INTERVIEW: JEANNIE JOUGHIN, CSL BEHRING

Enable Injections has developed a platform technology to deliver high-viscosity / high-volume payloads up to 20cc to the subcutaneous tissue. The system, which was presented in detail in ONdrugDelivery Magazine, July 2014, Issue 51, pp 30-33, is wholly mechanical and uses standard vial, syringe or cartridge container closure, and can automatically mix lyophilised solutions. Founded in February 2010, the company has R&D and manufacturing facilities in Franklin, OH, US.

In October 2014, Enable Injections and global biotech giant CSL Behring announced a major agreement for the development of Enable's drug delivery system to improve the comfort, convenience and treatment compliance for patients with rare and serious diseases. Under the agreement, Enable will initially develop, manufacture and sell its innovative delivery device, which was specifically designed for subcutaneous dosing, to CSL Behring for use with one of CSL Behring's products on an exclusive worldwide basis. Here, Dr Jeannie Joughin, CSL Behring's Vice-President of Business Development, speaks exclusively with ONdrugDelivery Magazine about the agreement with Enable, how it came about, what it means to the two companies, and how it's going so far.

Q: Please could you give us a short overview about CSL Behring's business?

A: CSL Behring is a global biopharmaceutical company specialising in protein therapeutics also targeting products to treat patients with rare and difficult-to-treat disorders. Our products help to save lives or to improve quality of life.

In terms of our size, we have more than 13,000 employees worldwide and our market cap is close to US$40 billion. Our head office is in Australia as we are listed on the ASX. However the major operational hub is in King of Prussia, PA, US. We have major manufacturing sites in Australia, the US, Germany and Switzerland. Each site is a centre of excellence with individual specialities – not specific single protein products but specific groups of products.

As mentioned in the press release announcing the agreement with Enable Injections, this deal is with our Bern, Switzerland site, because they are responsible for certain products that we are looking to bring through development for delivery using the Enable device.

Q: Different pharma companies have different ways of looking at drug delivery and different strategies for getting their products into the right drug delivery devices. Could you give us an idea of how CSL Behring approaches drug delivery?

A: Our expertise and our heritage is in plasma therapeutics, therapeutic proteins and monoclonal antibodies, so as we develop these proteins in the key therapeutic areas that we focus on – always relating to rare and serious diseases – we now are really focusing our strategy on how we deliver those to patients. We have products approved around the world; often state-of-the-art products, leaders in their field, and first to market in some instances. For example, Hizentra®, our 20% immunoglobulin solution for subcutaneous self-administration, was the first product of its kind to reach the market.

We often lead innovation in protein therapeutics, so now we are trying to think about how we can lead innovation in delivery of our products to patients and how we can make the patient experience better. Now although we are focusing on this, our experience lies in maintaining the highest quality of our protein products and as such we know we are not a device company. Thus we're looking to form partnerships with other companies whenever it makes sense. With Enable it made sense to partner their technology with our products in certain patients with certain indications where high dose volumes and / or viscous formulations are delivered subcutaneously. However, this device is not going to be our one device applied across the board for all of our plasma protein portfolio, because there are different requirements. Some products of course are delivered only by intravenous injection, and some are only very small volume or only require very quick SC injections. Nonetheless, the Enable device is an important component of our strategy for the development of delivery devices with our products, specifically devices that meet patient needs.

Speaking generally, some of our products can be delivered both IV and SC, and the chosen route is the individual patient's choice. Some want to go to hospital and have the comfort of people who know them and nurses looking after them – some people prefer that and will go once every month or every two weeks for IV. For other people who are perhaps busier, or children, for example, SC delivery fits their lifestyle better. And within those who prefer SC delivery, there are some who want the medication administered quickly, to get it over with and get on with their day because they perhaps have work or school commitments or just don't want to be reminded about their condition. Others don't mind sitting with an SC pump for a couple of hours reading a book, and they don't mind being tethered to the pump with long tubes because they are used to that system and they trust it.

So, we see the Enable device appealing to needle-phobic patients, perhaps younger patients who are more active, patients who are working and busy and want to continue to go about their business, and various other segments that we have identified and probably others that we have not yet identified.

It offers the convenience and that's what really appeals to us and it really appeals to patients.

> "We lead innovation in protein therapeutics, so now we are trying to think about how we can lead innovation in delivery of our products to patients and how we can make the patient experience better"

We can also make the Enable technology specific to our products. Enable can make a device that delivers at a specific infusion rate, or which has a particular needle depth. It is all leading toward the end goal of delivering our products in the best possible way to our patients. That's what really drove us. And also, it's a really funky looking device, it's cool, people responded well to it, and that matters.

Q: Tell me, how are things going with Enable since partnering with them in October?
A: We have an excellent collaboration with Enable. We brought them into our company, into many of our team meetings. You can imagine – we're a really large company, we have a lot of infrastructure and many meetings, there are a lot of people involved in lots of different areas. We've invited Enable in to get to know our structure and they are adapting aspects of their structure to meet our needs. At present we are very much in the middle of the stages of planning and producing specification documents. We're also in the very early stages of running our regulatory studies. Enable is in the process of gearing up for manufacturing. So there is a lot of activity at the moment!

> "The Enable device is an important component of our strategy for the development of delivery devices with our products, specifically devices that meet patient needs"

Q: Could you give us some detail on how the agreement came into being? How did the two companies come together?
A: Sure. I've been searching for devices that could be compatible with any of our products. It has been a really thorough search in all of our different therapeutic areas. As part of that search I went to see Enable President Mike Hooven's presentation at BIO 2013 and arranged to meet with him. Immediately I could see the technology's applicability to several of our proteins.

That was the commencement of our relationship if you like – June 2013. Then, over the next year, we had several meetings discussing their technology. I introduced Enable to several members internally, and then it was a process of working through discovering whether using their technology would be feasible. So we exchanged products in effect – they sent us some of their devices and we sent them samples of our products. This was essentially to see if our products could actually be delivered using their device. This was done under a material transfer agreement. Once we'd proven it was technically feasible, that was when we moved on to discussing what a relationship between us could look like and that was when the internal presentations to CSL Behring senior management were made. We agreed in June 2014 – only one year after first meeting Enable – to offer terms. We negotiated terms and progressed to signing the agreement. So it was very fast but over that time we had interaction with Enable at all levels of our company.

Q: Whilst it's obviously a prerequisite that the technology fits with your products and other aspects of the two companies need to align for a partnership to be possible, I was wondering do you place much emphasis on the softer factors – company culture, personalities and the like – when you are looking for a partner?

A: Yes, very much! As mentioned, we started looking for device technology partners in 2010 (and I should mention that our searches in that area are still ongoing) and we have had the opportunity to review several companies, to meet with several companies, have in depth discussions. What really stood out from Enable ever since Day One – and I think everyone in our organisation who has dealt directly with them would agree with this – is that they are responsive. Incredibly responsive.

Every time we were brainstorming internally and came up with a potential roadblock I would just pick up the phone, call Mike and say, "About this aspect, we've been discussing it and we can see that we could have X issue on our side because of Y." And it would be one or two days later he would come back to us with a new prototype, a new design, completely addressing our issue. And that continued – whatever we threw at them, they would come back with a solution or an alternative, which made us really confident to go ahead in the end. You know, we didn't have the final specification nailed down when we settled the terms and signed the agreement, but we knew we were on the way and that for any issues that came up the design could be adapted. We had that much confidence in them. They are very, very attentive and customer focused I would say.

Q: This is a hugely important partnership for Enable as a relatively small company. How significant is a deal like this for a very large company such as CSL Behring?

A: It's a very important deal for us because it allows us to expand upon our patient focus. The Enable device is going to be an important offering but it is not going to be the only offering. We want to put forward a range of alternatives for our patients because we know one size does not fit all. This strategy is really going to establish us as a very customer-focused company within our sector, intent on delivering products that improve patient quality of life. The direct feedback we have had from our patient focus-groups is that the Enable design will improve their quality of life.

Q: Looking towards the future and the way things are moving in the industry with respect to parenteral drug delivery, could you speak a little on how this fits with the types of products CSL Behring develops?

A: One thing I've noticed by attending industry meetings is that interest in the area of parenteral drug delivery devices is growing, particularly for biopharmaceutical companies because in many of the therapeutic areas there is very little differentiation and companies are trying to differentiate their products for a better offering to patients. We are seeing an increasing number of "me-too" products and so the need for differentiation will likely continue.

At the moment though a lot of biopharma companies, like CSL Behring, are still very focused on the quality of our own products and so are not ready to take a leap into diversification into device development, preferring to partner. It could be that in the future larger companies will increasingly internalise device development and manufacturing but – my personal feeling is – it is probably better for pharma companies to focus on their products and look outside for devices that make the best fit. If you have invested in development of an internal device then you may be tempted to try to make that fit when in fact it doesn't quite fit. Forcing the fit with your internal device should not be the key driver – the key driver is whatever device works best for that particular product and that particular patient group.

In terms of the future of our collaboration with Enable, we signed the initial agreement with one product focus in mind. However we are working on a second product with them which we think will really benefit from the Enable Injections delivery system. So as we look to our future pipeline and the attributes line up between our products and their system, we will likely continue to expand our relationship. Naturally that will be dependent on the success of our first launch, and the continuing good collaboration and relationship between Enable and CSL Behring.

> "What really stood out from Enable ever since Day One – and I think everyone in our organisation who has dealt directly with them would agree with this – is that they are responsive. Incredibly responsive"

> "It's a really funky looking device, it's cool, people responded well to it, and that matters"

Dr Jeannie Joughin
Vice-President, Business Development
T: +1 610 878 4000

CSL Behring
1020 1st Avenue
King of Prussia
PA 19406
United States

www.cslbehring.com

Dr Jeannie Joughin is responsible for managing CSL Behring's current business licensing arrangements and relationships as well as building the business for tomorrow. Dr Joughin began her pharma industry career in 1992 as a Clinical Research Manager with Bristol-Myers Squibb, moving into New Product Commercialisation. From there, she worked in Brand Management. After successfully completing several marketing roles in the National Stroke Foundation, MediMark International and Mayne Pharma, Dr Joughin joined CSL Biotherapies in 2005 as Director, Pharmaceuticals Marketing and In-licensing. She has also held various scientific positions including Senior Research Scientist, Post-Doctorate and Senior Post-Doctorate positions in Australia at The Alfred Hospital, The Walter & Eliza Hall Institute, as well as internationally in Austria (University Clinic, Innsbruck) and Switzerland (Ludwig Institute for Cancer Research, Lausanne). Dr Joughin holds a Bachelor's degree (Hons) and PhD (Immunology) from Australia's Monash University and a diploma in marketing from Melbourne University.