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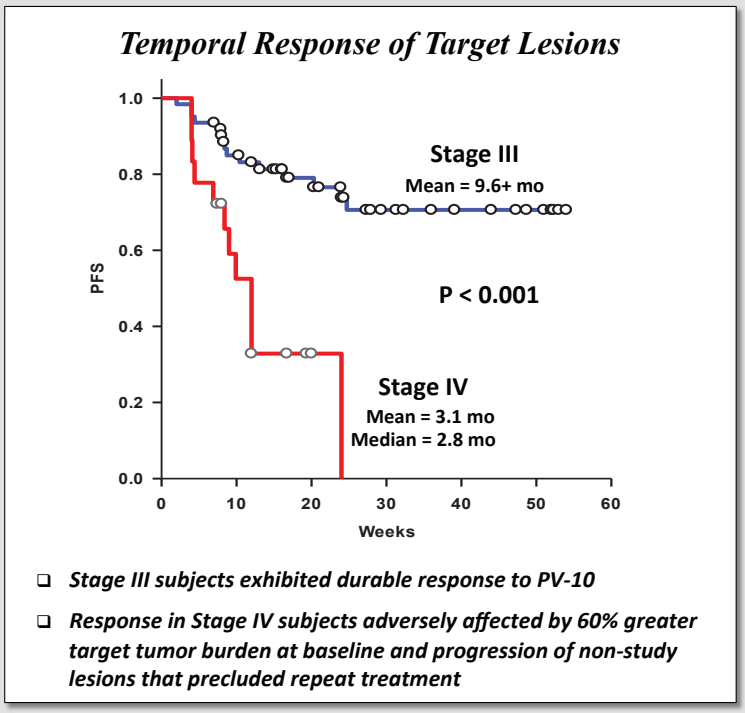
Provectus looks to Phase III with positive melanoma data



Provectus Pharmaceuticals has reported top-line final data from a Phase II trial of PV-10 for metastatic melanoma, which it says will help inform the design of Phase III trials.

"Based upon strong response rate and progression free survival results, stage III melanoma patients are expected to be the targeted patient population for Phase III," the oncology and dermatology biopharmaceutical company said.

"These preliminary analyses using final, fully validated study data confirm trends previously reported using preliminary data, and are also consistent with trends we observed in our earlier Phase I trial." The company plans to complete the analysis and report the full data at ESMO 2012 in September (the annual meeting of the European Society for Medical Oncology).

Knoxville, Tennessee-based Provectus said that the response rate and progression free survival data underscored its patient population selection and primary endpoint for its proposed Phase III trial protocol of PV-10 for melanoma, and will support its efforts to conduct a trial under a special protocol assessment with the US FDA.

The company told *Scrip* that Phase III trials of the product, which is both an intralesional chemoablative agent and an immunotherapeutic agent, could begin later this year, once it reaches consensus with the FDA on the pivotal Phase III trial design for PV-10 principally to treat stage 3 melanoma.

PV-10 could reach the market "anywhere from next year, 2013 with accelerated approval to 2015 without accelerated approval", said the company, adding that all markets, including the EU, Australia, Japan, China, India and other signatory countries to ICH, are being pursued.

PROVECTUS PHARMACEUTICALS, INC.

Provectus expects "$1 billion plus revenue per year for PV-10 to treat melanoma (by itself and in combination with other agents) and in excess of that for primary HCC. Additional revenues will be from other solid tumour indications, such as recurrent breast cancer, head and neck cancers, cancers that metastasise to the liver, etc".

trial results

The announced results, which were presented at the European Post-Chicago Melanoma Meeting 2012, Interdisciplinary Global Conference on Developing New Treatments for Melanoma, on 22 June in Munich, Germany, showed an objective response rate (OR) of 50% in patients' target lesions (25% complete response and 25% partial response). There was 70% disease control in these lesions (combined complete, partial and stable response subjects).

When response rates were analysed by disease stage, stage III subjects experienced a substantially higher response rate (58% OR and 81% disease control) than Stage IV subjects (22% and 33%, respectively).

Similar trends were noted in response metrics for bystander lesions between these two subpopulations, the company said, adding that analysis of temporal data showed that stage III subjects also experienced significantly greater mean progression free survival (PFS) of at least 9.6 months, versus 3.1 months for Stage IV subjects. Median PFS for Stage III subjects was not reached during the 12-month study interval.

Provectus said that as the trial of PV-10 progress, later-stage patients may be excluded from the study because of the higher response rates seen in early-stage subjects.

Pial Ganguli