BRAF

BRAF is a human gene that makes a protein called B-Raf. The gene is also referred to as proto-oncogene B-Raf and v-Raf murine sarcoma viral oncogene homolog B1, while the protein is more formally known as serine/threonine-protein kinase B-Raf.

The B-Raf protein is involved in sending signals inside cells, which are involved in directing cell growth. In 2002, it was shown to be faulty (mutated) in some human cancers.

BRAF in neurosurgery

- Real-life implementation of molecular criteria for diagnosing gliomas according to 2021 WHO Classification: a national survey from the Italian Association of Neuro-Oncology and Society of Neurosurgery
- Tumor Microenvironment in Melanoma Brain Metastasis: A New Potential Target?
- BRAF/MEK inhibition induces cell state transitions boosting immune checkpoint sensitivity in BRAF(V600E)-mutant glioma
- 38-Year Delayed Spinal Leptomeningeal Dissemination of a Paediatric Pilocytic Astrocytoma: A Case Report
- Erdheim-Chester with central nervous system involvement: Complex histopathological diagnosis and neurosurgical challenges in a rare histiocytic disorder
- MRI features of pleomorphic xanthoastrocytoma defined by DNA methylation profile
- The safety and efficacy of dabrafenib plus trametinib for patients with brain metastatic melanoma: a systematic review and meta-analysis
- A comprehensive, multi-center, immunogenomic analysis of melanoma brain metastases

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The highest incidence of CNS tumors that harbor BRAF V600 E-mutations occurs in pediatric patients [1)].

In particular, a relatively high frequency of these mutations has been identified in pediatric pilocytic astrocytomas, pleomorphic xanthoastrocytomas, malignant astrocytomas, gangliogliomas, and the epithelioid subtype of glioblastoma multiforme.

Somatic BRAF mutations have been reported in 1-4% of non-small cell lung cancer (NSCLC), primarily in adenocarcinomas with the BRAF (V600E) mutation in about 50% of the cases. The role of BRAF mutation in NSCLC and the treatment for tumors with such mutations is still evolving.

This is a brief overview of information related to FDA’s approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA’s approval.

Product Name: cobas® 4800 BRAF V600 Mutation Test PMA Applicant: Roche Molecular Systems, Inc Address: 4300 Hacienda Drive P.O Box 9002 Pleasanton, CA 94566-0900 USA Approval Date: August 17, 2011 Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110020a.pdf

What is it? The cobas® 4800 BRAF V600 Mutation Test is an automated molecular assay designed to detect the presence of a mutation in the BRAF gene in the most serious type of skin cancer (melanoma).disclaimer icon In normal skin tissue, the B-raf protein transmits signals in cells to regulate cell growth and cell death. In melanoma tissue, a mutation referred to as BRAF V600E, causes an altered form of the B-raf protein. This mutant form of the B-raf protein results in abnormal functioning of the protein and stimulates melanoma growth.

Zelboraf® (vemurafenib) is a drug used to treat patients with melanoma that can't be removed by surgery or has spread in the body. Zelboraf® blocks the mutant V600E version of B-raf. This test is used to determine a patient's eligibility for treatment with Zelboraf®. If the test result indicates that the mutation is present in the melanoma cells, then the patient may receive treatment with Zelboraf®.

How does it work?

The doctor takes a small amount of tissue sample from the patient's melanoma and examines it (biopsy).

The tissue is embedded in a block of paraffin wax and a thin slice is cut from the block for use in the test.

DNA is isolated from the patient's tumor cells and is mixed with reagents that specifically detect, bind to, and make copies of the tumor's BRAF gene. This reaction produces fluorescence, which is then measured to determine the presence or absence of the mutation in the tumor sample.

The presence of the mutation in the BRAF gene indicates that a patient is eligible for melanoma treatment with Zelboraf®.

When is it used? To determine if a patient's melanoma characteristics suggest that they might be a candidate for Zelboraf® therapy.

What will it accomplish? The cobas® 4800 BRAF V600 Mutation Test helps to determine the eligibility of patients with melanoma for Zelboraf® treatment, which may prolong their life.

When should it not be used? There are no known contraindications.

Additional information : Summary of Safety and Effectiveness and labeling are available online [2)].

BRAF fusion

BRAF fusion

BRAF mutation

BRAF mutation

1)

Schindler G, Capper D, Meyer J, Janzarik W, Omran H, Herold-Mende C, Schmieder K, Wesseling P, Mawrin C, Hasselblatt M, Louis DN, Korshunov A, Pfister S, Hartmann C, Paulus W, Reifenberger G, von

Deimling A. Analysis of BRAF V600E mutation in 1,320 nervous system tumors reveals high mutation frequencies in pleomorphic xanthoastrocytoma, ganglioglioma and extra-cerebellar pilocytic astrocytoma. Acta Neuropathol. 2011;14:397–405. doi: 10.1007/s00401-011-0802-6.

2) http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm268836.htm