A first-in-human Phase 1 study of anti-cancer stem cell (CSC) agent OMP-54F28 (FZD8-Fc) targeting the WNT pathway in patients with advanced solid tumors

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CONCLUSIONS
• OMP-54F28 is well tolerated.
• Further dose escalation is ongoing.
• OMP-54F28 clearance is dose-dependent and saturated around the 5 to 10 mg/kg dose levels.
• OMP-54F28 has pharmacodynamic (PD) effects on hair follicles.
• PD effects are consistent with Wnt biology.
• PD effects extend beyond serum exposure.
• PD effects of OMP-54F28 on markers of bone metabolism are less pronounced than for vanditumab.
• Three Phase 1b studies will be initiated in late 2013 to early 2014.

ACKNOWLEDGMENTS
We thank all patients who participated in this study and their families. OMP-54F28 and vanditumab are part of OncoMed’s Wnt pathway collaboration with Bayer Pharma AG.

PHARMACOKINETICS

Effect of OMP-54F28 on CSCs in patient-derived pancreatic cancer xenografts

Estabished NPC xenograft models with significant treatments (five patients) per dose level; OMP-54F28 was administered weekly for 2 weeks, followed by 1 week off. Tumor volume (mm3) was measured every 4 days during treatment and every 7 days thereafter.

Baseline characteristics

Number of patients
10
Age (years)
Median age (range)
54 (24-74)
Sex (male/female)
7/3
Number of prior systemic therapies, median (range)
4 (1-6)

Tumor Types

Pancreatic
Metastatic tumor

Nonclinical results (continued)

Activity of OMP-54F28 in patient-derived pancreatic cancer xenografts

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STUDY OVERVIEW

• Patients with selected withdrawal
• 3+3 dose escalation
• Dose levels:
  - 0.5, 1, 2, 3, 10, 15, and 20 mg/kg every three weeks
• DLT assessment window: 6 weeks
• Pharmacodynamic: blood RNA, hair follicles, tumor (optional)
• Tumor assessments: every 6 weeks

NONCLINICAL DATA (continued)

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