Biotherapeutics: Novel Formulation and Delivery Approaches (Focus on Antibodies and Proteins)

Description:

Biopharmaceuticals is currently one of the fastest growing segments in the pharmaceutical industry. They have a vital use in the treatment of chronic diseases and also result in high profit margins for the drug developers. There are several therapeutic areas for which biopharmaceuticals are being investigated; these include oncology, metabolic disorders, viral infections, genetic disorders and immunological disorders.

Biotherapeutics (both approved and under investigation) include monoclonal antibodies, cell therapies, clotting factors, cytokines, enzymes, hormones and vaccines. In fact, several antibody based therapies have already been approved across the globe. Humira®, by AbbVie, is a well-known example; the drug has been generating multibillion dollar sales annually for several years.

The major challenge for biologics has been the mode of administration. For most large molecule drugs, IV is an established route. Through this method, the drug directly enters systemic circulation bypassing degradation in the gastrointestinal (GI) tract. However, there are other challenges; these include the requirement of healthcare experts for drug administration (in turn, increasing the cost of therapy) and associated pain during therapy administration (negatively impacting patient compliance).

Companies developing biologics are continuously on the lookout for novel formulation and delivery systems in order to exploit their full therapeutic and commercial potential. Amongst the various aspects being studied, technologies for facilitating oral, subcutaneous (SC) and transdermal delivery of biologics are highly sought after and have received widespread attention from researchers and manufacturers across the globe.

Several start-ups, with innovative technologies, have surfaced in the past decade and have continuously encouraged the use of biotherapeutics by providing novel approaches to improve patient compliance. These technologies are broadly classified either as formulation technologies (approaches with primary objective of changing the formulation of drug, thereby facilitating an alternate route of administration in many cases) or delivery systems (approaches with primary objective of developing a physical system to deliver the drug via an alternate route).

The overall interest continues to rise as is evident from the number of partnerships / agreements that have taken place amongst the stakeholders. Technology licensing agreements have been very common and are likely to play an active role in industry's development. In addition, several venture capitalists have led multiple funding rounds in these companies, acting as a key enabler behind the evolution.

Example Highlights

- There are over 150 technologies, being developed by around 120 companies, which are focused on developing novel formulations and / or systems for delivering antibodies and proteins. Amongst the delivery systems, prime focus of the stakeholders is on oral, SC and transdermal drug delivery technologies.

- The market has attracted several start-ups; these companies, in collaboration with big pharma, are expected to foster more innovation in the near future. Some of the well-known players with proprietary technologies are (in alphabetical order) Adocia, Aegis Therapeutics, Arecor, Corium International, Cosmo Pharmaceuticals, Durect Corporation, Emisphere Technologies, Excelse Bio, Generex Biotechnology, Halozyme Therapeutics, Merrion Pharmaceuticals, Oramed Pharmaceuticals, Rani Therapeutics, Xeris Pharmaceuticals and Zosano Pharma (complete list in Chapter 4 of the report).

- These approaches focus on a wide range of mechanisms; amongst others, these include modifying the release properties along with pharmacokinetic properties, creating cold-chain free and stable liquid formulations of the drug and delivering the drugs in a targeted manner.

- Within the technologies focused on targeted delivery, there seems to be heavy focus on delivery of drugs across the Blood Brain Barrier (BBB). Delivery across the BBB has been a big challenge in case of large sized biologics. We have identified over 15 players, which aim to successfully overcome this challenge in the
coming few years.

- Venture capitalists have shown an enormous amount of interest and confidence in the technology developers. In total, we traced over 200 instances of funding with the total investment amounting to an encouraging sum of USD 2.9 billion over the last decade. In addition, government agencies, such as the NIH, have also encouraged technology developers by issuing grants for a wide range of research projects.

- Driven by several factors, such as rising incidence of chronic diseases, growing popularity of biologics / biosimilars and use of delivery / formulation technologies as life cycle management tools for near patent expiry drugs, the market for such technologies is expected to grow aggressively at a healthy annual growth rate of 9.6% between 2015 and 2025.

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