

# Dealdoc

Research and development, marketing and option agreement for OMP-18R5

Bayer Schering Pharma
OncoMed Pharmaceuticals

Jun 17 2010

## Research and development, marketing and option agreement for OMP-18R5

Companies:

Bayer Schering Pharma

**OncoMed Pharmaceuticals** 

Announcement date: Jun 17 2010 1937.5 : sum of upfront and milestone payments for five successful Deal value, US\$m: candidates **Details Financials** Termsheet **Press Release** Filing Data Contract **Details** Jun 17 2010 **Announcement date:** Bigpharma Biotech Industry sectors: Pharmaceutical Research tools Compound name: OMP-18R5 Oncology Therapy areas: Oncology » Solid tumors Antibodies » Monoclonal antibodies Biological compounds Discovery tools **Enabling technology** Genomics Technology types: Peptides Processes **Proteomics** Regenerative medicine » Stem cells Small molecules Collaborative R&D Licensing Deal components: Marketing Option Stages of development: Discovery Geographic focus: Worldwide **Financials** 1937.5 : sum of upfront and milestone payments for five successful Deal value, US\$m: candidates Upfront, US\$m: 40.0 : upfront payment per candidate 20.0: advancement to clinic triggers milestone payment 15 : related to achieving a dose escalation milestone in the Phase 1a Milestones, US\$m: clinical trial of OMP-54F28 347.5 : based on optioned candidate successfully achieving

development and commercial milesones

## **Termsheet**

Bayer Schering Pharma AG and OncoMed Pharma announced a global strategic alliance to discover, develop and commercialize novel anti-cancer stem cell therapeutics targeting the Wnt signaling pathway.

The strategic alliance provides Bayer with the option to exclusively license antibody and protein therapeutic product candidates at any point up to the completion of Phase I testing.

In addition, Bayer and OncoMed will share technology and know-how to discover and develop small molecule inhibitors of the pathway.

Bayer and OncoMed will develop antibodies, protein therapeutics, and small molecules as potential novel anti-cancer stem cell therapeutics targeting the Wnt signaling pathway.

In addition to an upfront payment of \$40 million, OncoMed is eligible to receive cash payments for product candidates that Bayer options and possible additional payments upon achievement of certain development and commercialization milestones.

The collaboration could potentially include up to five compounds.

The agreement includes potential significant near-term milestone payments from Bayer.

OncoMed's payments for each biotherapeutic or small molecule drug candidate successfully developed through Phase III clinical trials and regulatory approval, could total up to \$387.5 million (biotherapeutic drug) and \$112 million (small molecule drug) per program, already including net sales milestones.

#### **Press Release**

5 November 2013

OncoMed Pharmaceuticals, Inc.'s OMP-54F28 (Fzd8-Fc) Program Reaches Dose Escalation Milestone in Phase 1a Clinical Trial; Triggers \$15 Million Payment From Bayer Pharma S.A. (TEVA)

OMP-54F28 (Fzd8-Fc) Program Reaches Dose Escalation Milestone in Phase 1a Clinical Trial; Triggers \$15 Million Payment From Bayer Pharma AG

REDWOOD CITY, Calif., Nov. 5, 2013 (GLOBE NEWSWIRE) -- OncoMed Pharmaceuticals, Inc. (Nasdaq:OMED), a clinical-stage company developing novel therapeutics that target cancer stem cells (CSCs), or tumor-initiating cells, announced today that it has earned a \$15 million milestone payment from Bayer Pharma AG related to achieving a dose escalation milestone in the Phase 1a clinical trial of OMP-54F28 (Fzd8-Fc). OMP-54F28 is an antagonist of the Wnt pathway, a key cancer stem cell pathway.

The Phase 1a clinical trial of OMP-54F28 is an open-label dose escalation study in patients with advanced solid tumors. It is designed to assess OMP-54F28 for safety, immunogenicity, pharmacokinetics, biomarkers, and initial signals of efficacy. In the ongoing study, OMP-54F28 has been well tolerated at doses up to 15 mg/kg every three weeks, which is above the target efficacious dose based on OncoMed's preclinical studies in minimally passaged human tumor xenograft models. First-in-human data from the Phase 1a study detailing OMP-54F28 safety, pharmacokinetics, pharmacodynamics and early signs of efficacy were recently presented at the 2013 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Boston.

Jakob Dupont, M.D., OncoMed's Chief Medical Officer, commented, "OMP-54F28 demonstrates promising tolerability and early signs of potential anti-tumor activity, as well as Wnt pathway modulation in clinical samples. The early clinical data from the OMP-54F28 program indicate that this compound is a distinct and differentiated Wnt pathway antagonist that is ready for later-stage clinical development in combination with standard-of-care chemotherapy and targeted therapy."

"With the contribution of this \$15 million milestone payment from Bayer, OncoMed has achieved a total of \$33 million in milestone payments this year from our two corporate partners," said Paul J. Hastings, Chairman and Chief Executive Officer of OncoMed Pharmaceuticals. "We look forward to initiating multiple Phase 1b studies for OMP-54F28 in the coming months in parallel with the continued advancement of our four other ongoing anti-cancer stem cell clinical programs."

OMP-54F28 is one of five anti-CSC product candidates currently being advanced through clinical studies by OncoMed and the company's second distinct Wnt-pathway modulating therapeutic to enter the clinic as part of the collaboration between OncoMed and Bayer. OncoMed's first Wnt pathway anti-cancer stem cell compound, vantictumab (OMP-18R5, Anti-FZD7), is being advanced into three Phase 1b combination clinical studies. The first of these trials was recently initiated in patients with advanced breast cancer to evaluate the combination of vantictumab with paclitaxel. Bayer retains an option to exclusively license OMP-54F28 and/or vantictumab at any point through completion of certain Phase 1 trials.

28 April 2011

FDA Approves Trials of OncoMed Pharmaceuticals, Inc. Cancer Drug; \$20 Million Milestone Payment Triggered

REDWOOD CITY, Calif., April 28, 2011 /PRNewswire/ -- OncoMed Pharmaceuticals, Inc., a company developing novel therapeutics that target cancer stem cells or tumor-initiating cells, today announced that the FDA has accepted an IND filing for OMP-18R5, which allows OncoMed to commence Phase 1 clinical testing.

OMP-18R5 is a monoclonal antibody that binds selected receptors in the Wnt signaling pathway and is the first antibody to specifically block these targets to enter human studies. The Phase 1 clinical trial of OMP-18R5 is a single-agent study designed to evaluate the safety of escalating doses of OMP-18R5 in patients with advanced solid tumors. The study will also assess pharmacokinetics, biomarkers and initial evidence of efficacy. The Phase 1 trial is being conducted at leading U.S. cancer drug development centers. Preclinical studies have shown that OMP-18R5 decreases the frequency of tumor-initiating cells across a variety of tumor types.

"The acceptance from the FDA to begin clinical testing for OMP-18R5 represents an important milestone for OncoMed. OMP-18R5 is our first Wnt pathway program cleared to begin clinical trials, and we now have three novel agents in the clinic in multiple clinical trials," said Paul Hastings, President and Chief Executive Officer of OncoMed Pharmaceuticals. "We are excited to continue building and advancing our rich pipeline of first-in-class anti-cancer stem cell therapeutics with the potential to dramatically transform cancer treatment by directly targeting tumor-initiating cells."

OMP-18R5 is part of OncoMed's collaboration with Bayer HealthCare Pharmaceuticals and its advancement to the clinic triggers a \$20M milestone payment from Bayer to OncoMed. In June 2010, OncoMed and Bayer entered into a broad strategic alliance valued at up to \$387.5M per program to develop cancer stem cell antibody and protein therapeutics targeting the Wnt signaling pathway. Bayer has the option to license OncoMed's biologics in the Wnt pathway at any point through the completion of Phase 1 studies. In addition, Bayer and OncoMed are working together to discover small molecule Wnt signaling inhibitors as part of the collaboration.

#### About Cancer Stem Cells

Cancer stem cells, a small, resilient subset of cells found in tumors, have the capacity to self-renew and differentiate, leading to tumor initiation and driving tumor growth, recurrence and metastasis. Also referred to as "tumor-initiating cells," these cells were first discovered by OncoMed's scientific founders in breast cancer and have subsequently been identified in many other types of solid tumor cancers, including cancer of head and neck, lung, prostate, pancreas and glioblastoma. Cancer stem cells appear to be preferentially resistant to both standard chemotherapy and radiotherapy. OncoMed's strategy is to improve cancer treatment by specifically targeting the key biologic pathways which are thought to be critical to the activity and survival of cancer stem cells. OncoMed's novel therapeutics target cancer stem cell proteins and have the potential to be developed against a range of tumor types.

#### About OncoMed Pharmaceuticals

OncoMed Pharmaceuticals is a clinical-stage company that discovers and develops novel therapeutics targeting cancer stem cells, the cells believed to be capable of driving tumor growth, recurrence and metastasis. A leader in cancer stem cell research, the company has established a library of antibodies to cancer stem cell proteins for the treatment of solid tumors such as pancreatic, breast, colorectal and lung cancers. OncoMed has advanced three anti-cancer stem cell monoclonal antibodies into the clinic, OMP-21M18, OMP-59R5 and OMP-18R5, which target key cancer stem cell signaling pathways including Notch and Wnt. In addition, OncoMed's pipeline includes several novel preclinical product candidates targeting multiple validated cancer stem cell pathways. OncoMed has formed strategic alliances with Bayer HealthCare Pharmaceuticals and GlaxoSmithKline. Privately-held, OncoMed's investors include: US Venture Partners, Latterell Venture Partners, The Vertical Group, Morgenthaler Ventures, Phase4 Ventures, Delphi Ventures, Adams Street Partners, De Novo Ventures, Bay Partners and GlaxoSmithKline. Additional information can be found at the company's website: www.oncomed.com.

#### 17 June 2010

Develop Anti-Cancer Stem Cell Therapeutics; OncoMed to Get \$40 Million Upfront; up to \$387.5 Million

WAYNE, N.J., June 17 /PRNewswire/ -- Bayer Schering Pharma AG and OncoMed Pharmaceuticals, Inc., today announced a global strategic alliance to discover, develop and commercialize novel anti-cancer stem cell therapeutics targeting the Wnt signaling pathway. Cancer stem cells are a subset of tumor cells believed to play a significant role in the establishment, metastasis and recurrence of cancer and agents targeting the Wnt pathway have the potential to be developed as pan-tumor drugs. The strategic alliance provides Bayer with the option to exclusively license antibody and protein therapeutic product candidates at any point up to the completion of Phase I testing. In addition, Bayer and OncoMed will share technology and know-how to discover and develop small molecule inhibitors of the pathway.

"At Bayer, we recognize the high unmet medical need for cancer treatments. This collaboration with OncoMed demonstrates our commitment to developing new and innovative treatment options," said Prof. Andreas Busch, Head of Global Drug Discovery and Member of the Board of Management at Bayer. "The development of anti-cancer stem cell therapeutics together with OncoMed is a highly innovative approach with the potential to perfectly complement our oncology portfolio. Anti-cancer stem cell research could turn out as one of the missing pieces in today's cancer therapy."

"Our alliance with Bayer represents a major opportunity to discover and develop an entirely new class of anti-cancer stem cell therapeutics with one of the leading pharmaceutical companies in the world. Bayer shares our vision for the potential of anti-cancer stem cell therapeutics, and we look forward to working closely with them," said Paul J. Hastings, President and CEO of OncoMed. "OncoMed has established a rich pipeline of

product candidates targeting a number of critical cancer stem cell pathways. Through this collaboration, we will gain significant additional funding to support the discovery and development of therapeutics targeting the Wnt pathway, as we continue, with our already strong cash position, and our other sources of collaborative revenue to fully finance and advance all of our programs for years to come."

Under the terms of the agreement, Bayer and OncoMed will develop antibodies, protein therapeutics, and small molecules as potential novel anti-cancer stem cell therapeutics targeting the Wnt signaling pathway. In addition to an upfront payment of \$40 million, OncoMed is eligible to receive cash payments for product candidates that Bayer options and possible additional payments upon achievement of certain development and commercialization milestones. The collaboration could potentially include up to five compounds. The agreement includes potential significant near-term milestone payments from Bayer. For each biotherapeutic or small molecule drug candidate successfully developed through Phase III clinical trials and regulatory approval, OncoMed's payments could total up to \$387.5 million (biotherapeutic drug) and \$112 million (small molecule drug) per program, already including net sales milestones.

OncoMed will utilize its proprietary human cancer stem cell models to discover and advance three potential first-in-class antibody and protein therapeutics into clinical testing and through Phase I studies. Bayer receives an option to exclusively license antibody and protein therapeutic product candidates at any point up to the completion of Phase I testing. Following option exercise, Bayer will lead development and commercialization of licensed product candidates and will have rights to commercialize approved products in all markets. OncoMed will be eligible to receive double-digit royalties on net product sales. The agreement contains provisions under which OncoMed may co-develop biologic therapeutics with Bayer. The collaboration includes for example OncoMed's lead Wnt pathway antibody, [OMP-18R5], which is intended to enter clinical testing in 2011.

In addition to the biologics approach, Bayer will use its in-house expertise and lead the discovery and development of small molecule compounds as therapeutic candidates modulating Wnt signaling. OncoMed will assist Bayer in the evaluation and advancement of such candidates by providing its proprietary assay technology and in vitro/in vivo profiling of the compounds. OncoMed will be eligible to receive single-digit royalties on net product sales.

About Cancer Stem Cells and the Wnt Signaling Pathway

Cancer stem cells, a small, resilient subset of cells found in tumors, have the capacity to self-renew and differentiate, leading to tumor initiation and driving tumor growth, recurrence and metastasis. Also referred to as "tumor-initiating cells," these cells were first discovered by OncoMed's scientific founders in breast cancer and have subsequently been identified in many other types of solid tumors, including cancer of the head and neck, lung, prostate, pancreas, and glioblastoma. Cancer stem cells appear to be preferentially resistant to both standard chemotherapy and radiotherapy. OncoMed's strategy is to improve cancer treatment by specifically targeting the key biologic pathways which are thought to be critical to the activity and survival of cancer stem cells. OncoMed's antibody therapeutics target cancer stem cell proteins and have the potential to be developed against a range of solid tumor types.

The Wnt signaling pathway is one of several identified by OncoMed as an important therapeutic target in halting cancer stem cell activity. In preclinical studies of monoclonal antibody drug candidates that target Wnt signaling, OncoMed scientists have observed broad-spectrum anti-tumor and anti-cancer stem cell activity in a number of solid tumor types.

#### About OncoMed Pharmaceuticals

OncoMed Pharmaceuticals is a clinical-stage company that discovers and develops novel therapeutics targeting cancer stem cells, the cells believed to be capable of driving tumor growth, recurrence and metastases. A leader in cancer stem cell research, the company has established a library of antibodies to cancer stem cell proteins for the treatment of solid tumors such as pancreatic, breast, colorectal and lung cancers. OncoMed's lead candidate, OMP-21M18 is currently in Phase I clinical trials. In addition to OMP-21M18, OncoMed's pipeline includes several novel preclinical product candidates targeting multiple validated cancer stem cell pathways. OncoMed is a privately-held company. Additional information can be found at the company's website: www.oncomed.com.

## About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of healthcare, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Bayer Schering Pharma, Consumer Care and Medical Care divisions. Bayer HealthCare's aim is to discover, manufacture and market products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

# Filing Data

Not available.

### Contract

Not available