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press release

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NRG Oncology's GOG-0218 Trial Leads to FDA Approval of Chemotherapy with Bevacizumab for Women with Ovarian Cancer Following Initial Surgery

PHILADELPHIA, PA —The U.S. Food and Drug Administration (FDA) recently approved the use of bevacizumab (Avastin®) in combination with carboplatin and paclitaxel followed by Avastin as a single agent, as a treatment for women with advanced stage III or IV ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection. The FDA approval stems from the results of the double blind, placebo-controlled, phase 3 NRG Oncology trial GOG-0218, which revealed the addition of bevacizumab improved progression-free survival (PFS) for women when compared to chemotherapy alone. GOG-0218 was conducted by the Gynecologic Oncology Group (GOG, now part of NRG Oncology) and sponsored by the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI) under its Cooperative Research and Development Agreement with Genentech, a member of the Roche Group, for bevacizumab.

Robert A. Burger, MD
NRG-GOG-0218
Principal Investigator

"I wish to thank all of the patients who participated on the study, as well as their loved ones, for helping to discover new therapies to improve the lives of women with ovarian cancer. More than seven (7) years have elapsed since the release of the results of this important study. The 2018 FDA approval based on this study's findings is a testament to the value of bevacizumab in the treatment of this difficult disease," stated Robert A. Burger, MD, the Principal Investigator of NRG-GOG-0218 and Director of Clinical Research and Fellowship Program in Gynecologic Oncology at the Perelman School of Medicine at the University of Pennsylvania.

The FDA approved bevacizumab at 15mg/kg in addition to carboplatin and paclitaxel chemotherapy for primary therapy, followed by up to 22 cycles of single-agent bevacizumab for maintenance therapy. NRG Oncology's GOG-0218 trial randomly assigned one of three study arms to 1,873 women. In those three arms, the investigators assessed the now FDA-approved treatment alongside an arm that consisted of chemotherapy and placebo followed by placebo and an arm that treated patients with bevacizumab combined with chemotherapy and followed by a placebo. The primary endpoint was investigator-assessed progression-free survival (PFS) and overall survival (OS) was a secondary endpoint.

The data from the phase 3 trial indicated that median PFS of women treated with bevacizumab/chemotherapy, followed by bevacizumab was 18.2 months, compared to 12.0 months for the women who received chemotherapy alone and 12.8 months for patients receiving bevacizumab with chemotherapy. The median OS was 43.8 months for women treated with bevacizumab/chemotherapy followed by bevacizumab, compared with 40.6 months with chemotherapy alone and 38.8 months for those treated with bevacizumab/chemotherapy. Common grade 3 and 4 adverse events included fatigue, high blood pressure, decrease platelet count, and decrease white blood cell count.

"NRG-GOG-0218 is truly a milestone study that offers an additional treatment option for women with late-stage epithelial ovarian cancer aside from the usual chemotherapy. At NRG Oncology, we strive to make advances in our research that improve the lives of our patients and simultaneously influence the research community so we may continue to build upon these discoveries. Congratulations to the NRG-GOG-0218

study team, Genentech, and all who participated in making this trial a success," added Robert S. Mannel, MD, one of NRG Oncology's Group Chairs and Director of the Stephenson Cancer Center at the University of Oklahoma.

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www.nrgoncology.org

NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of patients with cancer. Founded in 2012, NRG Oncology is a Pennsylvania-based nonprofit corporation that integrates the research of the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Radiation Therapy Oncology Group (RTOG), and the Gynecologic Oncology Group (GOG). The research network seeks to carry out clinical trials with emphases on gender-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types. NRG Oncology's extensive research organization comprises multidisciplinary investigators, including medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians, and encompasses more than 1,300 research sites located world-wide with predominance in the United States and Canada. NRG Oncology is supported primarily through grants from the National Cancer Institute (NCI) and is one of five research groups in the NCI's National Clinical Trials Network.