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Research from University of Arizona, College of Medicine in the area of drug development described 11/24/2010 Biotech Week
Data detailed in 'Mycophenolic acid exposure in high- and low-weight renal transplant patients after dosing with mycophenolate mofetil in the Opticept trial' have been presented. "The Opticept trial was an open-label, randomized, multicenter trial involving 720 kidney recipients. Three immunosuppressant dosing regimens were evaluated, including both fixed and concentration-controlled dosing of mycophenolate mofetil in combination with standard and reduced calcineurin inhibitor levels," scientists writing in the journal Therapeutic Drug Monitoring report (see also ).

"Mycophenolic acid (MPA) levels were measured, yielding one of the largest databases to assess the impact of variables on MPA exposure. The present subset analysis evaluated the effect of baseline body weight in three noncontiguous weight categories on MPA exposure at steady state (Day 90) in patients receiving tacrolimus. Multivariate linear regression models assessed the relationship between area under the concentration-time curve (AUC) and several variables. In all, 219 patients had baseline weights in the three categories and an MPA AUC at Day 90: 50 kg or less (n=12, all female); 60 to 80 kg (n=136); or 100 kg or greater (n=71). In overall comparisons by weight class, clearance increased with increased weight, resulting in an inverse relationship between dose-corrected MPA AUCs and weight at Day 90 (p <0.0001). In patients of extreme weight, wide disparities of MPA exposure were measured despite the mean mycophenolate mofetil dose, notably in those 50 kg or less who had comparatively high dose-corrected MPA AUCs," wrote B. Kaplan and colleagues, University of Arizona, College of Medicine. The researchers concluded: "Patients at the extremes of weight might be at risk of over-or underimmunosuppression unless doses are adjusted."

Kaplan and colleagues published their study in Therapeutic Drug Monitoring (Mycophenolic acid exposure in high- and low-weight renal transplant patients after dosing with mycophenolate mofetil in the Opticept trial. Therapeutic Drug Monitoring, 2010;32(2):224-7).

Additional information can be obtained by contacting B. Kaplan, University of Arizona College of Medicine, Tucson, AZ 85724-5022 USA.

Published Results Show Denosumab Superior to Zometa® in Delaying or Preventing Bone Complications in Patients With Bone Metastases From Advanced Breast Cancer
11/24/2010
Biotech Week

Published Results Show Denosumab Superior to Zometa® in Delaying or Preventing Bone Complications in Patients With Bone Metastases From Advanced Breast Cancer
Amgen (Nasdaq: AMGN) announced the publication of results from a pivotal Phase 3 study of 2,046 patients which compared denosumab with Zometa® (zoledronic acid) in delaying or preventing skeletal-related events (SREs) in breast cancer patients with bone metastases. An SRE consists of any of the following: a pathologic fracture, the need for radiation or surgery to ameliorate bone pathology secondary to tumor growth, or spinal cord compression. The study, published in the Journal of Clinical Oncology, found that denosumab was superior to Zometa in delaying or preventing SREs in breast cancer patients with bone metastases (see also ).

"Patients with bone metastases from cancer are at increased risk of experiencing debilitating pathologic fractures and other skeletal-related events. The results of this study show that denosumab is better than the current standard of care (Zometa) in delaying or preventing these skeletal complications for our patients with advanced breast cancer," said Alison Stopeck, M.D., associate professor of Medicine, Arizona Cancer Center, University of Arizona Health Sciences Center. "In addition to improving skeletal outcomes, denosumab has no requirement for renal monitoring and is administered as a simple subcutaneous injection."

Semafore Pharmaceuticals Receives FDA Orphan Drug Designation for SF1126 in the Treatment of Chronic Lymphocytic Leukemia
11/24/2010
Semafore Pharmaceuticals announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to the Company's SF1126 product candidate for the treatment of B-cell chronic lymphocytic leukemia (CLL). In April 2010, the Company initiated an expansion of its ongoing Phase I clinical study into this disease setting. SF1126 is a novel peptidic prodrug that converts to LY294002, one of the most widely studied small molecule inhibitors of both phosphatidylinositol 3-kinase (PI3K) and mammalian target of rapamycin (mTOR).

"SF1126 is the first PI3K inhibitor to receive orphan drug designation from the FDA for the treatment of CLL, which is an important milestone for Semafore Pharmaceuticals," said Joseph Garlich, Ph.D., Semafore's Chief Scientific Officer. "We are committed to developing SF1126 as a potential treatment for this disease and look forward to presenting interim clinical data at ASH."

SF1126 will be the subject of a poster presentation at the 52nd American Society of Hematology (ASH) Annual Meeting and Exposition being held December 4-7, 2010 in Orlando, FL. A summary of the presentation is below, and the full abstract can be accessed on the ASH website at www.hematology.org.

Phase I Study of Novel Prodrug Dual PI3K/mTOR Inhibitor SF1126 In B-Cell Malignancies Saturday, December 4, 2010, 5:30 p.m. to 7:30 p.m. Eastern Time (ET)

New skin infection research reported from University of Arizona, Brain Research Institute

New investigation results, 'An improved method for recording tail skin temperature in the rat reveals changes during the estrous cycle and effects of ovarian steroids,' are detailed in a study published in Endocrinology. According to recent research published in the journal Endocrinology, "In the rat, tail skin vasomotion is a primary heat loss mechanism that can be monitored by changes in tail skin temperature (T(SKIN)). Previous studies showed that ovariectomy and estrogen replacement modify T(SKIN) in the rat."

"Based on these findings, the ovariectomized (OVX) rat has been used as a model to study the mechanisms and treatment of menopausal hot flushes. It is not known, however, if T(SKIN) changes across the estrous cycle in intact rats. Here, we describe an improved method for monitoring T(SKIN) in freely moving rats using a SubCue Mini datalogger mounted on the ventral surface of the tail. This method is noninvasive, cost-effective, and does not require restraints or tethering. We observed a distinct pattern of T(SKIN) across the estrous cycle characterized by low T(SKIN) on proestrous night. To determine whether this pattern was secondary to secretion of ovarian steroids, we monitored the thermoregulatory effects of 17β-estradiol (E(2)) and E(2) plus progesterone, administered via SILASTIC capsules to OVX rats. E(2) treatment of OVX rats significantly reduced T(SKIN) in the dark phase from 2 to 21 d after hormone treatment. The T(SKIN) of E(2)-treated OVX animals was not significantly different from OVX rats receiving E(2) plus progesterone. These data provide evidence that the reduction in T(SKIN) on proestrous night was secondary to elevated levels of ovarian estrogens," wrote H. Williams and colleagues, University of Arizona, Brain Research Institute (see also). The researchers concluded: "This study provides the first description of T(SKIN) changes with the estrous cycle and supports the role of estrogens in normal thermoregulation in the rat."

Williams and colleagues published their study in Endocrinology (An improved method for recording tail skin temperature in the rat reveals changes during the estrous cycle and effects of ovarian steroids. Endocrinology, 2010;151(11):5389-94).

For additional information, contact H. Williams, University of Arizona College of Medicine, Dept. of Pathology, Evelyn F McKnight Brain Research Institute, 1501 North Campbell Avenue, Tucson, Arizona
New ovarian cancer study results reported from M.A. Bookman et al
11/24/2010
Biotech Week

"Advanced-stage epithelial ovarian cancer is generally managed with cytoreductive surgery and chemotherapy consisting of carboplatin and paclitaxel, achieving clinical complete remission in the majority of patients. However, most tumors recur, and are associated with progressive chemotherapy resistance," scientists in the United States report (see also ).

"Techniques to optimize chemotherapy have included intraperitoneal administration and weekly scheduling of paclitaxel. Efforts to improve on the long-term results of primary therapy through addition of a third cytotoxic agent have not been successful, including extended maintenance, as well as strategies to overcome chemotherapy resistance. Limited data emerging from phase III trials using bevacizumab suggest some advantage in progression-free survival, particularly in the maintenance setting, and further data are awaited. At present, primary therapy with carboplatin and paclitaxel remains a well-tolerated standard regimen, including the option of weekly paclitaxel dosing, intraperitoneal delivery and neoadjuvant therapy in selected patients," wrote M.A. Bookman and colleagues.

The researchers concluded: "Emerging biological paradigms will hopefully contribute to individualized treatment options in the future."


For more information, contact M.A. Bookman, Arizona Cancer Center, 1515 N Campbell Avenue, 2942F, POB 245024, Tucson, AZ 85724, USA.

Publisher contact information for the journal Annals of Oncology is: Oxford University Press, Great Clarendon St., Oxford OX2 6DP, England.

Ardea Announces Data on MEK Inhibitor BAY 86-9766 RDEA119 to be Presented at EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics
11/24/2010
Biotech Week

Ardea Biosciences, Inc. (Nasdaq: RDEA) announced that data from preclinical and clinical trials of BAY 86-9766 (formerly known as RDEA119) will be presented at the 22nd European Organisation for Research and Treatment of Cancer (EORTC) - National Cancer Institute (NCI) - American Association for Cancer Research (AACR) symposium on "Molecular Targets and Cancer Therapeutics" in Berlin, Germany. BAY 86-9766 is a mitogen-activated ERK kinase (MEK) inhibitor licensed to and being developed by Bayer HealthCare AG (see also ).

The results of a multi-center, Phase 1, monotherapy, dose-escalation study of BAY 86-9766 in advanced cancer patients will be presented by Colin Weekes, MD, PhD, Assistant Professor, Division of Medical Oncology at the University of Colorado School of Medicine. The principal investigators for this study included Dr. Weekes, Daniel D. Von Hoff, MD, Professor of Medicine at the University of Arizona School of Medicine and Executive Vice President of the Translational Genomics Research Institute (TGen), and Alex Adjei, MD, PhD, Professor and Chair, Department of Medicine at the Roswell Park Cancer Institute. In addition, data from preclinical studies of BAY 86-9766, demonstrating its potential for administration in combination with other anti-cancer agents will be presented by Bayer.

"Based on the good tolerability and impressive number of patients who achieved stable disease in this Phase 1 monotherapy trial in refractory patients with advanced solid tumors, we believe BAY 86-9766 has the potential to be a clinically important drug in the treatment of patients across multiple tumor types," said Dr. Adjei. "These monotherapy results support our ongoing Phase 1/2 study of BAY 86-9766 in
combination with sorafenib at the maximum tolerated dose defined in this trial and the continued research
by Bayer Healthcare on this important new targeted therapy."
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Winoma Shirley 'Sue' Schneider | View Clip
11/24/2010
Williston Daily Herald

Winoma Shirley (Sue) Schneider, 61, Safford, Ariz., entered the loving arms of our Lord on Thursday
morning, Nov. 18, 2010, at the University Medical Center, Tucson, Ariz.

Sue was born on Dec. 11, 1948, in Faribault, Minn., the daughter of August and Winoma (Kirkman)
Borchert. She graduated from Faribault High School in 1966.

Sue had a great love for children.

It was while serving as a house parent at Charles Hall Youth Services, a home for disadvantaged Indian
children, in Bismarck, that she fell in love with her husband, Rick Schneider, a special sections editor and
sales representative for the Bismarck Tribune. They served as house parents and tutors for the children
for four years and were married in 1973 in Bismarck.

Sue and Rick were also foster parents for more than 20 children. Some of the children they cared for
while serving as house parents and foster parents kept in regular contact with Sue, and some still referred
to her as their mom. Rick's newspaper career took them to stays in Garrison, Libby, Mont., Williston,
Sidney, Mont., and their present home in Safford, where Rick serves as publisher of the Eastern Arizona
Courier and the Copper Era.

Sue dearly loved Arizona, and she and Rick had recently purchased a retirement cabin on San Carlos
Lake. Though she could only enjoy a couple of weeks at her beloved cabin, it was a place she cherished.

Sue is survived by husband, Rick, Safford, Ariz.; daughter, Tonya Schneider and her children, Bridget,
Madison and Kennedy, Williston; daughter, Tara Anderson, her husband, Troy, and their children,
Jessica, Nathan and Dakota, Mankato, Minn.; son, Marlon, a high school student in Safford; brother,
August (Danny), Warsaw, Minn.; mother- and father-in-law, John and Lillian Schneider, Strasburg; sister-
in-law, Karen and husband, Bert Olson, Fargo, brother-in-law, John and wife, Michelle Schneider, Lake
Havasu, Ariz.; sister-in-law, Mary and husband, Steve Kilwein, Hettinger; sister-in-law, Nancy Borchert,
Winona, Minn.; great-grandchildren, Cameron, Marleigh, Oscar and Brinley Sue due in February 2011;
nieces, Heather and Jeremy Christian, Shelly and Patrick Morgan, Pennsylvania, Kimberly and Troy
Krenz, Warsaw, Minn., and nephew, Mark Borchert, Kansas, Mo.

Her dearest friend in Safford was Mellissa Skinner.

Sue was proceeded in death by her father, August; her mother, Winoma; a brother, Roger; a son, Troy;
and sister-in-law Pamela Borchert. Sue experienced the unbearable grief of losing her mother, brother
and son in a year's time.

A memorial service will be held for Sue on Saturday, Dec. 4, at the North Mankato Mortuary Northview,
2060 Commerce Dr., North Mankato, Minn. The visitation will be at 10 a.m., services are at 11 a.m. and
lunch will follow. Sue will be buried in the family plot with her parents, brother, son and sister-in-law at
Meadow Ridge Memorial Park Cemetery in Faribault.

A Sue Schneider Memorial Fund has been established. In lieu of flowers, the family asks that memorial
gifts be directed to Tara Anderson at 112 Inverness Court, Mankato, Minn. 56001.
Though Sue suffered through years of many serious health issues, the family takes comfort in the fact that God has a special place in Heaven for those who suffer the most on Earth.