

## Esmo preview - Like Asco, now unmissable



Jacob Plieth

With the curtain lifting last night on many studies due to be presented at the Esmo meeting next week immuno-oncology is again set to seize many of the headlines, and starring roles have been given to Astrazeneca, Merck & Co, Bristol-Myers Squibb and Roche.

But there is also plenty for followers of more traditional approaches, and one of the most important presentations features the Monarch 3 trial of Lilly's abemaciclib (see table below). It seems that for the second year running data timing has allowed Esmo to rival Asco as the biopharma calendar's unmissable oncology meeting.

Abemaciclib, a CDK4/6 inhibitor, impressed at Asco in the Monarch 2 trial, but it is Monarch 3 that is expected to allow a proper comparison with its rivals, Pfizer's Ibrance and Novartis's Kisqali. The trial, in HR-positive, Her2-negative breast cancer, met its primary endpoint of progression-free survival at interim analysis, so full data are keenly awaited.

Monarch 3 will be featured at Esmo's presidential symposium. Along with the Esmo late-breakers the full text of the abstract has not been unveiled, so investors will have to sit tight until September 10.

### Immuno-oncology

Among the various presentations on PD-(L)1 inhibitors one of the most keenly awaited features data from the Pacific study of Astrazeneca's Imfinzi in stage III lung cancer.

With the Mystic trial, which failed at its first analysis, dominating investor thinking, Imfinzi's positive PFS hit in Pacific came out of the blue. None of Imfinzi's rivals is approved specifically in stage III NSCLC - an earlier disease than stage IV and a potentially bigger commercial opportunity.

Followers of Merck can look to an update from Keynote-021 cohort G, which served as the basis for accelerated US approval of Keytruda plus chemo in first-line NSCLC. The Keynote-040 trial in head and neck cancer, meanwhile, will be scrutinised for reasons as to why it failed, though chances of Keytruda's accelerated US approval here being revoked are slim.

In this sense urothelial bladder cancer is similar: all five of the leading anti-PD-(L)1 agents are approved for this cancer, four under accelerated approval, though Roche's confirmatory trial of Tecentriq subsequently failed. At Esmo Merck will reveal full data of its successful Keynote-045 study, which will no doubt be compared against its anti-VEGF MAb rival, Lilly's Cyramza.

Other non-immuno-oncology approaches to be profiled at Esmo include Parp data from Tesaro (Zejula) and Clovis (Rubraca), as well as a study of a low-profile PI3K inhibitor, Roche's alpha-selective tselisib.

### Selected abstracts from Esmo 2017

Project	Company	Study	Indication	Esmo abstract	Comment
<i>Friday, September 8</i>					
Tselisib	Roche	Lorelei	ER+/Her2-breast cancer	LBA10	<a href="#">ECC - More setbacks leave PI3Ks in immuno-oncology's shadow, September 26, 2015</a>
Keytruda	Merck & Co	Keynote-059	Alone or + chemo in gastric cancer	LBA28_PR	<a href="#">Asco - Merck reveals its gastric cancer hand, June 4, 2017</a>
Rubraca	Clovis	Ariel3	Maintenance ovarian	LBA40	<a href="#">Ariel3 puts Rubraca on Parp with Zeiula. June 19, 2017</a>

			cancer		<a href="#">Merck Keytruda, June 10, 2017</a>
Keytruda	Merck & Co	Keynote-021G	Chemo combo 1L NSCLC	LBA49	<a href="#">Merck cements its lung cancer lead, May 11, 2017</a>
<i>Saturday, September 9</i>					
Keytruda + Lenvima	Merck & Co & Eisai	Keynote-022	Renal cancer	8470	<a href="#">Asco-GU – Roche’s renal success spells danger for all-comer studies, February 22, 2017</a>
Epacadostat + Keytruda	Incyte & Merck & Co	Echo-202/Keynote-037	Melanoma	12140	<a href="#">Asco – Solid progress for IDO inhibitors, June 6, 2017</a>
Binimetinib	Array	Columbus (pt 2)	Braf-mut melanoma	12150	<a href="#">Snippet roundup: Sighs of relief for Astra and Glaxo, May 12, 2017</a>
Imfinzi	Astrazeneca	Pacific	2L stage III NSCLC	LBA1	Met primary PFS endpoint
<i>Sunday, September 10</i>					
Flotetuzumab	Macrogenics		AML	9950	CD123xCd3 bispecific, possible dose-expansion data
Cabometyx	Exelixis	Cabosun	1L renal cancer	LBA38	<a href="#">Opdivo’s renal failure boosts Exelixis – or does it?, August 16, 2017</a>
Keytruda	Merck & Co	Keynote-045	Urothelial cancer	LBA37	<a href="#">Tecentriq failure puts accelerated approval in a spin, May 10, 2017</a>
Cyramza	Lilly	Range	Urothelial cancer	LBA4	<a href="#">Lilly edges towards the bladder cancer queue, May 31, 2017</a>
Abemaciclib	Lilly	Monarch 3	HR+/Her2-breast cancer	2360_PR	<a href="#">Asco preview – Breast cancer and I-O combos grab the early headlines, May 18, 2017</a>
Opdivo + Yervoy	Bristol-Myers Squibb	Checkmate-214	1L renal cancer	LBA5	<a href="#">Opdivo’s renal failure boosts Exelixis – or does it?, August 16, 2017</a>
BMS-986016 + Opdivo	Bristol-Myers Squibb		Lag3 in PD(L)1 progressors	LBA18	Showed some activity at Asco
<i>Monday, September 11</i>					
Alecensa	Roche	Alex	vs Xalkori in 1L Alk+ve NSCLC	12980_PR	<a href="#">Therapy focus – Roche looks ready to rule another cancer niche, March 6, 2017</a>
Zejula + Keytruda	Tesaro & Merck & Co	Topacio/Keynote-162	Ovarian & TNBC	1143PD	<a href="#">Asco – Lynparza gets Parp edge in breast cancer, June 4, 2017</a>
Alecensa	Roche	Alur	vs chemo in 2L Alk+ve NSCLC	12990_PR	Reported positive PFS data
Keytruda	Merck & Co	Keynote-040	Squamous cell head & neck cancer	LBA45	<a href="#">Merck’s Keynote falls flat, and that’s just fine, July 25, 2017</a>

Opdivo	Bristol-Myers Squibb	Checkmate-238	Adjuvant melanoma, vs Yervoy	LBA8	Demonstrated improvement in recurrence-free survival
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Among smaller companies one of the most keenly awaited readouts will come from Exelixis's Cabosun trial, which supported a recent Cabometyx filing in first-line renal cancer.

Many of the data from Cabosun are out, but Esmo is set to reveal an update on Cabometyx's overall survival, which at last year's Esmo was numerically superior to Sutent, though not statistically significant. Approval is likely, but Cabometyx's position against Opdivo - also dependent on OS readout - will be determined by fine details from Cabosun and the Checkmate-214 trial.

Investors will also focus on Array Biopharma's binimetinib, which features in an analysis of part two of the Columbus study that served as the basis for its US filing with encorafenib in Braf-mutated melanoma. Also in melanoma, Incyte has already [revealed](#) an incremental update from a study of epacadostat plus Keytruda, suggesting an improvement in remissions versus historical data on standalone Keytruda.

There will also be results from a safety run-in cohort of binimetinib's phase III Beacon study in colorectal cancer. While there will be plenty for everyone, watchers of smaller companies might find their favourite groups struggling to fight for attention over the noise of what will be another big pharma-focused conference.

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