

Alliance for Clinical Trials in Oncology Friday, November 3, 2017 Loews Hotel Chicago O'Hare 3:30 pm – 6:30 pm Teleconf #: 1-800-501-8979

Access code: 3057352 / Chair code: 3307

Neurooncology Committee Meeting Agenda

Chair: Evanthia Galanis, MD

<u>Welcome – Overview</u>

E. Galanis

Newly Diagnosed GBM

Active Protocols

A071102: Randomized Trial of ABT-888 or Placebo in Combination with J. Sarkaria Adjuvant Temozolomide in Newly Diagnosed GBM with MGMT Promoter Hypermethylation

Phase I/II Study of AZD1775 with Radiation and Temozolomide in Patients with Newly Diagnosed Glioblastoma

B. Alexander

Recently Completed Trials

N0874 Phase I/II Study of Vorinostat (Suberoylanilide Hydroxamic Acid) [SAHA]Temozolomide, and Radiation Therapy in Patients with Newly Diagnosed Glioblastoma (in press, Neurooncology)

N0877 Phase I Randomized Phase II Trial of Either Dasatanib or Placebo Combined with Standard Chemo-Radiotherapy for Newly Diagnosed Glioblastoma Multiforme (GBM)

Recurrent GBM

A071101: A Phase II Randomized Trial Comparing the Efficacy of O. Bloch Heat Shock Protein-Peptide Complex-96 (HSPCC-96) NSC #725085, I. Parney BB IND# Pending) Vaccine Given with Bevacizumab versus Bevacizumab alone in the Treatment of Surgically Resectable Recurrent Glioblastoma Multiforme (GBM) – Closed following interim analysis

Recently Completed Trials

N1174: Phase I/Randomized Comparative Phase II Trial of TRC105 plus Bevacizumab versus Bevacizumab in Bevacizumab-Naïve Patients with Recurrent Glioblastoma (Accrual goal met 9/4/2015)

N0872 Phase I Randomized Phase II Double Blinded Study of Either Dasatanib or Placebo Combined with Bevacizumab in Recurrent Glioblastoma (Accrual goal met on 3/27/14)

Approved Concepts in Development

A071702: A Phase II Study of Anti-PD-1/PD-L1 Blockade

Immunotherapy in Patients with Hypermutated Recurrent Glioblastoma

G. Dunn

E. Galanis

D. Reardon

Brain Metastases

New Concept

CCTG/Alliance CE.7: A Phase III Trial of Radiosurgery (SRS) vs.

WBRT for Multiple (5-15) Brain Metastases

M. Chan

Phase III Trial of Post-Surgical Single Fraction Stereotactic

Radiosurgery (SRS) Compared with Fractionated SRS for Resected

Metastatic Brain Disease

P. Brown

Approved Concepts in Development

A071701: Molecularly-driven trial in brain metastases

P. Brastianos

Recently Completed Trials

N017C A Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy In Addition to Radiosurgery in the Management of Patients with One to Three Cerebral Metastases (Brown et al, Lancet Oncology 2017)

N0574 A Phase III Trial of Post-Surgical Stereotactic Radiosurgery (SRS) Compared with Whole Brain Radiotherapy (Brown and al, JAMA 2016)

Medulloblastomas

New Concept

Prospective Randomized Phase II Trial for newly diagnosed patients with Medulloblastoma and Pineoblastoma

A. Mahajan H. Shih

Anaplastic Gliomas – Newly Diagnosed

Active Protocols

N0577 Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with 1p/19q Codeleted Anaplastic Glioma K. Jaeckle

Recently Completed Trials

EORTC 26053-22054 Phase III Trial on Concurrent and Adjuvant Temozolomide Chemotherapy in Non-1p/19q Deleted Anaplastic Glioma: The CATNON Intergroup Trial

Low Grade Gliomas

E3F05 Phase III Study of Radiation Therapy with or without Temozolomide for Symptomatic or Progressive Low-Grade Gliomas (Temp. Closed)

Symptom Control

A221101: A Phase III Randomized, Double-Blind Placebo

A. Porter Controlled Study of Armodafinil (Nuvigil®) To Reduce Cancer-Related Fatigue in Patients with Glioblastoma Multiforme

A221208: Bevacizumab vs. Steroids (BeSt) for Radionecrosis after C. Chung Radiosurgery: A Randomized Phase II Trial

Leptomeningeal Metastases

Approved Concepts in Development

A Randomized Open-Label, Multi-Center Study of ANG1005 Compared with Physician's Best Choice in Breast Cancer Patients with Newly Diagnosed Leptomeningeal Carcinomatosis and Previously Treated Brain Metastases (on hold pending funding) P. Kumthekar

Meningiomas

A071401: Phase II Trial of SMO/AKT Inhibitors in Progressive P. Brastianos Meningiomas with SMO/AKT Mutations

Craniopharyngiomas

A071601: Phase II Trial of BRAF/MEK Inhibitors in Papillary P. Brastianos Craniopharyngiomas

Other Studies

AFT-28 Direct Oral Anticoagulants (DOACs) Versus LMWH +/- Warfarin D. Schrag for VTE in Cancer: A Randomized Effectiveness Trial (CANVAS Trial)