Protein Sciences' FluBlok – finally here but much still to be done.

LONDON, UK----17th January 2012----ExpertREACT. The recent US FDA approval of Protein Sciences Corporation FluBlok, like Novartis Vaccines Flucelvax is a historical milestone in the development of influenza vaccines. This does not mean either will threaten the *status quo* in today's global market dominated by Sanofi Pasteur.

On January 17th privately owned Protein Sciences Corporation announced that the US FDA had finally approved its recombinant influenza vaccine FluBlok for individuals 18-49 yrs old **(1)**. FluBlok joins 9 other influenza vaccines **(2)** which currently battle for share of an estimated 145 million doses for use during the US 2012-13 influenza season. Along with Novartis' Flucelvax, which received FDA approval back in November 2012 **(3)** FluBlok raises the number of US available vaccines to 11 and similarly is not produced by classical egg-based production systems. Instead, FluBlok is manufactured using Protein Sciences' proprietary baculovirus expression vector system (BEVS) technology and expresSF+® cell line which does not use live virus. This means the vaccine can be manufactured much faster (~ 2 months) than traditional methods – an important consideration especially in light of unpredicatable influenza pandemics. The vaccine is also non-adjuvanted and contains 3 times the usual amount of hemagglutinin (HA) at 135μg per dose factors which can confer other potential product advantages.

FluBlok's approval has been based on efficacy studies at various sites across the US which compared the use of the vaccine in ~2,300 people to a placebo that was given to a control group of similar size. FluBlok was approximately 44.6 percent effective against all circulating influenza strains i.e. those included in the vaccine and mis-matching strains. The safety of FluBlok had been evaluated at total doses as high as 405μg and in individuals >18 yrs the vaccine was consistenly shown to have an acceptable tolerability profile.

FluBlok's US approval has been a long time coming. Clinical studies were initiated as far back as 1993 but the formal IND was not submitted until 2004. US FDA fast track designation was granted in 2006 with nine out of fourteen clinical studies being performed with US NIH/NIAID up until BLA submission in April 2008 requesting accelerated approval. Early clinical development of FluBlok and its "sister" pandemic product Panblok were supported by generous grants from the National Institutes of Health through the Vaccine Treatment and Evaluation Units.

Back in 2007 the company confidently stated that it expected first sales to be for the US 2008/09 influenza season and already began to exercise a global distribution strategy by signing an agreement with UMN Pharma (now in partnership with Astellas), a Japanese company, granting the latter an exclusive license to sell FluBlok in Japan **(4)**. However, in 2008 a FDA complete response letter began to slow the approval process requesting additional data on clinical efficacy.

With enormous levels of perseverance along the way, a failed acquisition by Emergent Biosolutions in 2009 and many "false dawns" in terms of its approval timeline, a strong signal of pending success was finally given by a Protein Sciences' annoucement in early December that it had acquired the former Pearl River, Wyeth plant to facilitate future FluBlok production **(4)**. The company was planning a mulitmillion dollar investment to render operational around 83,000 sq. ft. of production space which would be in additional to that in the company's facilities at Meridien, CT. Now with approval FluBlok should be widely available for the 2013-2014 influenza season and is available in limited supply for the current season.

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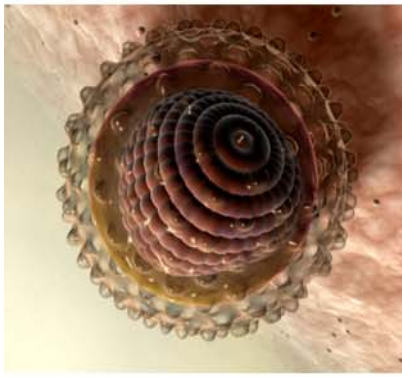

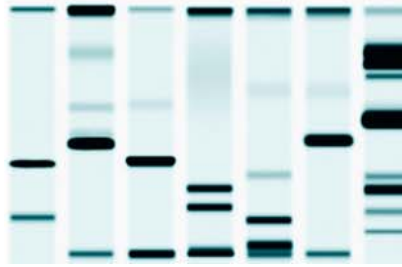

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Flublok has made US approval history being the first available recombinant vaccine for use in the US market. However, beyond all the excitement and hype – can FluBlok being a truly successful commercial product on a global scale? Undoubtedly many of the major influenza vaccine manufacturers looked at FluBlok but declined its acquisition – why?

Firstly, to date most of Flublok's development has been exclusively US-based although recently it was announced that the Japanese UMN/Astellas partnership had recently completed administration of a Phase III study in Japan (ASP7374) **(5)**. Much more time and investment will be required to expand the global penetration of Flublok into EU and important ROW/Southern Hemisphere regions. Moreover, capturing share within the important pediatric segment which is still dominated by Sanofi's Fluzone and making the transition to quadrivalent (QIV) format are other potential weaknesses of Flublok.

Apart from the production timeframe advantage of Flublok (which is less applicable to the seasonal market) many of Flublok's other potential product differentiators such as being egg-free, antibiotic/preservative free and even having a higher hemagluttinin content have already been tackled by competitors who at best only expect to occupy a niche position. To fully leverage potential cost advantages embedded in the Flublok production process requires economies of scale and big volumes. These in turn require the stimulation of significant demand. Step forward a powerful global marketing partner willing to invest and support Protein Sciences Corporation – a potential slice of a multibillion dollar global market awaits.

***Top 5 companies:** GSK Biologicals, Sanofi Pasteur, Merck & Co, Pfizer (Wyeth) and Novartis Vaccines and Diagnostics.

References and Notes:

1) Protein Sciences Corporate Press Release. January 16, 2013. Available at: http://www.proteinsciences.com/PDF/pscp1.pdf. Accessed January 2013
2) US CDC. Influenza vaccines 2012-2013 season. Available at: http://www.cdc.gov/flu/protect/vaccine/vaccines.htm. Accessed January 2013
3) Novartis Vaccines Corporate Press Release. November 2012. Available at: http://www.novartisvaccines.com/downloads/flucelvax/GLOBAL_Press_Release.pdf Accessed January 2013
4) Protein Sciences Corporate Press Releases. Available at: http://www.proteinsciences.com. Accessed January 2013
5) Protein Sciences Corporate Press Release. December 11, 2012. Available at: http://www.proteinsciences.com/PDF/pscp2.pdf. Accessed January 201

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