

Key data readouts in the second half of 2012



[Joanne Fagg](#)

The second half of the year holds some important data readouts for the industry's smaller players in both oncology and the much rarer orphan diseases.

While both Clovis and AB Science are studying drugs in the notoriously hard-to-treat pancreatic cancer, Amicus, Swedish Orphan Biovitrium and Biomarin are anticipating results in Fabry disease, haemophilia A and Morquio Syndrome, respectively.

Other results include Oncolytics' attempt to treat head and neck cancer with an oncolytic virus and Active Biotech's antibody for renal cell cancer. Rheumatoid arthritis continues to feature in the second half of the year for MorphoSys while the rollercoaster ride continues for Resverlogix with its second attempt to get its atherosclerosis approach to work (see table).

Cancer read outs

Oncolytics is awaiting interim phase III results of its lead product, head and neck cancer treatment Reolysin. The trial uses Reolysin in combination with carboplatin and paclitaxel and the results could validate the company's approach of using a Ras-activated oncolytic virus to fight cancer.

Despite limited success of oncolytic virus-based drugs, which have all previously fallen at phase III, expectations around the drug are high with 2018 forecast sales of \$911m ([Event - Oncolytics prepares for big test with cancer data, April 16, 2012](#)).

In June a data monitoring committee recommended continued enrolment in the study after reviewing safety data. The company plans to enrol between 100 and 400 patients in the second stage of the trial; the first stage included 80 patients.

Top line phase II results of Clovis Oncology's biggest growth driver CP-4126 are expected in the fourth quarter ([Clavis making hay while sun shines on cancer candidate, January 18, 2012](#)).

The company, which licensed the drug from Clavis Pharma back in 2009, is testing the drug in a subset of pancreatic cancer patients whose tumours express low levels of a cell surface transporter called hENT1. hENT1 is a dominant transporter for gemcitabine, the current standard of care in inoperable pancreatic cancer, and tumours with low levels of the transporter have shown to be resistant to gemcitabine therapy.

In a phase II trial in 21 patients, those treated with CP-4126 lived for median 9.1 months versus 3.3 for those treated with gemcitabine. The big test is yet to come with top-line survival data from the Leap study in 360 patients, 64% of which were classified as hENT-1 low.

AB Science is expecting phase III results from its oral tyrosine kinase inhibitor AB1010 (masitinib) in advanced metastatic pancreatic cancer. The trial in 350 patients compares masitinib in combination with gemcitabine to placebo and gemcitabine with overall survival as the primary endpoint ([Event - AB Science awaiting first test of scattergun approach, September 22, 2011](#)).

Masitinib has already shown positive results in gleevec-resistant GIST: after 18 months 82% of patients treated with the drug were still alive versus 33% of those treated with Sutent.

Results of the pancreatic trial were due to be released in April this year. However the company announced a postponement because data analysis, and in particular genetic data analysis, was taking longer than expected. Analysts at Edison note that characterising a sub-population would be significant for the drug.

Results of Active Biotech's renal cell cancer MAb Anyara are expected in the second half of the year ([Active gets boost as pipeline hopes rise, May 22, 2012](#)).

The binary phase II/III trial is studying the effect of Anyara in combination with interferon-alpha compared with interferon-alpha alone in patients with advanced renal cell cancer. With a primary endpoint of overall survival,

Reolysin	Oncolytic virus - Ras activated	Oncolytics Biotech	III	Head and neck cancers	H2	2,693	9
Plecanatide	Guanylate cyclase type-C receptor agonist	Synergy Pharmaceuticals	III	Chronic idiopathic constipation	Q4	2,655	9
GALNS	N-acetyl-galactosidase-6-sulfatase	BioMarin Pharmaceutical	III	Morquio Syndrome	Q4	799	1
Vosaroxin	Naphthyridine analogue	Sunesis Pharmaceuticals	III	AML	H2	769	4
Allovectin-7	HLA-B7 gene therapy	Vical	III	Melanoma	Q4	678	2
CP-4126	Pyrimidine analogue	Clovis Oncology	II	Pancreatic cancer	Q4	639	1
Naloxegol	Mu opioid antagonist	Nektar Therapeutics	III	Opioid induced constipation	H2	610	0
Zymafos	Alkylating agent	ZIOPHARM Oncology	III	Soft tissue sarcoma	H2	590	1
GRN163L	Telomerase inhibitor	Geron	II	Breast Cancer and NSCLC	Q4	476	2
TZP-102	Ghrelin agonist	Tranzyme Pharma	II	Diabetic gastroparesis	Q4	449	4
CXA-201	Cephalosporin & beta-lactamase inhibitor	Cubist Pharmaceuticals	III	Urinary tract infections	Q4	310	1
Amigal	Alpha galactosidase chaperone	Amicus Therapeutics	III	Fabry disease	Q3	309	1
OMS302	Anti-inflammatory agent & anti-cholinergic	Omeros	III	Intra-ocular lens replacement surgery	H2	256	1
rFVIII Fc	Factor VIII	Swedish Orphan Biovitrum	III	Hemophilia A	H2	202	1
Arbaclofen placarbil	GABA agonist	XenoPort	III	Spasticity in MS	Q3	183	1
QVA149	LAMA & LABA	Vectura	III	COPD	H2	108	28
Zerenex	Phosphate binder	Keryx Biopharmaceuticals	III	Hyperphosphatemia	H2	102	70
OMS103HP	Anti-inflammatory agent & analgesic	Omeros	III	Postoperative pain	H2	69	28
Prochymal	Mesenchymal stem cell	Osiris Therapeutics	II and III	Acute Myocardial Infarction and Crohn's disease and	Q4	57	17
AZD9773	Anti-tumour necrosis factor alpha TNFa polyclonal MAb	BTG	II	Sever sepsis	H2	55	39
	Anti-5T4 MAb-						

Anyara	SEA/E-120 toxin conjugate	Active Biotech	III	Renal cancer	H2	9	29
AB1010	c-kit tyrosine kinase & platelet-derived growth factor receptor inhibitor	AB Science	III	Pancreatic cancer	Q3	-	-
ADX71149	mGluR2 agonist	Addex Therapeutics	II	Schizophrenia	Q3	-	-
BVF-036	5-HT2A (serotonin) antagonist	ACADIA Pharmaceuticals	III	Parkinson's disease	Q3	-	-
Cevira	Photodynamic therapy	Photocure	II	HPV infections	H2	-	-
MOR103	Anti-GM-CSF MAb	MorphoSys	II	RA	Q3	-	-
RVX-208	Apolipoprotein A-I enhancer	Resverlogix	II	Atherosclerosis	Q3	-	-
Talactoferrin	Immunomodulator	Agennix	III	NSCLC	Q3	-	-

Data source: EvaluatePharma's Calendar of Events.

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