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Four different strategies for biobetter drug developments

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We have developed 4 different methods for functional improvements of current biosimilars in clinics. In these works our concepts have been based on "modifications on the protein should be simple and *in vivo* or friendly or proved their feasibility such that the product may not increase risks of safety concerns in the processes of late stage of clinical developments".

Firstly we have adopted N-glycosylation variations from human immunoglobulins Ig -A, -D, -E, and -M into Ig -G1 which is the dominant type of antibody drugs. Advantages of this modification on the antibody drugs are increased 1) plasma half life and 2) tissue penetrations into the therapeutic targets.

We have also developed 3 different methods to increase binding of proteins to their targets via 1) duplicating binding units of Ig-fusion proteins, 2) mutagenesis of aminoacid of cytokine type drugs to increase the binding forces to their receptors, or 3) sorting out a highly ionic-charged fraction in the middle of current botulinum toxin preparation for injection.

By a simple duplication of the DNA codes binding domain of Ig-fusion proteins, we have developed tetravalent type Ig-fusion therapeutics. Biologics such as romiplostim (Nplate®) and aflibercept (Zaltrap®) have shown the benefits of tetravalent type Ig-fusion proteins though their structural compositions differ from those of in inventions. Our tetravalent Ig platform is applicable to various drugs such as etanercept (Enbrel®), abatacept (Orencia®), ranibizumab (Lucentis®) for their therapeutic- and marketing- benefits. Advantages of this modification are 1) reduced dose and 2) increased efficacy of Ig-fusion type drugs.

We have also developed a single F to V modification to increase force of binding of cytokine drugs such as EPO (Neorecormon®), TPO, and IFNs etc. This simple modification is able to produce single amino acid variants with hundreds folds higher affinity to the targets *in vitro*. Advantages of this modification are increased 1) efficacies- and 2) acting durations of them.

For therapeutic improvement of onabotulinumtoxinA (Botox®), we have further separated a more ionic-charged fraction in the middle of current preparation in use. Advantages of using this sub-fraction are 1) reduced local tissue diffusions, 2) faster onset and 3) increased duration of action of the toxin injection.

We have worldwide patents regarding these 4 different methods and drug candidates which seemed to be competitive in the current biosimilar markets.

Biography

Yong Hoon Chung completed his M.D. and Ph.D. from Hanyang University at Seoul Korea and postdoctoral studies from Memorial Sloan Kettering Cancer Center at NYC. He is a Professor of Medical Microbiology and Immunology of Hanyang University College of Medicine and presently the President of MedExGen Inc. at Seoul Korea. He has published more than 50 papers in journals of medical microbiology or immunology. He also has more than 50 patents in the fields of therapeutic protein innovations.

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