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The application of releasable pegylation linkers to improve the pharmaceutical properties of bisimilars and biobetters

Hong Zhao
Enzon Pharmaceuticals Inc., USA

PEGylation technology is a proven drug delivery technology. Currently there are 11 marketed PEG conjugated drug products with total annual sales over $7B in 2011. Permanent PEGylation is applicable to molecules which can maintain a certain degree of biological activity and the lost activity can be compensated through the prolonged presence of the drug in the circulation. However, there are many drug molecules which will lose all their biological activity after PEG conjugation. These molecules may include peptides, small molecules, cytokines, certain hormones, and small engineered binding molecules such as scFv, V_h, V_L, bi-specific scaffold, etc. These molecules may also suffer from poor pharmaceutical properties such as short circulating half-life, poor solubility, immunogenicity, and stability. In order to extend the benefit of PEGylation to these molecules, novel releasable PEG linkers have been developed which will allow programmed release of intact, fully functional, native drug molecules inside the body. The utility of releasable PEG linkers will be illustrated by examples of both small molecules and antibody fragments to demonstrate the potential of this technology to create biosimilars and biobetters.

Biography

Hong Zhao is currently Senior Director of Chemistry at Enzon Pharmaceuticals, Inc. Zhao received his Ph.D. in Organic Chemistry from Rutgers University in 1997. His research interest is to expand the application of PEGylation technology to all types of drug molecules by developing novel linker technologies to address the modern drug delivery need. Dr. Zhao has 33 papers published in peer-reviewed journals, 2 book chapters; 56 issued U.S. patents and patent applications; 3 invited speeches, 31 poster presentations. He is a member of the ACS, AACR, CRS, AAAS, and AAPS.

hong.zhao@enzon.com