NCCN Announces First Patient Dosed in NCCN-Peregrine Pharmaceuticals Collaborative Study of Baviximab

Glioblastoma is the most common malignant primary brain tumor and is a uniformly fatal disease, with 5-year survival rates of <4% despite aggressive treatment with surgery, radiation, and chemotherapy.¹ Consequently, new therapies for this patient population are desperately needed.

NCCN announced the dosing of the first patient in its Oncology Research Program (ORP)–funded study to investigate the effectiveness of baviximab with radiation and temozolomide in patients with newly diagnosed glioblastomas.

The study, initiated by Elizabeth Gerstner, MD, Massachusetts General Hospital Cancer Center, is 1 of 3 studies funded through a collaboration between NCCN ORP and Peregrine Pharmaceuticals—this patient marks the first enrollment into an NCCN ORP-funded investigator-initiated baviximab trial.

“NCCN ORP congratulates Dr. Gerstner and Dana-Farber/Brigham and Women’s Cancer Center | Massachusetts General Hospital Cancer Center for initiation of this study, as well as the other investigators who will soon embark on their research of baviximab in patients with cancer,” said Susan Most, MBA, RN, Director, Clinical Operations, NCCN ORP. “The fact that Peregrine Pharmaceuticals has entrusted the NCCN ORP with these investigator-initiated studies is an honor, and we are happy that patients at our esteemed institutions will have access to this novel immunotherapy.”

The following researchers received funding through a grant from Peregrine Pharmaceuticals:

- Elizabeth Gerstner, MD, Massachusetts General Hospital Cancer Center, “Phase II Clinical Trial of Baviximab with Radiation and Temozolomide for Patients with Newly Diagnosed Glioblastoma”
- Jessica Frakes, MD, Moffitt Cancer Center, “A Phase I Trial of Sorafenib and Baviximab Plus Stereotactic Body Radiation Therapy (SBRT) for First-Line Treatment of Unresectable Hepatocellular Carcinoma”
- Raneer Mehra, MD, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, “Phase II Study of Pembrolizumab and Baviximab for Progressive Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck”

Drs. Frakes and Mehra will begin enrolling patients in the coming months.

“We are hopeful that results from this trial, as well as from the 2 additional studies at NCCN Member Institutions, will continue to support our belief that baviximab works to create a more immune-active tumor microenvironment in which other therapies are able to have a greater antitumor effect,” said Joseph Shan, MPH, Vice President, Clinical and Regulatory Affairs of Peregrine. “We look forward to following this important study at the Massachusetts General Hospital Cancer Center, as well as the planned trials at Moffitt Cancer Center and The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins.”

Baviximab is an investigational immune-modulatory monoclonal antibody that targets phosphatidylserine (PS), a phospholipid that inhibits the ability of immune cells to recognize and fight tumors. Baviximab is believed to reverse PS-mediated immunosuppression by blocking the engagement of PS with its receptors, as well as by sending an alternate immune activating signal.² According to Peregrine, PS-targeting antibodies have been shown to shift the functions of immune cells in tumors, resulting in multiple signs of immune activation and antitumor immune responses. This mechanism may play an important role in allowing other cancer therapies to more effectively attack tumors by reversing the immunosuppression that limits the impact of those treatments.

Importantly, baviximab has also demonstrated a favorable safety and tolerability profile across several clinical trials conducted to date, which may offer the compound a key

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advantage as the evolving cancer treatment landscape continues to shift to a combination therapy approach.

The awardees responded to a Request for Proposals issued by ORP to NCCN Member Institutions and their affiliate hospitals. Submissions were peer-reviewed by the NCCN Bavituximab Scientific Review Committee. The funded concepts were selected based on several criteria including scientific merit, existing data, and types of studies necessary to further evaluate the efficacy of bavituximab.

NCCN ORP draws on the expertise of investigators from NCCN Member Institutions and their affiliated hospitals to facilitate all phases of clinical research. The research is made possible by collaborations with pharmaceutical and biotechnology companies in order to advance therapeutic options for patients with cancer.

For more information about NCCN ORP, visit NCCN.org/ORP.

References

1. CBTRUS (2008) Statistical report: primary brain tumors in the United States, 2000-2004. Hinsdale, IL: Central Brain Tumor Registry of the United States; 2008.
2. Yin Y, Huang X, Lynn KD, Thorpe PE. Phosphatidylserine-targeting antibody induces M1 macrophage polarization and promotes myeloid-derived suppressor cell differentiation. *Cancer Immunol Res* 2013;1:256–268.

NCCN Chemotherapy Order Templates to be Integrated Into MEDITECH's Web EHR

NCCN is collaborating with MEDITECH to integrate the NCCN Chemotherapy Order Templates (NCCN Templates) into MEDITECH's Web electronic health record (EHR) as standard cancer treatment protocols for use at point of care.

"NCCN's collaboration with MEDITECH further ensures that practitioners have access to timely, unbiased clinical treatment protocols at the point of care so they can provide patients with the most appropriate regimens for their diagnosis," said Robert W. Carlson, MD, Chief Executive Officer, NCCN.

As part of the integration, MEDITECH's Web EHR will provide clinicians direct access to the NCCN Templates and will link to NCCN.org and the corresponding NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines).

"MEDITECH's collaboration with NCCN is a major part of the company's strategy to help clinicians streamline oncology care to better treat their patients," says Hoda Sayed-Friel, Executive Vice President of Strategy, MEDITECH. "We're thrilled to be including these regimens into our standard content to enhance patient safety and help guide clinicians' cancer treatment efforts by providing up-to-date, evidence-based standard protocols and best practices within MEDITECH's Oncology Management Solution."

The information contained in the NCCN Templates enhances patient safety by empowering health care providers to standardize patient care, reduce medical errors, and anticipate and manage adverse events.

NCCN continues to expand its library of chemotherapy order templates to work toward improved safe and effective use of drugs and biologics in cancer care.

For more information about NCCN Templates, visit NCCN.org/templates.

NCCN Guidelines to be Integrated into the Evinance Decision Support Platform

NCCN is collaborating with Evinance to integrate the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) into the Evinance Decision Support Platform to allow for point-of-care access to treatment recommendations derived from the NCCN Guidelines.

"Integration of the NCCN Guidelines into Evinance's Decision Support system will directly benefit both clinicians and patients by offering evidence-based clinical recommendations at the point of care, as well as empowering patients to partake in the

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shared decision-making process to determine the best course of treatment for their disease,” said Robert W. Carlson, MD, Chief Executive Officer, NCCN.

Through their health information technology platform, Evinance provides decision support and adherence tracking based on the leading evidence-based guidelines. With integration directly into the clinical workflow, the Evinance Decision Support Platform improves the shared decision-making process by using virtual patient paths to enhance communication so that doctors and patients can choose the best course of action together.

“Clinicians cannot keep up with the exponential growth of new clinical information, and patients are overwhelmed with what they read online. Most institutions have no centralized, electronic method to provide answers to either group that meet the patient’s needs and that ensure adherence to the latest protocols and treatment plans, which is also critical for reimbursement,” said Chad Armstrong, Chief Executive Officer, Evinance. “This collaboration will ensure the latest evidence-based clinical recommendations are always available at the point of care, enabling better communication with patients.”

The NCCN Guidelines are the recognized standard for clinical policy in cancer care and are the most thorough and most frequently updated clinical practice guidelines available in any area of medicine.

For more information about integration of NCCN content into health information technology, visit NCCN.org/HIT.

Translations and Adaptations

of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

More than **100 International Adaptations and Translations** of the NCCN Guidelines® are available on NCCN.org **representing 13 languages.**

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