design at Just including development of our high throughput biophysical characterization platform, formulation platform, and commercial drug product. He has worked in the biotechnology industry for more than 20 years and is a recognized expert in protein formulation and drug product development. In prior roles at Amgen he led numerous project teams developing novel solutions to formulation problems such as high viscosity, high concentration and protein aggregation. He contributed to numerous programs that successfully brought drug candidates through development with contributions to commercialized biopharmaceuticals such as Aranesp®, Vectibix®, Imlygic™ and Kineret®.

His work on large and small volume parenteral formulations included monoclonal antibodies, antibody drug conjugates, PEGylated proteins, glycosylated and non-glycosylated proteins and viruses. Bruce was also intimately involved with alternative drug delivery systems at Amgen such as slow release and nanoparticle formulations. He has over 50 research publications relating to protein science and formulation development, is an inventor on multiple patents and holds an adjunct appointment as an Associate Professor on the faculty of the School of Pharmaceutical Chemistry at the University of Kansas.