

## 2009 Best Hits

### Product Development

Positive results announced in November 2009 from the second of two Phase III trials of **Benlysta** in systemic lupus erythematosus sent shares of **HGSI** up 70%. Pharmawire had reported on the details of the trial in October 2009, identifying trial advantages such as steroid locking and patient population details that proved crucial to the trial's success. In the month before the positive trial results were announced, Pharmawire covered the company from multiple angles, including trial design, patient population, M&A potential, and the effects of background therapies.

10-Jul-09	Human Genome Science's use of steroid locking, landmark trial protocol in BLISS studies for Benlysta seen as likely advantages in trial design – experts
	Pharmawire

**Merck-Serono's cladribine's** application was met with a 'Refuse to File Letter' by the FDA, determining that a better data package was required before it could consider approval. Pharmawire wrote extensively on this possibility, particularly expressing skepticism over multiple articles that data from one Phase III trial would prove insufficient.

01-May-09	Merck Serono's cladribine should be tested against active comparator in Phase III trials, neurologists say
	Pharmawire

In December 2009 Pharmawire spoke to leading oncologists, reporting that **Celgene's Revlimid** would be unlikely to meet the hype and high expectations of stellar **MM-015** Phase III results at ASH 2009. Data released at ASH a few days later showed that on the subject of curve separation disappointed, sending Celgene shares down 5% when the news was released. Pharmawire was ahead of the market, informing readers that expectations for conclusive results were premature.

01-Dec-09	Celgene's Revlimid: MM-015 data too premature to see survival differences at ASH, needs 6-8 month PFS difference - oncologists
	Pharmawire

In February 2009, **Synta Pharmaceuticals** suspended its **elesclomol** metastatic melanoma trial, sending shares down over 75%. Pharmawire covered the company in detail with multiple stories the month prior, reporting how the trial could falter due to trial design inconsistencies and due to an ambiguous mechanism of action, making it very clear for readers that the drug's development faced significant challenges.

20-Jan-09	Synta/GSK's melanoma drug elesclomol may falter in development due to Phase III trial design inconsistencies, physicians say
	Pharmawire

### CRO

Pharmawire was the first and only news service to hone in on the seriousness and widespread implications of the **ceftobiprole** inspections by the FDA, which resulted in an unprecedented CRO warning letter. Pharmawire detailed the involvement of and ongoing troubles between all parties involved, also correctly predicting where the drug would end up after the dust settled. Prior Pharmawire coverage almost a year earlier identified that all was not well in the relationship between **Basilea** and **Johnson & Johnson**, indicating that legal proceeds could commence, and identifying the CRO in the midst of the drama.

17-Sep-09	Johnson & Johnson's ceftobiprole warning letter 'serious' for J&J and Icon; indicative of FDA crackdown on GCP of trial data, experts say
	Pharmawire

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Pharmawire reported a non-public investigation by the FDA into **Pfizer's** post-market reporting, highlighting a number of issues found by the regulator with the potential to have serious consequence for one of the world's biggest drug developers.

30-Nov-09	Pfizer receives 483 by FDA following HQ inspection; regulatory action and warning letter could follow, sources say
	Pharmawire

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Pharmawire started targeting some of its coverage towards an early trend within the industry that it considers to be of great importance - the heightened scrutiny by regulatory agencies on the conduct of clinical research organizations (CROs) and the potential for good clinical practice (GCP) breaches to impact new drug approvals. Pharmawire reported non-public information that GCP breaches involving **K-Force**, the CRO hired by **Pfizer** to conduct hundreds of its clinical trials, are known to Pfizer and this may expose the drug giant to regulatory issues with certain new drug applications in the future.

11-Oct-09	Pfizer aware of inadequate oversight of CRO K-Force; clinical trial monitoring and documentation issues could expose Pfizer to future regulatory scrutiny - source
	Pharmawire

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### Licensing/Partnership:

In December of 2009, **Seattle Genetics** signed a partnership deal with **Takeda** worth up to USD 365m and another with **GlaxoSmithKline** worth up to USD 390m. Two days before the first of the two partnerships was announced, Pharmawire reported that the company's lead drug, **SGN-35**, was seeing a lot of interest, and that the company was being approached regarding partnership opportunities. Pharmawire also reported on the likelihood of a partnership for SGN-35 in May of 2005, when an interview with the CEO explored the fact that the company was in active talks to license the lead candidate.

28-May-09	Seattle Genetics in 'active talks' to secure ex-US deal for SGN-35, a lot of interest, CEO says
	Pharmawire

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Pharmawire reported that **NeurogesX** was looking to partner **Qutenza** in May 2009 when shares were trading at USD 2.85. Just over a month later, the treatment was partnered with **Astellas** in a deal worth USD 42m with shares trading at USD 5.86, for an increase of over 100% in value.

06-May-09	NeurogesX currently seeking partners for pain product, open to specialty and large pharma, CEO says
	Pharmawire

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Pharmawire identified **Targacept** as an attractive target in May 2009 when shares were trading at USD 3, reporting that **AstraZeneca** was the most likely suitor, and that the two companies could do a deal if a key trial met primary endpoints. In June 2009, positive results led to a significant increase in Targacept's share price, and by December, the company was trading at USD 20 on news of a USD 200m payment from AstraZeneca. Pharmawire was correct in reporting that a deal could go down after positive results, alerting readers to an exciting company at a pivotal point in its development.

22-May-09	Targacept may draw suitors when ADHD results come out in June, industry sources say
	Pharmawire

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## M&A

Pharmawire wrote on this subject of BioForm Medical's acquisition twice in 2009, reporting that the company had retained an investment bank to sell itself and then reporting that **BioForm** was unlikely to be bought by **Medicis Pharmaceutical**. In the first week of 2010, BioForm was acquired by **Merz Pharma**, sending shares soaring 60%. From the date in April when Pharmawire first reported that the company was said to have retained an investment bank, shares are up over 400%.

20-Apr-09

BioForm Medical believed to be working with investment bank to sell itself, sources say

Pharmawire

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