18-0376/Kazia
Phase 2a study (Part 1): A phase 2a study to evaluate the safety, pharmacokinetics and clinical activity of the PI3K/mTOR inhibitor GDC-0084 administered to patients with glioblastoma multiforme characterized by nmethylated O6-methylguanine-methyltransferase promoter status
Phase 2b study (Part 2): A randomized, open-label, multicenter, phase 2b study to assess the efficacy and safety of the PI3K/mTOR inhibitor GDC-0084 compared to temozolomide as adjuvant therapy for the treatment of newly diagnosed glioblastoma multiforme with unmethylated O6-methylguanine-methyltransferase promoter status following surgical resection and standard concomitant chemoradiation therapy with temozolomide
- Measurable disease required for expansion cohort required; non-measurable allowed in dose-escalation
- No prior treatment except Stupp - Optune not allowed while on study
- Maintenance therapy
- Enrollment 1

17-1974/Diffusion
Open-label, Randomized, Controlled, Phase 3 Safety and Efficacy Study of Tran Sodium Crocetinate (TSC) with Radiation Therapy and Temozolomide in Newly Diagnosed GBM Biopsy-Only Subjects

17-486/BeiGene
Phase 1b/2 to assess safety, tolerability, and efficacy of BGB-290 in combo w/radiation and/or temozolomide in first-line or recurrent/refractory glioblastoma

16-0200/RTOG Foundation Intellance I Randomized Phase 2b/3 of ABT-414 with concurrent chemoradiation and adjuvant temozolomide

17-1610/AbbVie F16-249 Radiological Evident Treatment Effects in Subjects w/GBM Non-treatment trial
Previous treatment with ABT-414 required

Hepatic-Sub-study Arm Open Current enrollment 6 out of 12
University of Colorado Cancer Center Brain Disease Site Schema

GBM - RECURRENT

17-1986
A Randomized Phase 2 Trial of Cediranib and Olaparib Compared to Bevacizumab in Patients with Recurrent Glioblastoma Who Have not Received VEGF Therapy First or Second Recurrence Only) (No Prior Parp Inhibitors or Treatment Affecting VEGF Pathways)

15-752/Tocagen
Phase 2/3 of Toca 511, retroviral replicating vector, w/Toca FC vs SOC for recurrent GBM or Anaplastic Astrocytoma for first or second recurrence Must be surgical candidates:
(1)max diameter
(2) candidate for ≥75% to 80% resection

17-486/BeiGene
Phase 1b/2 to assess safety, tolerability, and efficacy of BGB-290 in combo w/radiation and/or temozolomide in first-line or recurrent/refractory glioblastoma Recurrent/refractory setting - can be MGMT methylated or unmethylated No prior systemic

13-592/Immunomedics
Phase I Team/sponsor approval required IMMU-132 for epithelial cancers

15-2153 Vigilant Registry Gliadel Wafer

05 MAR 2019
OLIGODENDROGLIOMA

MENINGIOMAS

Protocol# 10186/ 11-0221: A Phase I/II Study of Nivolumab Plus or Minus Ipilimumab in combination with Multi-Fraction Stereotactic Radiosurgery for Recurrent High-Grade Radiation - Relapsed Meningioma

15-1747 / A071401
SMO/AKT/NF2 inhibitors for progressive meningiomas
Any grade meningioma allowed
Prior therapy allowed but not required
NF2 cohorts for Grade I and Grade II/III are closed
SMO/PTCH1 cohorts for Grade I and Grade II/III remain open
(Suspended Mfg. study drug discontinued to new patients)
Enrollment 1
RECURRENT ANAPLASTIC ASTROCYTOMOAS

18-1336/Stellar Orbus
Phase 3, Randomized Open-Label Study to Evaluate the Efficacy and Safety of Efornithine with Lomustine Compared to Lomustine alone in Patient with Anaplastic Astrocytoma the Progress/Recur After Irradiation and Adjuvant Temozolomide

15-1752 / Tocagen
Phase 2/3 of Toca 511, retroviral replicating vector, w/Toca FC vs SOC for first of second recurrence

15-2153 Vigilant Registry
Gliadel Wafers

05 MAR 2019
BREAST CANCER W/ BRAIN METS

14-2283 / Lilly
Abemaciclib PO
Breast Ca or Melanoma mets allowed
Leptomeningeal mets excluded
Want brain met tissue

MELANOMA W/ BRAIN METS

14-2209 / Bristol-Myers Squibb
Nivolumab + Ipilimumab followed by Nivolumab
Prior therapy allowed
Symptomatic cohort open

ALL BRAIN METS

15-2153/ Vigilant Registry Gliadel Wafers open
University of Colorado Cancer Center Brain Disease Site Schema

CNS LYMPHOMA

16-1217 / OHSU
Maintenance
Obinutuzumab for
Primary Central
Nervous System
Lymphoma Complete
Responders
Enrollment 3

OTHER

18-0916/BMS Research
and Development
Characterizing the
Burden of Caregivers of
Individuals with
Glioblastoma Multiforme
(GBM)

17-1138
Assessment of
Neuroimaging
measurements in
predicting post-operative
outcomes following
respective surgery for
brain tumors