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Development and commercialization of oral peptide and protein therapeutics: Trends and perspectives

The oral route is the most preferred non-invasive route of drug administration due to increased patient compliance. However, advancing oral peptide and protein therapeutics from bench to clinic and commercialization has been a formidable task. Despite major investments and scientific advances in this area over the last three decades, there is no oral water-soluble and poorly permeable (BCS III) peptide/protein drug product on the market. Oral drug delivery approaches used alone and in combination in preclinical and clinical studies include, chemical modifications, intestinal permeability/absorption enhancers, such as lipids, surfactants, and proprietary molecules, and lipidic and polymeric micro-/nanoparticles with and without targetable ligands directed towards M-cells/Peyer's patches in the intestinal mucosa. Upon introductory remarks on the Biopharmaceutics Classification Scheme (BCS) as applied to peptide therapeutics and characteristics of an ideal oral formulation, advantages and limitations with peptide therapeutics and drug development needs will be presented during the first part of the talk. Then preformulation and formulation development aspects of oral peptides, assessment criteria and development considerations with various delivery technologies will be discussed, followed by lessons learned from preclinical and clinical studies. The last part of the talk will summarize accomplishments to date, address commercialization issues and conclude with future developments in this field.

Biography

Panayiotis P Constantinides is President of Biopharmaceutical & Drug Delivery Consulting, LLC in Gurnee, USA that he founded in 2004, and he has more than 30 years of industrial experience in drug delivery and pharmaceutical development. He did diploma in chemistry from Athens University in 1977 and PhD in Biochemistry from Brown University in 1983. He was a postdoctoral fellow in the Pharmacology Department and Associate Research Scientist in the Comprehensive Cancer Center of Yale University School of Medicine (1983-1987). Past industrial positions held included: Vice President of R&D with DOR Biopharma and Morton Grove Pharmaceuticals (2000-2004), Director of Research at SONUS Pharmaceuticals (1997-2000) and from 1987 to 1997 a number of R&D positions of increasing responsibilities with LipoGen, SmithKline Beecham Pharmaceuticals and Abbott Laboratories. He is inventor in 33 patents and patent applications, has authored more than 130 publications including review articles, book chapters and presentations on the parenteral and oral drug delivery of small molecules and peptides/proteins and has presented more than 100 invited talks at many national and international conferences, pharmaceutical companies and universities. Dr Constantinides is AAPS Fellow, Past Chair of the AAPS Formulation Design and Development Section, the Nanotechnology and Lipid-Based Drug Delivery Systems Focus Groups. He has received numerous honors and awards and serves as Associate Editor of the AAPS Open journal since its launch in the fall of 2015..

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