The current dynamic environment of the healthcare and drug development industry is well known. One focal point of change is the rising cost of healthcare. This has proven a heavy burden to patients and finding ways to cushion these costs is increasingly important. Along with rising costs there is another focal point of change. The patent cliff of 2012 and the coming years has caused companies to assess options for cost savings as blockbuster drugs will no longer hold the marketshare previously enjoyed; between 2012 and 2016, 38 major pharmaceuticals will fall off the patent cliff in the US alone. According to a recent analysis, $33 billion in lost sales is forecast for 2012 due to the largest patent cliff in pharmaceutical history; furthermore it is forecast that over $290 billion in sales is at risk between 2012 and 2018. Blockbusters coming off patent will no longer be able to offer the financial security previously afforded, and companies are now reassessing business models.

Blockbusters during the early 2000s have dwindled significantly compared with the boom of the late 1980s and 1990s. In four of the last seven years, fewer than 30 new chemical entities per year were brought to market, illustrating clearly the dry pipelines now plaguing pharma. In an effort to combat increasing development costs and billions lost in development to drugs that never make it to market, the industry has undertaken an immense shift in development. Budgets the size of those of the 80s and 90s are a thing of the past and the search for “the next blockbuster” is being replaced by an overhaul in development strategy. As such, the simultaneous changes in patient needs and drug development needs make this a unique time for those seeking to meet these needs. With this changing pharma landscape, there is a newly concentrated effort which leaves the blockbuster-drug paradigm on the back burner. In this article, Dr Shunji Haruta, Executive Officer, SNBL Ltd, General Manager, NDS Division, describes some of the challenges being faced by the pharmaceutical industry and how it is adapting to face them, and explains how the company’s powder nasal delivery technology, Mucotm System fits well with the new environment.

“How Nasal Delivery Can Meet The Changing Needs Of Patients And The Drug Development Industry”

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“Therapeutic effect is not achieved through a good carrier formulation alone, it is also highly dependent on the formulation being delivered fully”

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order to combat these current hurdles, focus has shifted in four major ways: first, towards bringing drugs to market for smaller patient populations; second, developing drugs that are less costly to patients in an attempt to appeal to larger population segments; third, developing drugs designed for at-home care; and fourth, an increase in collaborative partnerships throughout development.

Now, non-traditional therapies such as orally inhaled and nasally delivered products are drawing much attention and exploration. Using such alternate routes of administration has the potential to address both the needs of patients and development. Coupled with service providers taking on greater roles as partners in development, “service provider” is increasingly being replaced with “solution provider”. These solution providers offer much in the way of new OINDP technologies and are at the forefront of new drug development.

One company which offers this advantageous solution provider partnership is SNBL, Ltd. For more than a decade, SNBL has been ahead of the curve through the development of its nasal delivery technology, Muco™ System. Invented, designed and developed fully in-house, Muco™ System addresses a great number of needs for the systemic delivery of small molecules and peptides, while the experience of having developed this technology in-house has given SNBL unparalleled experience in nasal drug product development, from specialised delivery characterisation testing capabilities to a validated nasal administration PK model in NHPs.

So how does Muco™ System fit in this new pharma environment?

As touched upon previously, alternate routes of delivery have gained much attention, especially nasal delivery. It is well known that delivery into the nasal cavity has distinct advantages when one considers the highly vascularised capillary bed which theoretically translates to easy access to the bloodstream. This is especially important as it then allows for a compound to avoid first-pass metabolism.

Thanks to this direct access to the bloodstream, especially nasal delivery.
and loss of metabolism, therapeutic onset is significantly faster.

In recent years, one can see how drug development companies have worked to harness the distinct advantages of nasal delivery. From migraine products to vaccines, nasal products have been able to offer a different route of administration to drug companies, along with more patient-friendly products that enable self-administration in the at-home setting. However, the field of nasal products has been dominated by liquid sprays.

**THE DIFFICULTY OF LIQUID NASAL SPRAYS**

As with every new technology, the beta years of new drug products help to highlight any shortcomings and points out to drug makers the areas where improvement is greatly needed. When it comes to nasal drug products, liquid sprays present a number of areas in need of improvement. To begin, administration of liquid into the nasal cavity is accompanied by an almost immediate running of the liquid from the nasal cavity into the pharynx, eventually making its way into the GI. While a portion of the drug may be absorbed at the site of initial administration, often the majority of the drug is absorbed through the GI. Naturally, the negative impact of running liquids on absorption in the nasal cavity has been acknowledged and the remaining inactive carrier from the nasal cavity and it is then expelled naturally.

The second cornerstone of Muco™ System is Fit-lizer™, a line of powder delivery devices designed for use with Muco™ System (Figure 2). The line offers both single and multiple use devices with excellent, proven delivery results.

SNBL noted that therapeutic effect is not achieved through a good carrier formulation alone, it is also dependent on the formulation being delivered fully. SNBL set out to address this challenge and developed a highly effective device. Delivery characteristic studies have proven that Fit-lizer™ delivers more than 95% of a formulation, every time.

Aside from proof of concept which shows Muco™ System to be a viable technology to replace liquid nasal sprays, Muco™ System also offers a patient-friendly alternative to other traditional therapies. Designed for the delivery of small molecules and peptides, Muco™ System has the ability to give patients a more convenient and controllable alternative to therapies which typically require a hospital or physician setting, namely, injections. Muco™ System can also provide a faster alternative to oral therapies. Two products developed by SNBL using Muco™ System (a granisetron product and a zolmitriptan product) are excellent examples of achievement in high and fast absorption without the use of an injection.

**SNBL: A SOLUTION PROVIDER**

Through the development of Muco™ System, SNBL has gained an invaluable amount of experience in the development of nasal products. At its core, SNBL is a CRO with over 55 years of experience, with special focus on work with NHPs. Services for nasal drug product development include in-house developed and validated NHP models. Unique to SNBL, these models are offered with both blood and CNS sampling in unanaesthetised animals. Other early development services which help to provide solutions to early development hurdles are also offered, such as assay development and validation, formulation development and optimisation, as well as delivery characterisation and particle size testing.

SNBL can also provide expertise in CMC development of nasal products. In addition to the abovementioned offerings, the nasal drug development team has regulatory experience in taking nasally delivered products through IND approval and into clinical trials, taking full advantage of the 505(b)(2) pathway.

All of this know-how and experience positions SNBL as an ideal solution provider. With the growing need of the pharma industry to outsource work, the ability to choose one outsourcing provider allows for better control and communication throughout the development process. SNBL meets this need, along with the ability to offer fast study starts and competitive timelines.

A Muco™ System nasal drug product coupled with the services by SNBL is a step towards addressing the changing environment of the pharma industry previously cited. Muco™ System allows for high patient compliance and ease-of-use without necessitating a hospital or physician setting. Outsourcing to SNBL, the development necessary for nasal products allows pharma companies to work with a solution provider, which is ultimately cost and time saving. The benefits inherent to this pairing are ready for the next challenge.

**REFERENCES**


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Great things come in pairs. Have you paired yet?

Impressive preclinical & clinical efficacy
Proprietary powder carrier & devices
Excellent predictive study model
Choice knowledge & know-how

Undeniably better nasal drug delivery
The benefits for your drug product are endless

Find out why our pair works:
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