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Key clinical trial readouts for big pharma in the second half



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Data on the Alzheimer's disease candidates bapineuzumab and solanezumab might remain the most hotly expected clinical trial results this year, but the world's biggest drug makers have several other late-stage candidates in the locker due to report make-or-break data before 2012 is out.

Gilead investors will be keenly awaiting further data on GS-7977, the hepatitis C candidate the company bought with Pharmasset for \$11bn, and strong results are needed to justify that acquisition price. From the big pharma camp Merck & Co is looking for boosts to already-marketed products from closely watched trials of Vytorin and Tredaptive, the Improve-IT and HPS2-Thrive studies. Meanwhile Eli Lilly is awaiting results from six late-stage candidates, making this a crucial period for one the industry's most beleaguered big pharma players (see table).

Sky high

Expectations about the commercial potential of GS-7977 might have been tempered in recent months – largely due to an increasingly competitive environment – but hopes are still sky high for Gilead's most valuable pipeline candidate. Consensus has sales reaching \$5.3bn by 2018, and the product needs to shine in pivotal studies to hope to achieve these revenues.

Due in the fourth quarter are readouts from two phase III studies, Fission and Positron, in genotype 2/3 patients, while phase II studies testing the agent in combination with other oral drugs, including Bristol-Myers Squibb's daclatasvir, should also yield data.

Merck could have a big year end for data, although both events could slip into 2013.

The Improve-IT study, a huge 18,000-patient outcome study started in 2005, is testing whether Vytorin – a combination of a statin and a cholesterol absorption inhibitor, Zetia – is more effective at preventing cardiovascular events and deaths than using the statin alone. Sales of Vytorin dropped from a peak of \$2.8bn in 2007 to \$1.9bn after evidence emerged suggesting this was not the case, a scandal of withheld trial data that still taints the reputation of Merck today.

The Improve-IT study is unlikely to complete until next year but an independent monitoring board said in March that it would be conducting its next analysis in about nine months time. That means late 2012, and while few expect the results at that stage to be so overwhelmingly positive that the trial stops, there is still a slim chance that this might happen.

With many commentators expecting the trial to fail to show any benefit, a positive readout could stem declines for a fading product that is still fairly important for Merck – sales are seen reaching \$1.8bn this year. Should the trial find the drug causes harm, the US company is looking at an even bigger disaster on the PR front.

Also in the cardiovascular space, the even more substantial 26,000 HPS2-Thrive study with the HDL-boosting agent Tredaptive might yield results towards the end of the year, although this could well not emerge until 2013. Again, evidence that the miacin-based product is cardioprotective would likely give a big boost to a currently insignificant product for Merck – sales reached \$26m last year – and help provide valuable evidence in the ongoing HDL debate ([Vantage Point - Functionality in focus as HDL hypothesis awaits confirmation, September 8, 2011](#)).

Hard to beat

As recently discussed by *EP Vantage*, Eli Lilly has a big period of data readouts approaching, and as a trenchant defender of the R&D model it needs some wins. The failure of pomaglumetad a few weeks ago in phase II does not bode well for an interim look at a larger phase III study, due later this year ([After Lilly shrugs off schizophrenia failure pipeline must deliver, July 12, 2012](#)).

The Indianapolis company will be hoping that its other CNS and diabetes hopefuls deliver the goods. Data on Eli Lilly and partner Boehringer Ingelheim's biosimilar insulin product LY2963016, a version of Sanofi's Lantus,

will be closely watched, particularly given the delay to Novo Nordisk's new insulin entrant, degludec.

Of course the readout on solanezumab and Pfizer and Johnson & Johnson's bapineuzumab will be hard to beat in terms of big clinical events this year, even though both are widely expected to fail to show any benefit ([Event - Amyloid-targeting Alzheimer's therapies seek crumbs of comfort, June 26, 2012](#)).

Lilly has said that it expects to report information in the latter half of the third quarter while J&J confirmed recently that the bapi data would also come this quarter, with the first detailed presentation at a European medical conference shortly afterwards, likely the EFNS Congress in Stockholm.

Data read outs								
Product	Pharmacological Class	Company	Event-trial results	Indication	Date	Product NPV (\$m)	NPV as % of Market Cap	Tri
GS-7977	Hepatitis C nucleoside NS5B polymerase inhibitor	Gilead Sciences	II and III	Hepatitis C	Q3	18,398	47%	NC NC NC NC
Afinitor	Rapamycin analogue (mTOR inhibitor)	Novartis	III	Breast cancer	Q4	7,004	5%	NC
Vytorin	Statin/ HMG CoA reductase inhibitor & cholesterol absorption inhibitor	Merck & Co	III	Hyperlipidaemia	Q4	3,083	2%	NC
Tredaptive	Vitamin B3 & prostaglandin D2 receptor antagonist	Merck & Co	III	Lipid disorders	Q4	2,287	2%	NC
Abraxane	Taxane	Celgene	III	Pancreatic cancer	Q4	2,234	8%	NC
Nexavar	Multi-kinase inhibitor	Bayer	III	Breast cancer	Q3	1,985	3%	NC
New insulin glargine product	Insulin	Eli Lilly	III	Diabetes	Q3	1,856	4%	NC NC
Riociguat	Guanylate cyclase activator	Bayer	III	Pulmonary hypertension	Q3	1,790	3%	NC
Dulaglutide	GLP-1 agonist	Eli Lilly	III	Diabetes	Q3	1,081	2%	NC
Pomaglumetad Methionil	mGluR2/3 agonist	Eli Lilly	III	Schizophrenia	Q4	886	2%	NC
LY2216684	Norepinephrine reuptake inhibitor	Eli Lilly	III	Major Depressive Disorder	Q4	819	2%	NC
Bapineuzumab	Anti-beta amyloid MAb	Pfizer	III	Alzheimer's Disease	Q4	770	0%	NC NC
Bapineuzumab	Anti-beta amyloid MAb	Johnson & Johnson	III	Alzheimer's Disease	Q4	491	0%	
Solanezumab	Anti-beta amyloid MAb	Eli Lilly	III	Alzheimer's Disease	H2	675	1%	NC NC
	B lymphocyte stimulator							

Atacicept	Stimulator & proliferation-inducing ligand inhibitor	Merck KGaA	II	Systemic Lupus Erythematosus	Q3	461	2%	NC
BI10773 (empagliflozin)	Sodium-glucose cotransporter-2 (SGLT2) inhibitor	Eli Lilly	III	Type 2 Diabetes	Q4	396	1%	NC NC NC NC NC
Cilengitide	Integrin inhibitor	Merck KGaA	III	Glioblastoma	Q3	348	2%	NC
AMG 103	Anti-CD19 MAb	Amgen	II	ALL	Q4	306	1%	NC
rFVIII-Fc	Factor VIII	Biogen Idec	III	Hemophilia A	Q4	265	1%	NC
IDegLira	GLP-1 agonist & insulin	Novo Nordisk	III	Diabetes	Q4	19	0%	NC
AMG 145	Anti-PCSK9 MAb	Amgen	II	Hyperlipidaemia	Q4	-	-	NC
Talimogene laherparepvec	Oncolytic virus	Amgen	III	Melanoma	H2	-	-	NC

Data source: EvaluatePharma's Calendar of Events.

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