



IMPORTANT NEWS FROM

IDP, DNA, MEDI, STEM, SQNM

IDERA (IDP)

Idera Pharmaceuticals. ([IDP - news](#)) announced that it has submitted to the FDA a protocol amendment for its ongoing Phase 2 trial of **HYB2055** in patients with **metastatic or recurrent clear cell renal carcinoma**. The Company submitted the amendment in response to a higher than expected enrollment rate of treatment-naive patients in the Phase 2 trial. The amendment provides for enrollment of up to 23 treatment-naive patients at each of the two dose levels being used in the trial, in addition to the 23 second-line patients per dose level described in the original study design. HYB2055 (also known as IMO-2055 or IMOxine(R)) is Idera's lead Toll-like Receptor 9 (TLR9) agonist for the treatment of cancer and is based on Idera's proprietary Immune Modulatory Oligonucleotide (IMO(TM)) technology.

The discovery of Toll-like Receptors is a breakthrough in immunology that might change the way cancer and chronic diseases are being managed. Idera's 9 (TLR9) agonist for the treatment of cancer is based on Idera's proprietary Immune Modulatory Oligonucleotide (IMO™) technology. The Company conducted a Phase 1 clinical trial of HYB2055 at Georgetown University Medical Center, Washington, D.C., which was reported at ASCO 2005 (Abstract 2503). As described in this press release, patient enrollment is ongoing for a Phase 2 multi-center, open-label study of HYB2055 for injection in patients with metastatic or locally recurrent clear cell renal carcinoma. The primary objective is to determine tumor response by RECIST (Response Evaluation Criteria in Solid Tumors). Secondary objectives are safety, duration of response, time to progression, survival one year after the last HYB2055 dose, and effect on quality of life. The Company is planning additional trials for HYB2055 in non-small cell lung cancer (NSCLC) patients. **Read more:** [Idera Pharmaceuticals Amends HYB2055 Phase 2 Renal Cell Carcinoma Protocol](#)

GENENTECH (DNA)

Here **Genentech** . ([DNA - news](#)) did it again, bringing good news to breast cancer patients and to its shareholders. This time it is **Herceptin**, which has proven in two pivotal Phase 3 trials that when used with chemotherapy it significantly **reduce the risk of breast cancer recurrence by 52% in women with early-stage, operable human epidermal growth factor receptor 2 (HER2)-positive breast cancer**, compared to those patients who received chemotherapy alone.

These extremely promising results came after four years of study follow-up. The results show that only **15%** of women treated with Herceptin plus chemotherapy experienced disease recurrence, compared to **33%** of women treated with chemotherapy alone, the firm noted. Needless to remind that HER2-positive breast cancer is an aggressive form of the disease that affects approximately 25% of women with breast cancer. Read more: [Pivotal Herceptin Data in The New England Journal of Medicine Showed Significant Improvement in Disease-Free Survival in Early-Stage HER2-Positive Breast Cancer](#)

MEDIMMUNE (MEDI)

MedImmune. ([MEDI - news](#)) announced today that it has entered into a licensing and collaboration agreement with Avidia, Inc. to develop anti-cancer products targeting cMET, a receptor tyrosine kinase found in high levels in certain cancer cells. The collaboration also calls for the development of two additional targets using Avidia's Avimer technology. Avimers, which are small, stable proteins that can act like antibodies and bind selectively to different receptors or ligands, may have several advantages as therapeutic products in terms of biological activity, tissue distribution, reduced immunogenicity, and improved manufacturing efficiencies. **Read More** [MedImmune Further Expands Oncology Pipeline With New Target Based on Innovative Technology From Avidia](#)

STEM CELL (STEM)

StemCells ([STEM - news](#)) today announced that it has received clearance from the FDA to begin a Phase I safety and preliminary efficacy trial of the Company's proprietary human neural stem cell product **HuCNS-SC™** to treat Batten



disease. Batten disease is a rare, fatal genetic disorder that affects the central nervous system of children. This is the first-ever FDA-approved clinical trial to use a purified composition of human neural stem cells as a potential therapeutic agent in humans. **Read more:** [MStemCells, Inc. Receives FDA Clearance to Initiate Phase I Clinical Trial of Neural Stem Cells to Treat Batten Disease; First-Ever FDA-Approved Trial to Transplant Human Neural Stem Cells](#)

SEQUENOM (SQNM)

Sequenom (SQNM - news) has acquired exclusive rights in the United States, United Kingdom and other European countries and elsewhere, to **non-invasive prenatal diagnostic intellectual property** from Isis Innovation Ltd., the technology transfer company of the University of Oxford, it was announced today. The intellectual property covers **non-invasive prenatal genetic diagnostic testing on fetal nucleic acids derived from plasma or serum, which includes tests such as cystic fibrosis, hemoglobinopathies (sickle cell anemia and the thalassemias), and chromosomal aneuploidies (e.g. Down Syndrome)**, on any platform including mass spectrometry and real time polymerase chain reaction amplification platforms. Financial terms include up-front fees, milestone payments and royalties on product sales.

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