Baywind Bioventures: Developing Novel Delivery Technologies for Unmet Medical Needs

For much of my career in the industry over the last 27 years, I have been interested in creating non-injectable formulations for biologics. Small molecules are easily designed to be absorbed and their mechanisms for absorption are well understood. As a result, 90% of the global pharmaceutical products are small molecules in tablet and capsule formulations for swallowing orally. The same cannot be said for biologics.

Challenges of Biologics Oral Delivery

Biologics (peptides, proteins, antibodies, enzymes, oligonucleotides) are large molecules with many positive and negative charges distributed across the molecules. As a result, absorption of biologics across the gut is far less than 0.01% of the administered dose.

The desire to create more patient friendly non-injectable formulations for biologics is not new. In fact, when insulin was first discovered in the 1920s it was not long before it was tested orally. While a small amount of absorption was observed, the variability in exposure and the dose needed made this a non-starter for insulin therapy.

Over the last 90 years, we seem to keep teaching ourselves the same lessons. Perhaps the most significant development in the oral delivery of biologics is the FDA 2019 approval of semaglutide (Rybelsus, Novo Nordisk), a long half-life GLP-1 agonist for Type 2 diabetes. The permeation enhancing formulation achieves ~0.5% bioavailability. The long half-life alleviates the issue of dose to dose variability in exposure.

Device Advances in Oral Delivery of Biologics

The oral delivery of biologics is still an area of intense research with many companies and academics searching for a generalizable approach that is suitable to all biologics, no matter the size or dose. A very bright device engineer by the name of Mir Imran took a different approach more than 10 years ago. He decided that a device approach in which microneedle formulations are poked into the wall of the gut could be a suitable alternative. His company Rani Therapeutics (www.ranitherapeutics.com) developed a microneedle inside an enteric coated capsule that is designed to inject into the gut tissue. I first saw his data 10 years ago and was astounded at the 50% bioavailability for several biologics.
I am indebted to Mir for introducing me to the concept of a device for oral delivery and for stimulating a resurgence in my interest in oral biologics delivery. While microneedle technologies are maturing, they have some challenges—primarily related to dose and manufacturing. The proprietary technology holders have manufacturing systems for clinical development, but there are no drug product manufacturers that can be hired to make microneedles at commercial scale. In addition, microneedles have severe dose limitation of 1 to 3 mg of active per dose.

The genesis of the JetCAP™ system was to look at fluid delivery for larger volumes, higher doses, and simpler manufacturing. JetCAP™ is made up of a plastic capsule, a plunger, a spring, enteric coatings, and a rapidly dissolving tablet—all well understood pharmaceutical components. The capsule reservoir is able to hold much greater doses (at least 10 to 30 mg per dose) to provide flexibility for dosing solutions and suspensions. Applications could range from oral biologics to ultra-long-acting orals to gut vaccines.

Baywind Bioventures leverages the resources of Drug Delivery Experts to develop new delivery systems including Propel Biologics JetCAP™ and SubQ Biologics™ nano/micro particle technology. Drug Delivery Experts is a contract drug product R&D laboratory in San Diego and specializes in simple solution formulations to complex injectables and long-acting systems. The breadth of formulation experience at Drug Delivery Experts has led to great working relationships and partnerships with many biotech, pharma, and virtual companies.

Visit www.baywindbio.com and www.ddelabs.com to learn more.

Christopher Rhodes, Ph.D. is President and Founder of Baywind Bioventures. Baywind Bioventures was Biocom's 2019 DeviceFest & Digital Health Conference Hot Seat Winner.