New NCI Director is focused on cancer research

As most of you know by now, Harold Varmus, was appointed the Director of the National Cancer Institute (NCI). Dr. Varmus is a Nobel laureate and former Director of the National Institutes of Health (NIH). He spent the last 10 years as president of Memorial Sloan-Kettering. He has every intention of leading his administration at the NCI in an “effort to control cancer through science.”

When asked why he was interested in the NCI position, since he had been NIH Director 10 years ago, he replied “There is no better time for working in cancer research. We have known over the last 20 years with increasing certainty that cancer is a genetic disease.”

“there is no better time for working in cancer research”

- Harold Varmus
Director, NCI

Varmus continued, “We currently have incredible specificity thanks in part to genomics and information technology.”

He said he will have “three basic principles” in running the NCI:

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Dr. DiSaia elected to third term as GOG Group Chair

The Gynecologic Oncology Group (GOG) principal investigators elected Philip J. DiSaia, MD, to a third term as Group Chair. DiSaia, who has held the Group Chair position since 2003, is the Emeritus Professor of Ob-Gyn, Division of Gynecologic Oncology, Department of Ob-Gyn, University of California, Irvine College of Medicine, Orange, Calif.

As Group Chair, DiSaia is principal investigator of the six-year GOG cooperative group grant from the
Obtaining informed consent for non English-speaking subjects

The U.S. Department of Health and Human Services regulations for the protection of human subjects require that informed consent information be presented “in language understandable to the subject.” In addition, in most situations, informed consent should be documented in writing (45 CFR 46.116 and 46.117).

Where informed consent is documented in accordance with 46.117(b)(1), the written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language that they understand. OHRP strongly encourages the use of this procedure whenever possible.

Alternatively, 46.117(b)(2) permits oral presentation of informed consent information in conjunction with a short-form written document (stating that the elements of consent have been presented orally), and a written summary of what is presented orally. A witness of the oral presentation is required, and the subject must be given copies of the short-form document and the summary.

When this procedure is used with subjects who do not speak English: (a) the oral presentation and the short form written document should be in a language understandable to the subject; (b) the IRB-approved English language, informed consent document may serve as the summary; and (c), the witness should be fluent in both English and the language of the subject.

At the time of consent: (a) the short form document should be signed by the subject (or the subject's legally authorized representative); (b) the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and (c) the short-form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

The IRB must receive all foreign language versions of the short form document as a condition of approval under the provisions of 46.117(b)(2). Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

It is the responsibility of the IRB to determine which of the procedures at 46.117(b) is appropriate for documenting informed consent in protocols that it reviews.

A sample short form can be found on the OHRP Website at: www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm.

CHAIR from Page 1

1. “Everything that we do and everything that we say will be based on evidence.”

2. “We have to remember that the great achievements of science have almost always originated with an individual scientist – a lone explorer – working in his or her lab.”

3. “Although scientific thought usually begins with individual scientists, it also depends on a community of scientists who share, validate and modify ideas.”

Varmus mentioned the Institute of Medicine (IOM) report recommending that “restructuring” of the NCI clinical trials cooperative group system was to be seriously considered. He stated “this is a very important moment for us to try to get the clinical trials system into much better shape”. He alluded again to the use of genetic information but with no details except an emphasis on biologic markers. He also mentioned that a working group of the National Cancer Advisory Board is producing a series of suggestions for issues which they hope he will pay attention to during his tenure as NCI Director.

Varmus is planning a series of his own meetings, inviting people from across the range of disciplines to establish a list of provocative questions that will help him think about what the next steps in cancer research ought to be.
Development of “fast track” study mechanism moving forward

The Gynecologic Oncology Group (GOG) leadership approved the development of a mechanism for the conduct of studies outside of the NCI/CTEP entity in April 2010. The intent of the mechanism is to allow the GOG to collaborate more effectively with industry as well as other entities capable of funding study conduct.

This mechanism will be known as GOG Plus. Oversight of the mechanism will be the responsibility of the Fast Track Task Force, which will be chaired by the Group Vice Chair for Science. This Task Force will report to the Protocol Development Committee for matters related to protocol development and to the Operations Committee for matters related to the conduct of studies. Its portfolio will include all non NCI-sponsored studies, which must be completely funded independently of NCI monies. Additional information about GOG Plus will be provided in the next edition of the Gynecologic Oncology Group Newsletter.

Current plans are to begin GOG Plus activities with phase II trials. Proposals for GOG Plus consideration may be submitted in one of several ways: The study concept may come from (a) a GOG scientific committee; (b) a GOG investigator; or (c), directly from potential study sponsors. The evaluation of studies will be based on scientific merit.

In order to get approval, the concept must compete with all other GOG proposals for the target patient population. All approved concepts will be developed as GOG studies and, if submitted by other than a GOG source, will be assigned a GOG study chair.

The target timing for initiation of GOG Plus activities will be the first quarter of 2011. The first meeting of the GOG Plus Task Force will be held at the January 2011 GOG Semi-Annual Meeting in San Diego, Calif. Proposals to be considered at the GOG Semi-Annual Meeting should be submitted by December 1, 2010 to the GOG Administrative Office via e-mail at: protocol_concepts@gog.org.

SAVE THE DATE

NEW FOR GYNECOLOGIC ONCOLOGY GROUP 82ND SEMI-ANNUAL MEETING

January 28, 2011

A 90-minute Complimentary CME-certified Luncheon Satellite Symposium to be held in conjunction with the GOG’s Semi-Annual Meeting. Friday afternoon beginning at 12:15 PM, immediately following the GOG General Session.

Please check www.GOG.org in the coming weeks for more information and registration.

This activity is not a part of the official GOG Semi-Annual Meeting.
New information for scientific manuscript preparation

The Publications Subcommittee would like to present new information to GOG members who are or will be writing manuscripts based upon GOG research.

The American College of Obstetricians and Gynecologists and Obstetrics and Gynecology have changed the historic policy on number of co-authors by ending its cap of six co-authors. There is no limit on the number of co-authors for papers for this journal, but the individual contribution of each co-author will need justification in accordance with the Uniform Requirements of the International Committee of Medical Journal Editors.

http://www.nlm.nih.gov/bsd/uniform_requirements.html

The American Society of Clinical Oncology and the Journal of Clinical Oncology have already published their position on negative Phase II trials. They indicated that these manuscripts will not be accepted unless additional, interesting research is presented.

In order to avoid inefficient submissions, the SDC will evaluate mature Phase II trials to determine if they are “interesting” or “not interesting.” If the first author designates JCO for a “not interesting” Phase II trial, the Publications Subcommittee Chair will communicate with the first author to find out whether this study will meet JCO’s published guidelines.

Cannistra SA. J Clin Oncology, 27:3073-76, July 1, 2009

Additionally, the ASCO Conflict of Interest (COI) policy has become considerably more stringent than the GOG COI policy. Therefore, when a first author designates JCO as the journal of interest, the SDC editorial associate will forward the ASCO Website link to the first author to assure that he or she can comply with the ASCO policy.

Members of the Publication Subcommittee will be using established standards for reporting clinical trials in their reviews. These include:

- STARD (for diagnostic tests)
- ConSoRT (for RCT’s)
- MOOSE (for reviews of observational studies)
- PRISMA (for systemic reviews of RCT’s)
- STROBE (for observational studies)

Finally, the Publications Subcommittee congratulates Larry J. Copeland, MD, on his appointment as an Associate Editor of the American Journal of Obstetrics and Gynecology.
GOG needs your institution’s help to get trials on track

The following list of GOG Protocols are lagging in accrual and need your institution’s help to get them on track. Dr Thigpen has often reminded the Group at the opening sessions of the GOG Semi Annual meetings about trials that are lagging and it is hoped that providing a written list will be helpful to institutions. Please make every effort to help the GOG to complete these important clinical trials.

**GOG-0086P:** A three arm randomized phase II study of paclitaxel/carboplatin/bevacizumab (NSC #704865, IND #7921), paclitaxel/carboplatin/temsirolimus (NSC #683864, IND #61010), and ixabepilone (NSC #710428 IND # 59699)/carboplatin/bevacizumab as initial therapy for measurable stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer. Activated 9-14-09 with expected 23 months of accrual to enter 330 patients. Accrual through August 2010 is 82.

**GOG-0212:** A Randomized Phase III Trial of Maintenance Chemotherapy comparing 12 monthly cycles Of Single Agent Paclitaxel or CT-2103 (IND# 70177) Versus No Treatment Until Documented Relapse In Women With Advanced Ovarian, Primary Peritoneal Or Fallopian Tube Cancer Who Achieve A Complete Clinical Response To Primary Platinum/taxane Chemotherapy. Activated 3-21-05 with expected seven years of accrual to enter 1100 patients. Accrual through August 2010 is 739.

**GOG-0213:** A Phase III Randomized Controlled Clinical Trial Of Carboplatin And Paclitaxel Alone Or In Combination With Bevacizumab (NSC #704865, IND #7921) Followed By Bevacizumab And Secondary Cytoreductive Surgery In Platinum-Sensitive, Recurrent, Ovarian, Primary Peritoneal And Fallopian Tube Cancer. NCI-Supplied Agents: Bevacizumab (NSC #704865, IND #7921). Activated 12-6-07 with expected 2.75 years of accrual to enter 660 patients. Accrual through August 2010 is 444. Surgical patients needed in particular but all accrual is encouraged.

**GOG-0237:** Comparative Analysis of CA-IX, p16, Proliferative Markers and Human Papilloma Virus (HPV) in the Diagnosis of Significant Cervical Lesions in Patients with a Cytologic Diagnosis of Atypical Glandular Cells (AGC). Activated 2-8-09 with expected accrual of seven years to enter 900 patients. Accrual through August 2010 is 43.

**GOG-0238:** A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin in Patients with Pelvic-only Recurrence of Carcinoma of the Uterine Corpus. Activated 2-25-08 with anticipated accrual 40 patients per year. Accrual through August 2010 is 25 of goal of 164.

**GOG-0250:** A Randomized Phase III Evaluation of Docetaxel (NSC #628503) and Gemcitabine (NSC #613327) Plus G-CSF with Bevacizumab (NSC #704865, IND #7921) versus Docetaxel (NSC #628503) and Gemcitabine (NSC #613327) Plus G-CSF with Placebo in the Treatment of Recurrent or Advanced Leiomyosarcoma of the Uterus. NCI-Supplied Agent Bevacizumab (NSC #704865, IND #7921). Activated 11-9-09 with expected accrual of 4.5 years to enter 804 patients. Accrual through August 2010 is 20.

**GOG-0258:** A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma. Activated 6-28-09 with expected accrual of 4.5 years to enter 804 patients. Accrual through August 2010 is 96.

DiSaia continued from Page 1

National Cancer Institute (NCI), and is Chair of the GOG’s Board of Directors and Principal Investigators committee.

GOG, an NCI-funded clinical trials cooperative group, promotes excellence in the quality and integrity of clinical and basic scientific research for gynecologic malignancies. The group conducts Phase I, II, and III clinical trials for patients with a variety of gynecologic malignancies, including ovarian, fallopian tube, cervical, uterine, vaginal and vulva cancers.
Boston meeting highlighted by second satellite symposium
Discussion focused on role of novel targeted therapies on gynecologic malignancies

The Gynecologic Oncology Group held its second satellite symposium for physicians at the 81st Semi-Annual Meeting in July 2010. The CME-accredited activity titled, “Targeted Agents in Ovarian Cancer & Other Gynecologic Malignancies: Trials, Triumphs, and Lessons Learned,” was chaired by Bradley J. Monk, MD, FACOG, FACS, from Creighton University School of Medicine at St. Joseph’s Hospital and Medical Center in Phoenix, Ariz. Participation was a tremendous success with 125 attendees, approximately half of whom reported attending the inaugural satellite symposium during the 80th Semi-Annual Meeting in January 2010.

Faculty presenters included Robert A. Burger, MD, from Fox Chase Cancer Center in Philadelphia, Pa., and Robert L. Coleman, MD, FACOG, FACS, from The University of Texas, Anderson Cancer Center in Houston, Texas.

The discussion highlighted the role of novel targeted therapies and current practice challenges in the treatment of ovarian cancer and other gynecologic malignancies. Clinical case illustrations using audience response technology allowed participants to show clinical competence and simulated performance during the educational activity.

The faculty presenters also provided updates from the American Society of Clinical Oncology 2010 Annual Meeting. Discussion included a review and commentary on the results of the GOG 218 trial evaluating bevacizumab-based regimens as well as future research directions. Additionally, the faculty provided insights into ongoing and accruing clinical trials to inform clinicians about opportunities for patient enrollment.

Dr. Monk had the following comments regarding the symposium:

“Clearly the GOG is excited about the results of GOG 218, and these results have been integrated into future trials. Replacement studies GOG 252 and 262 both include bevacizumab. The results of ICON 7 are eagerly anticipated, as is an application to the FDA for regulatory approval. It is important that the GOG membership participate in future satellite symposia during future GOG meetings in order to stay current on recently released results and ongoing clinical trials as the field of targeted therapeutics is moving very quickly.”
Nurses attend inaugural educational symposium in Boston

More than 110 U.S. and international registered nurses attended the inaugural satellite symposium for allied healthcare providers at the Gynecologic Oncology Group’s (GOG) 81st Semi-Annual Meeting in July 2010. The CEU-accredited activity titled “Optimizing Patient Outcomes in Epithelial Ovarian Cancer: Therapeutic Options, Nursing Interventions, and Patient Management Strategies,” was sponsored by IMER and chaired by Julie A. Ponto, PhD, RN, ACNS-BC, AOCN®, a professor in the graduate nursing program at Winona State University in Rochester, Minn. In addition to moderating the activity, Dr. Ponto discussed the complexities of ovarian cancer.

Faculty presenters included Sharon K. Stockman, BA, CCRP, from the University of Iowa Hospitals and Clinics in Iowa City, Iowa; Sharon Schwartz, MSN, RN, CRNP, from the Fox Chase Cancer Center in Philadelphia, Pa.; Sandy E. Kurtin, MS, RN, ANP, AOCN®, from Arizona Cancer Center in Tucson, Ariz.; and Paula A. Anastasia, RN, MN, AOCN®, from Cedars-Sinai Medical Center in Los Angeles, Calif.

Discussion addressed the challenging role of data managers in ovarian cancer research, evolving treatments such as intraperitoneal chemotherapy, nursing interventions for epithelial ovarian cancer, and highlights from the 2010 American Society of Clinical Oncology Annual Meeting. Audience response technology was used to engage attendees in an interactive experience that tested their clinical competence and performance.

Educational topics of interest recommended by attendees for the January 2011 GOG Semi-Annual Meeting included novel therapies, research updates, and supportive care strategies to help nurses and data managers improve the quality of life of women with ovarian cancer.

Dr. Ponto had these comments about the inaugural satellite symposium:

“The forum provided an excellent opportunity for nurses, data managers, and others interested in ovarian cancer to share their unique perspectives and learn the latest data on epithelial ovarian cancer staging, treatment and symptom management. The interest and attendance of oncology professionals at this symposium highlight the importance of peer-to-peer educational opportunities to keep current with the rapidly evolving treatments and challenges in epithelial ovarian cancer management.”

New Horizons GYN Cancer Research Fund

The GOG would like to thank the following individuals and families for their generous contributions to the New Horizons GYN Cancer Research Fund:

**In Memory of Dr. George C. and Betty Lewis**
- James Larson, MD
- and Karen Larson
- Marianne L. Daley
- Robert C. and Marjorie M. Park
- Paula Fracasso, MD

**Jack and Jan Kellner Memorial Fund**
- Marianne L. Daley
- Kristi K. Downey

**In Memory of Marie Marcucci and Phyllis Savarese**
- Jeffrey and Lydia Baum

**In Memory of Dr. George C. and Betty Lewis**
- Thomas Jefferson University, Department of Obstetrics and GYN faculty
- William and Iffatha Hoskins
- Francis J. Major, MD
- Howard Homesley, MD, Brookview Research Inc.
Michigan runners were “Chasing the Cure” at inaugural race

“I never imagined the turnout would be this big for a first race. This is so incredible . . .”

That was the reaction from Terra Draper after the inaugural “Chasing the Cure” 5K race in Sturgis, Mich. Proceeds from the Sept. 18, 2010 race were donated by Draper to the Gynecologic Oncology Group’s (GOG) “New Horizons GYN Cancer Research Fund.”

The Sturgis race was the most recent awareness and fundraising event under the “Chasing the Cure” theme. Draper, a lifelong Sturgis resident and avid runner, organized the race as a way to help raise awareness about ovarian cancer – the disease that her aunt, Joan Dykstra, is currently battling. Draper dedicated the race to her aunt.

“This thing is so close to my heart,” Draper said. “If this event helps just one person – then that’s all I want.”

According to Draper, the idea for the race was the result of a desire to support and give back to her Aunt Joan. In August of 2009, Aunt Joan found out that she had two large masses in her ovaries. This was her second round with the deadly disease.

“When we found out the news, the whole family was devastated,” said Draper. “So I wanted to do something. You can always help by listening, but I wanted to do more.”

That’s when the idea for the race came to fruition. Draper, along with her childhood friend and fellow runner, Leann Barnell, devised the idea while sitting at Barnell’s kitchen table after hearing the news.

“I never imagined the turnout would be this big for a first race. This is so incredible . . .”

made sense,” said Barnell. “It was something that even Aunt Joan could take part in.”

Draper said that she then approached Aunt Joan about the idea and asked her to choose the benefactor. “She didn’t even hesitate in choosing the GOG,” she said.

She went on to say that Aunt Joan chose the GOG because she took part in a GOG Trial 0218 (Avestin) at the University of Michigan at Ann Arbor. Her doctor was Angela Kueck, MD, who, coincidentally, also participated in the race.

Draper then proceeded to contact Kathy Shumaker, Director of Development at GOG, to express her aunt’s desire to support the GOG. Shumaker worked with her over the next year to give GOG support in preparing for the race.

“Kathy and the GOG gave me an incredible amount of support. My whole family is very thankful for the GOG,” she said.

Over the next year, Draper worked tirelessly with family, friends and local organizations to gain support and prepare for the race – ultimately targeting September 18, 2010 as the race date. “Having the race in September made sense because it is Ovarian Cancer Awareness Month,” she said.

Draper credits her small community, her family and the love of her Aunt Joan (who also participated in the race – just days after completing a treatment) for not only organizing the race – but for its successful completion.

“Terra’s entire family runs, so a race to raise awareness only

RACE continued on Page 10
AGO-OVAR 12/LUME-Ovar 1 is a multicentre, randomized, double-blind Phase III trial to investigate the efficacy and safety of BIBF 1120* in combination with carboplatin and paclitaxel compared with placebo plus carboplatin and paclitaxel in patients with advanced ovarian cancer.

AGO-OVAR 12 is a joint collaboration between several participating Academic Study Groups led by the Arbeitsgemeinschaft Gynäkologische Onkologie, Studiengruppe Ovarialkarzinom (AGO-OVAR). The Coordinating Investigator is Prof. Dr. Andreas du Bois (Wiesbaden, Germany).

**TRIAL DESIGN**

Patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer (N=1300)

2:1 Randomization

BIBF 1120* 200 mg p.o. BID PLUS paclitaxel 175 mg/m² + carboplatin AUC 5-6 mg/mL · min Every 21 days for 6 courses

Placebo p.o. BID PLUS paclitaxel 175 mg/m² + carboplatin AUC 5-6 mg/mL · min Every 21 days for 6 courses

BIBF 1120* /placebo monotherapy continued for a maximum of 120 weeks after randomization or until AEs or disease progression, whichever occurs first

**OBJECTIVE**

To investigate the efficacy and safety of BIBF 1120* plus chemotherapy as compared with placebo plus chemotherapy in patients with advanced ovarian cancer

**SELECTED ELIGIBILITY CRITERIA**

1. First diagnosis of histologically confirmed epithelial ovarian, fallopian tube or primary peritoneal cancer
2. FIGO stages IIB–IV
3. Females aged ≥18 years
4. Life expectancy of at least 6 months
5. Eastern Cooperative Oncology Group performance status 0, 1 or 2
6. Prior surgery
7. Planned application of first dose of chemotherapy after wound healing, but no later than 10 weeks after surgery

**STRATIFICATION**

- No macroscopic residual tumour (=0 cm) vs. macroscopic residual tumour (>0 cm) post surgery
- FIGO stage IIB–III vs. IV
- Carboplatin dose (AUC 5 vs. AUC 6 mg/ml x min)

**ENDPOINTS**

Primary endpoint: PFS (investigator’s assessment)

Secondary endpoints (efficacy): PFS (radiological assessment); overall survival; time to tumour marker progression (CA-125); objective response

Other important endpoints: incidence and intensity of adverse events; changes in safety laboratory parameters; patient-reported outcome; health-related quality of life

For more information about AGO-OVAR 12/LUME-Ovar 1, including eligibility criteria, please visit: www.clinicaltrials.gov

*BIBF 1120 is an investigational agent and is not approved for the treatment of ovarian cancer. Its efficacy and safety have not been established.
“Terra does nothing small. She just took this idea and ran with it,” said Barnell.

All told, the race attracted over 170 participants, 76 local sponsors (many of whom donated time, materials and space for the race), and raised over $8,000 for the GOG.

Draper is already planning the 2011 race. When asked what her goals are for next year, she said: “I’d love to see 10 percent more runners, 10 percent more donations — and hopefully help two people next time.”

As the runners crossed the finish line that day, Draper waited patiently. When her Aunt Joan trotted across the line, she ran up and threw her arms around her while tears streamed down both of their faces.

“I can’t believe this all came together,” Draper said. “This is for you Aunt Joan.”
At Genentech BioOncology, we’re leading the fight against cancer with innovative science and are working to transform cancer treatment.

**A family of firsts**—Our proven therapeutics are standards of care in 5 of the 6 leading causes of cancer mortality in the United States.

**A robust pipeline**—Our molecules in development target the fundamental mechanisms of cancer growth and include a HER dimerization inhibitor, a Hedgehog pathway inhibitor, an antibody–drug conjugate, and antibodies targeting cancer cell-surface antigens.

**A commitment to patients**—We actively pursue ways to ensure patient access to therapeutics through a variety of patient support programs so healthcare providers can remain focused on patient care.

Our goal is to fundamentally change the way cancer is treated—not just with incremental advances, but with new standards of care.
All health care professionals are invited to register for a complimentary independent educational satellite symposium to be held during the GOG semi-annual meeting.

Saturday, January 29, 2011
12:15 pm – 1:45 pm
Manchester Grand Hyatt
San Diego, California

Target Audience
This activity has been designed for gynecologists, medical oncologists, oncology nurses, oncology researchers, and other healthcare professionals interested in learning about personalized medicine as it relates to gynecologic oncology.

Registration
Visit the registration page on www.gog.org and click on the “New Trends in Managing Gynecologic Cancers…” link to register for this complimentary program.

Faculty
To be announced

Agenda
The agenda for this program will be posted on www.gog.org

This activity is not a part of the official GOG Semi-Annual Meeting.

Visit www.gog.org
For the latest news and information,