OncoMed Presents Data on Multiple Anti-Cancer Stem Cell Programs at American Association for Cancer Research Annual Meeting

REDWOOD CITY, Calif. April 7, 2014 - OncoMed Pharmaceuticals, Inc. (Nasdaq: OMED), a clinical-stage company developing novel therapeutics that target cancer stem cells (CSCs), or tumor-initiating cells, today announced data from an oral presentation and eight poster presentations at the American Association of Cancer Research (AACR) Annual Meeting in San Diego, CA April 5-9, 2014. The research presented at AACR highlighted OncoMed's drug discovery platforms along with preclinical and biomarker discoveries on its clinical-stage product candidates and several emerging product candidates. A brief summary of each presentation is provided below.

“The nine presentations at this year’s AACR Annual Meeting demonstrate the breadth and depth of OncoMed’s preclinical research and discovery work. Encompassing many of our clinical and preclinical stage candidates, data being presented this week highlight the potent anti-cancer stem cell activity seen across our portfolio, the opportunities to combine our compounds with standard-of-care, and our ongoing biomarker identification efforts being applied to programs in clinical development,” said John Lewicki, PhD, Executive Vice President, Chief Scientific Officer.

Oral Presentation

Timothy Hoey, PhD, OncoMed’s Senior Vice President of Cancer Biology, gave an oral presentation entitled, “Using PDX models for anticancer drug screening” as part of a Methods Workshop on Applications of Patient Derived Xenograft Models to Translational Cancer Research. Dr. Hoey discussed the central role of OncoMed’s patient-derived tumor bank to evaluate anti-tumor and anti-cancer stem cell activity of its novel drug candidates; provide insights into potential clinical indications and dosing regimens; and generate and evaluate predictive biomarker hypotheses for application in clinical trials. OncoMed has developed a large bank of patient-derived tumors, comprising more than 200 tumors from many different tumor types, including the detailed phenotypic, functional and genomic characterization of each tumor.

Poster Presentations

Clinical-stage Programs

Belinda Cancilla, PhD, Director, presented abstract #910 “NOTCH3 expression is predictive of efficacy in pancreas tumor models treated with OMP-59R5, a monoclonal antibody targeting the NOTCH2 and NOTCH3 receptors” in the Predictive Biomarker 1 Poster Session. Expression of NOTCH3 mRNA by next-generation sequencing in pancreatic tumor models correlated with response to OncoMed’s anti-Notch2/3 antibody, OMP-59R5, where tumor efficacy correlated with NOTCH3 biomarker levels. A Research Use Only (RUO) qPCR assay for quantifying NOTCH3 mRNA expression using Formalin-Fixed, Paraffin-Embedded (FFPE) samples and an immunohistochemistry (IHC) assay for measuring levels of NOTCH3 protein in tumor samples have been developed. These assays will be used to correlate NOTCH3 levels with patient response in ALPINE, a Phase 1b/2 clinical trial of OMP-59R5 in first-line advanced pancreatic cancer patients. OMP-59R5 is part of OncoMed’s collaboration with GlaxoSmithKline (GSK).
Marcus Fischer, Associate Scientist, presented abstract #3048 "OMP-59R5 (Anti-Notch2/3) inhibits tumor growth and reduces cancer stem cell frequency in patient derived SCLC xenografts" in the Cancer Stem Cell Phenotype and Function 2 Poster Session. OMP-59R5 was highly effective in reducing tumor growth and cancer stem cell populations in models of small cell lung cancer (SCLC). OncoMed is currently evaluating OMP-59R5 in the Phase 1b/2 PINNACLE trial in patients with SCLC. Treatment with OMP-59R5 increased the expression of differentiation markers and reduced CSC and Notch pathway genes.

Dr. Hoey also presented abstract #1898, "The combination of gemcitabine/nab-paclitaxel and anti-DLL4 (demcizumab) produces synergistic growth inhibition, delays tumor recurrence and reduces tumor initiating cells in pancreatic cancer" as part of the New Diagnostics, Therapeutic Targeting, and Response Assessments Poster Session. Demcizumab, in combination with nab-paclitaxel (Abraxane®) and gemcitabine produced profound anti-tumor activity and anti-CSC activity in a series of pancreatic tumor xenografts. The triple combination of demcizumab, Abraxane and gemcitabine was more efficacious compared with the combination of demcizumab plus gemcitabine alone and in several instances led to shrinkage of tumors to undetectable levels. OncoMed is currently testing the combination of demcizumab with Abraxane/gemcitabine in a Phase 1b study of advanced pancreatic cancer patients and plans to initiate a Phase 2 study in this patient population later this year. The demcizumab program is part of OncoMed’s collaboration with Celgene.

Chun Zhang, Senior Scientist II, presented abstract #2830 "Predictive biomarker identification for response to vantictumab (OMP-18R5; anti-Frizzled) by mining gene expression data of human breast cancer xenografts" in the Predictive Biomarkers 2 Poster Session. A novel six-gene signature was derived based on the responsiveness of breast cancer xenografts to vantictumab and has been used successfully to accurately predict the responsiveness of six additional xenograft models to this antibody. A clinical use test for this six-gene signature is under development and will be used in the analysis of patients from OncoMed’s ongoing Phase 1b study of vantictumab in breast cancer. Vantictumab is part of OncoMed’s Wnt pathway collaboration with Bayer Pharma AG (Bayer).

Pete Yeung, Associate Scientist, presented abstract #1907 "Wnt pathway antagonist OMP-54F28 (FZD8-Fc) inhibits tumor growth and reduces tumor-initiating cell frequency in patient-derived hepatocellular carcinoma and ovarian cancer xenograft models" in the Cancer Stem Cell Phenotype and Function 1 poster session. Researchers at OncoMed evaluated OMP-54F28 in models of hepatocellular cancer (HCC) and ovarian cancer, two of the three indications currently being pursued in Phase 1b studies of this therapeutic candidate. OMP-54F28 demonstrated activity as a single-agent and in combination with sorafinib in four HCC models and exhibited single agent and combination activity with paclitaxel in two ovarian cancer xenografts. A marked reduction in CSC frequency was observed following treatment with OMP-54F28 alone and in combination with chemotherapy in both tumor types. OMP-54F28 also induced the differentiation of these tumors and blocked Wnt pathway genes. OMP-54F28 is part of OncoMed’s collaboration with Bayer.

Wan-Ching Yen, PhD, Senior Scientist 2 presented abstract #4547 "Enhanced anti-tumor effect of WNT pathway antagonists in combination with taxanes" in the Cell Cycle Mechanisms of Anticancer Drug Action Poster Session. The combination of Wnt pathway antagonists with taxanes in patient-derived pancreatic or ovarian xenografts showed additivity and/or synergy that exceeded that observed when Wnt blockade is combined with DNA synthesis inhibitors gemcitabine and carboplatin. Both Wnt pathway antagonists and taxanes are active at the G2/M phase of the cell cycle, which is thought to explain observed synergies. Taxanes are currently being combined with either vantictumab or OMP54F28 in multiple ongoing Phase 1b studies.
“The presentations at AACR by OncoMed’s [expert] scientists reinforce the clinical data being generated across our development programs,” said Jakob Dupont, OncoMed’s Chief Medical Officer. “These research results provide valuable insights on potential combination regimens, where the addition of standard-of-care therapies may best enhance the activity of our anti-cancer stem cell candidates, and guide our predictive biomarker programs.”

Emerging Preclinical Programs

Dr. Yen also presented abstract #207 “Dual targeting of DLL4 and VEGF signaling by a novel bispecific antibody inhibits tumor growth and reduces cancer stem cell frequency” in the Stem Cell Expansion and Cancer Stem Cell Targeting Poster Session. OMP-305B83, OncoMed’s novel high affinity bispecific antibody targeting DLL4 and VEGF demonstrated significant in vivo anti-tumor efficacy in a range of solid tumor xenografts, delayed tumor recurrence following termination of chemotherapy, and decreased the frequency of cancer stem cells. Dual inhibition of these two targets appears to exhibit additive anti-tumor activity at doses where blockade of either target alone elicited sub-optimal activity. OncoMed expects to file an Investigational New Drug (IND) application with the US Food and Drug Administration for OMP-305B83 in the second half of 2014.

Austin Gurney, PhD, Senior Vice President of Molecular and Cellular Biology at OncoMed, presented abstract #1764 “Inhibition of R-spondin (RSPO) signaling reduces the growth of multiple human tumors” in the New Targets and Agents 1 Poster Session. Inhibition of RSPO-LGR signaling with novel anti-RSPO antibodies inhibited tumor growth in numerous patient derived xenograft models, including ovarian, colon, non-small cell lung and pancreatic cancers. The RSPO blockade was effective in reducing tumor growth in tumors overexpressing RSPO, including tumors with genetic translocations, suggesting that levels of RSPO expression may serve as biomarkers in identifying patients most likely to respond to RSPO blockade. OncoMed expects to file an IND for its lead anti-RSPO3 antibody within late 2014 or early 2015.

Both the anti-DLL4/anti-VEGF antibodies and anti-RSPO programs are encompassed within OncoMed’s collaboration with Celgene.

“Our strong presence at this year’s AACR Annual Meeting reflects the productivity of OncoMed’s platform technologies and our commitment to continued discovery research, proprietary human tumor xenograft models, and predictive biomarkers,” said Paul J. Hastings, Chairman and Chief Executive Officer. “OncoMed’s preclinical and translational medicine work informs and supports the efforts of our development organization, which is currently conducting 15 clinical trials for five anti cancer stem cell agents, and fuels the growth of our pipeline of anti-cancer stem cell therapeutics, as exemplified by the presentations of in vivo tumor efficacy data for our pre-IND candidates, OMP-305B83 and Anti-RSPO3.”

About Cancer Stem Cells

Cancer stem cells, or CSCs, are the subpopulation of cells in a tumor responsible for driving growth and metastasis of the tumor. CSCs, also known as tumor-initiating cells, exhibit certain properties which include the capacity to divide and give rise to new CSCs via a process called self-renewal and the capacity to differentiate or change into the other cells that form the bulk of the tumor. Common cancer drugs target bulk tumor cells but have limited impact on CSCs, thereby providing a path for recurrence of the tumor. OncoMed’s product candidates target CSCs by blocking self-renewal and driving differentiation of CSCs toward a non-tumorigenic state, and also impact bulk tumor cells. OncoMed believes its product candidates are distinct from the current generations of chemotherapies and targeted
therapies, and have the potential to significantly impact cancer treatment and the clinical outcome of patients with cancer.

**About OncoMed Pharmaceuticals**

OncoMed Pharmaceuticals is a clinical-stage company focused on discovering and developing novel therapeutics targeting cancer stem cells. OncoMed has five anti-cancer product candidates in clinical development, including demcizumab (Anti-DLL4, OMP-21M18), OMP-59R5 (Anti-Notch2/3), OMP-52M51 (Anti-Notch1), vantictumab (Anti-Fzd7, OMP-18R5), and OMP-54F28 (Fzd8-Fc), which target key cancer stem cell signaling pathways including Notch and Wnt. OncoMed has two other antibodies in preclinical development, OMP-305B83 (Anti-DLL4/Anti-VEGF bispecific) and Anti-RSPO3, with Investigational New Drug filings planned for late 2014 or early 2015. OncoMed is also pursuing discovery of additional novel anti-CSC product candidates. OncoMed has formed strategic alliances with Celgene Corporation, Bayer Pharma AG and GlaxoSmithKline (GSK). Additional information can be found at the company's website: www.oncomed.com.

**Forward-looking Statement**

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