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Biobetters, they had better be better

William R Strohl

BiStro Biotech Consulting, USA

“**B** iobetter” biologics are intended to improve on the salient characteristics of a known biologic for which there is at least clinical proof-of-concept or, optimally, marketed product data. Successful biobetter biologics have been generated by improving the pharmacokinetic properties of the innovative drug such as Neulasta®, a PEGylated, longer half-life version of Neupogen® (filgrastim), and Aranesp®, which is a longer half-life version of Epogen® (epoetin alpha). It is more difficult to generate and prove the superiority of a biobetter that is intended to have increased potency over the originator, as experienced with the development of AME-133v, a proposed biobetter of rituximab. There are several known and theoretical mechanisms of action that can be engineered into a monoclonal antibody (Mab) or Fc fusion protein preclinically that may have potential impact on efficacy, safety, convenience, manufacturing, supply chain, cost, and/or patient compliance. These include modifications of Fc function, half-life, potency, formulation, stability, and route of administration. Whether or not any of these discovery or early development-based modifications actually provide a clinical or marketing benefit without compromising safety, however, is often not adequately tested until phase 2 clinical trials. The cost of developing biobetter MABs and Fc fusion proteins is similar to that of developing innovator biologics, so the benefits must be clearly articulated. Thus, the strategy and design for developing a biobetter biologic needs to be continually put to the test during early development so that go/no go decisions can be made as early as possible to reduce risk and opportunity cost.

Biography

William Strohl owns BiStro Biotech Consulting LLC, founded in 2016 to help biotechnology companies expand their capabilities. Prior to retiring from J&J in 2016, Dr. Strohl was VP, Janssen BioTherapeutics. Before J&J, Dr. Strohl was at Merck from 1997-2008, leading Natural Products Biology and, later, leading Biologics discovery efforts. From 1980-1997, Dr. Strohl rose from Assistant to Full Professor in the Department of Microbiology and Program of Biochemistry at Ohio State. Dr. Strohl has >140 publications, 17 patents, and wrote the book "Therapeutic Antibody Engineering: Current and Future Advances Driving the Strongest Growth Area in the Pharma Industry" (2012).

wrstrohl@gmail.com

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