Evaluation of a New Anti-cancer Immunotherapy in Adult Acute Myeloid Leukemia Patients With a Suboptimal Clinical Response to Induction Chemotherapy

This study is currently recruiting participants.

Verified May 2012 by GlaxoSmithKline

First Received on December 8, 2009. Last Updated on May 31, 2012

Resource links provided by NLM:
- MedlinePlus
- Genetics Home Reference
- Related topics:
  - familial acute myeloid leukemia with mutated CEBPA
  - Acute Myeloid Leukemia
  - Cancer
  - Leukemia
  - Wilms' Tumor

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measures:
- Occurrence of severe toxicities as defined in the protocol [ Time Frame: During the study treatment period ] [ Designated as safety issue: No ]
- Clinical activity [ Time Frame: At several defined timepoints during the whole study, including the follow-up period ] [ Designated as safety issue: No ]

Secondary Outcome Measures:
- Immunogenicity of the WT1 ASCI [ Time Frame: At 21 defined timepoints during the whole study, including the follow-up period. ] [ Designated as safety issue: No ]
- Safety [ Time Frame: 1. Occurrence of adverse events (AE) and serious adverse events (SAE) during the study treatment period and ending 30 days after the last study treatment administration; 2. Occurrence of SAE related to study treatment during the whole study duration ] [ Designated as safety issue: No ]
- Clinical activity [other indicators] [ Time Frame: During the whole study, including the follow-up period ] [ Designated as safety issue: No ]

Estimated Enrollment: 40
Study Start Date: December 2009
Estimated Study Completion Date: December 2016
Estimated Primary Completion Date: December 2016 (Final data collection date for primary outcome measure)

Detailed Description:
At least 40 patients will be enrolled in this study, divided in two cohorts of 20 patients each. One cohort will include patients in partial remission after induction therapy and one cohort will include patients in complete remission but with incomplete blood count recovery. Patients in both cohorts will receive the same study treatment according to the same administration schedule.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- The patient has cytologically proven AML, as defined by the WHO classification. The pretreatment AML karyotype should be documented.
- The leukemia is a de novo or secondary AML.
- The patient's blasts cells show expression of WT1 transcript, detected by quantitative RT-PCR.
The patient received the following therapy according to the Institution's standard of care.

For patients <= 60 years old: at least two induction chemotherapy treatments.

For patients >= 60 years old: at least one induction chemotherapy treatment or alternative treatment.

The first ASCI administration should be given within 70 days (ten weeks) after the last chemotherapy administration.

In the investigator's opinion and in compliance with the Institutional Hematology Tumor Board's guidelines, the patient should not be eligible for any additional chemotherapy treatment before the ASCI treatment.

The clinical status of the patient at inclusion is one of the following (as defined by "Recommendations of the International Working Group for Diagnosis, Standardization of Response Criteria, Treatment Outcomes, and Reporting Standards for Therapeutic Trials in Acute Myeloid Leukemia" [Cheson, 2003]):

- Partial Remission (PR) i.e.
- A decrease of at least 50% in the percentage of blasts to 5% - 25% in the bone marrow aspirate following chemotherapy.
- In case the bone marrow contains <= 5% blasts, the presence of Auer rods also indicates a partial remission.

- Neutrophil count >= 1,000/µl
- Platelet count >= 1,00,000/µl
- The patient is independent of red blood cell transfusions
- Morphologic complete remission with incomplete blood count recovery (CRi) i.e. patients fulfill all criteria of the morphologic CR except for:
- Neutrophil count < 1,000/µl and/or
- Platelet count <= 1,00,000/µl. However, for the purpose of this clinical protocol platelet levels must be >= 50,000/µl.
- Written informed consent has been obtained prior to the performance of any protocol-specific procedure.
- The patient is >= 18 years of age at the time of signature of the first informed consent form.
- Eastern Cooperative Oncology Group performance status of 0, 1 or 2 at the time of enrolment.
- Adequate hepatic and renal function defined as:
  - Serum bilirubin < 1.5 times the Upper Limit of Normal (ULN).
  - Serum ALT < 2.5 times the ULN.
  - Calculated creatinine clearance > 50 ml/min.

In the view of the investigator, the patient can and will comply with the requirements of the protocol.

If the patient is female, she must be of non-childbearing potential, i.e. have a current tubal ligation, hysterectomy, ovariecetomy or be post-menopausal, or if she is of childbearing potential, she must practice adequate contraception for 30 days prior to treatment administration, have a negative pregnancy test and continue such precautions for 2 months after completion of the treatment administration series.

Exclusion Criteria:

- The patient was diagnosed with leukemic Central Nervous System (CNS) disease (e.g. before chemotherapy) or presents neurological symptoms at baseline suggestive of a CNS involvement.
- The patient has acute promyelocytic leukemia with t(15;17) (q22;q12), (PM/RARe) or variants.
- The patient has received, is receiving -or is due to receive- allogeneic SCT.
- The patient has received Fludarabine, Citofarabine or Clorotazine within 12 months preceding the ASCI treatment.
- The patient has hypercalcemia.
- The patient is known to be HIV positive.
- The patient has symptomatic autoimmune disease such as, but not limited to multiple sclerosis, lupus, and inflammatory bowel disease. Patients with vitiligo are not excluded.
- The patient has a history of allergic reactions likely to be exacerbated by any component of the study investigational product.
- The patient has other concurrent severe medical problems, unrelated to the malignancy, that would significantly limit full compliance with the study or expose the patient to unacceptable risk.
- The patient has another metastatic cancer disease.
- The patient has a history of congestive heart failure or previous myocardial infarction.
- The patient has psychiatric or addictive disorders that may compromise his/her ability to give informed consent, or to comply with the trial procedures.
- The patient has received any investigational or non-registered medicinal product other than the study treatment within 30 days preceding the first dose of study treatment or plans to receive such a drug during the study period.
- The patient requires concomitant chronic treatment (more than 7 consecutive days) with systemic corticosteroids or any immunosuppressive agents.
- Note: the use of prednisone, or equivalent, <0.5 mg/kg/day (absolute maximum 40 mg/day), or inhaled corticosteroids or topical steroids is permitted.
- The patient is receiving full dose subcutaneous heparins or is under anti-coagulation treatment (e.g. phenprocoumon).
- For female patients: the patient is pregnant or lactating.

### Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01051063

**Contacts**

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GlaxoSmithKline

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More Information
No publications provided

Responsible Party: GlaxoSmithKline

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Other Study ID Numbers: 111727

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Health Authority: France: Agence Française de Sécurité Sanitaire des Produits de Santé
Germany: Paul Ehrlich-Institut
United States: Food and Drug Administration

Keywords provided by GlaxoSmithKline:
adult partial remission
WT1 post-induction therapy
ASCI tumor antigen
complete remission with incomplete blood count recovery immunotherapy
leukemia

Additional relevant MeSH terms:
Leukemia
Leukemia, Myeloid, Acute
Leukemia, Myeloid
Neoplasms by Histologic Type
Neoplasms

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