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2015 AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Opdivo trial homes in on those most likely to benefit; PD-L1 as biomarker

By Michael Fitzhugh, Staff Writer

CHICAGO – Bristol-Myers Squibb Co.'s Opdivo (nivolumab), approved in March to treat certain patients with squamous non-small-cell lung cancer (NSCLC), can also provide significant benefit to patients with the more common nonsquamous form of NSCLC, especially those with tumors expressing high levels of tumor programmed death-ligand 1 (PD-L1), according to findings from the phase III CheckMate-057 study, presented Friday at the American Society of Clinical Oncology (ASCO) meeting.

See Opdivo, page 3

Gene screen PD-1 big gun? Mismatch catch pays off in Keytruda vs. colorectal

By Randy Osborne, Staff Writer

CHICAGO – Genomics may matter more than histology in predicting the response rate of patients treated with the programmed death-1 (PD-1) inhibitor

See PD-1, page 4

IN THE CLINIC

No red 'Heron' as Sustol proves 'MAGIC' in phase III

By Marie Powers, News Editor

Investors in Heron Therapeutics Inc. received the good news they were awaiting when the phase III MAGIC study of Sustol (granisetron injection, extended release) hit its primary endpoint as part of a three-drug regimen together with the intravenous (I.V.) neurokinin-1 (NK1)

See Heron, page 5

IN THE CLINIC

Nucana set to follow 'groundbreaking' ASCO data with phase III trial

By Nuala Moran, Staff Writer

LONDON – Nucana Ltd. is poised to start phase III development of its lead product Acelarin after reporting what it claimed as "groundbreaking" phase I/II data for the modified version of gemcitabine at

See Nucana, page 2

NEWCO NEWS

Glactone Pharma touts Stat3 inhibitor's potential in immuno-oncology

By Cormac Sheridan, Staff Writer

DUBLIN – Glactone Pharma AB, an early stage Swedish firm, is lining up with the big guns of the cancer world at the American Society of Clinical Oncology meeting this week with preclinical proof-

See Glactone, page 7

IN THIS ISSUE

BENCH PRESS

BioWorld Science Editor Anette Breindl takes a closer look at translational medicine

Read this week's edition

GENOMICS

AIMING FOR AN 'ADVANTAGE'

Strand launches new version of pan-cancer genomic profiling test

By Omar Ford, Staff Writer

Strand Life Sciences is hoping for a bigger seat at the table in the U.S. next-generation sequencing (NGS) market with the launch of an expanded version

See Strand, page 8

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IN THE CLINIC

By Nuala Moran, Staff Writer

Nucana set to follow 'groundbreaking' ASCO data with phase III trial

LONDON – Nucana Ltd. is poised to start phase III development of its lead product Acelarin after reporting what it claimed as "groundbreaking" phase I/II data for the modified version of gemcitabine at the American Society of Clinical Oncology meeting in Chicago on Saturday.

In all, 78 percent of 49 evaluable patients with advanced solid tumors who had failed on prior chemotherapy, including gemcitabine, showed a response to Acelarin. The disease control was durable, with progression-free survival standing at 6.7 months and ongoing.

"It is very unusual to see such a strong response in phase I/II, especially since about a dozen of the patients are receiving the recommended dose but most were on lower [doses]," said Hugh Griffith, CEO.

Nucana is not making the "groundbreaking" claim lightly; rather the company has checked the records to see how other – now successful – oncology products did in phase I/II.

Avastin (bevacizumab, Roche AG), for example, achieved disease control in 48 percent of patients, while Erbitux (cetuximab, Eli Lilly and Co.) showed a 54 percent rate of stable disease. "The Acelarin data are far and above anything reported for a number of drugs at the same stage of development," Griffith told ***BioWorld*** Today.

Patients with more than 18 different types of solid tumors have been treated in trial. While overall, disease control stands at 6.7 months, in 14 cases of gynecological cancers the effect has lasted for more than eight months. "This is another point of distinction; initially you might expect stable disease or a partial response, usually followed by relapse after two, three months. That hasn't happened here," Griffith said.

In addition, there was good safety and tolerability. "The side effect profile is comparable to gemcitabine; we've not seen any toxicity that is different. But what is more encouraging is that the breadth of the side effects is reduced, and they have tended to be more transient," said Griffith.

That is attributed to the fact that Acelarin does not generate the toxic metabolite dFdU (difluorodeoxyuridine), which is released by gemcitabine. Another factor is that the recommended dose of Acelarin is one-third of that for gemcitabine.

About half the patients in the phase I/II trial had been treated with gemcitabine previously. "In effect, they were their own control. The anecdotal evidence is that Acelarin is better tolerated," Griffiths noted.

Armed with those results, Edinburgh, UK-based Nucana is opening a 328-patient phase III pancreatic cancer trial in which Acelarin will be tested against gemcitabine as standard of care. The study opens in the UK this month and will be expanded to other sites in Europe and to the U.S. If the data are strong enough, they will be sufficient to file for approval, Griffith said.

In addition, the company is starting a phase Ib trial of Acelarin in combination with cisplatin in bilary cancer, preparing the way for a 600-patient phase III to start in the first half of 2016. Here, cisplatin plus Acelarin will be compared to cisplatin plus gemcitabine, as the standard of care.

Another phase Ib in ovarian cancer will test Acelarin in combination with carboplatin.

Nucana is also progressing work to apply its Protide approach to other nucleoside analogue chemotherapeutics. The technology weaves around resistance pathways by adding a phosphoramidite tag, which eliminates the need for active transport across the cell membrane and for kinase-mediated phosphorylation within the cell.

"Only around 10 percent of tumors respond to gemcitabine because most cells do not activate it. We are delivering the active metabolite," Griffith said.

A similar sleight of medicinal chemistry lies at the heart of Gilead Sciences Inc.'s antiviral platform, led by the breakthrough hepatitis C virus therapy Sovaldi (sofosbuvir). While not yet prepared to lay claims to Acelarin being the Sovaldi of cancer therapy, Griffith said the results to date are very encouraging and Acelarin has the potential to replace the standard chemotherapy backbone for many cancers.

Nucana raised $57 million in a series B round that closed in April 2014. The company will need another financing over the course of the next nine to 12 months. "The current investors are strong and committed to the programs. I've had informal discussions with potential additional investors," said Griffith. "But we've got $50 million, so there's no rush."