Trial record **1 of 1** for: CV-8102-008

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Study of Intratumoral CV8102 in cMEL, cSCC, hnSCC, and ACC

This study is currently recruiting participants.

See Contacts and Locations

Verified September 2017 by *CureVac AG*

Sponsor:
CureVac AG

ClinicalTrials.gov Identifier:
NCT03291002

First Posted: September 22, 2017
Last Update Posted: September 29, 2017

Information provided by (Responsible Party):
CureVac AG

Full Text View | Tabular View | No Study Results Posted | Disclaimer
How to Read a Study Record

Purpose

This study evaluates intratumoral CV8102 in patients with advanced melanoma, squamous cell carcinoma of the skin, squamous cell carcinoma of the head and neck, or adenoid cystic carcinoma.

Patients will receive CV8102 as single agent or in combination with SoC anti-PD-1 therapy.

Condition	Intervention	Phase
Melanoma (Skin) Squamous Cell Carcinoma of the Skin Carcinoma, Squamous Cell of Head and Neck Carcinoma, Adenoid Cystic	Biological: CV8102 Biological: CV8102 + anti-PD-1 therapy	Phase 1

Study Type: Interventional

Study Design: Allocation: Non-Randomized
Intervention Model: Parallel Assignment
Intervention Model Description:
Open-label, cohort-based, dose escalation and expansion study
Masking: None (Open Label)
Primary Purpose: Treatment

Official Title: Phase I Study of Intratumoral CV8102 in Patients With Advanced Melanoma, Squamous Cell Carcinoma of the Skin, Squamous Cell Carcinoma of the Head and Neck, or Adenoid Cystic Carcinoma

Resource links provided by NLM:

Genetics Home Reference related topics: head and neck squamous cell carcinoma

MedlinePlus related topics: Adenoids Melanoma

Genetic and Rare Diseases Information Center resources: Adenoid Cystic Carcinoma Cylindroma Carcinoid Tumor Neuroepithelioma

U.S. FDA Resources

Further study details as provided by CureVac AG:

Primary Outcome Measures:

- Dose determination for dose escalation cohorts [Time Frame: 2 weeks]
  - Maximum tolerated dose (MTD) and recommended dose (RD), respectively, for CV8102 alone

- MTD and recommended combination dose (RCD) for CV8102 in combination with anti-PD-1 therapy

- Incidence of treatment related (Serious) Adverse Events (Tolerability and Safety profile) [Time Frame: up to 9 months (end of study)]
  - Tolerability and safety profile of CV8102 alone and in combination with anti-PD-1 therapy

Secondary Outcome Measures:

- Tumor response [Time Frame: up to 9 months (end of study)]
  - Anti-tumor activity of CV8102 per irRECIST and RECIST 1.1

- Disease status [Time Frame: 6 months]
  - Tumor Assessment

- Tumor response [Time Frame: up to 9 months (end of study)]
  - Extent of tumor response at injected and non-injected lesions, if applicable

- Survival [Time Frame: up to 9 months (end of study)]
  - Survival time

Estimated Enrollment:	104
Anticipated Study Start Date:	September 2017
Estimated Study Completion Date:	December 2019
Estimated Primary Completion Date:	July 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Cohort A Dose escalation of CV8102	Biological: CV8102 CV8102 alone
Experimental: Cohort B Optional expansion cohorts of CV8102	Biological: CV8102 CV8102 alone
Experimental: Cohort C	Biological: CV8102 + anti-PD-1 therapy

Dose escalation of CV8102 + anti-PD-1 therapy	CV8102 in combination with standard of care anti-PD-1 therapy
Experimental: Cohort D Optional expansion of CV8102 + anti-PD-1 therapy	Biological: CV8102 + anti-PD-1 therapy CV8102 in combination with standard of care anti-PD-1 therapy

Eligibility

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Key Inclusion Criteria:

1. Patients enrolled into Cohorts A and B (single agent CV8102) must have:
   - histologically confirmed advanced cutaneous melanoma, cutaneous squamous cell carcinoma, head and neck squamous cell carcinoma, or adenoid cystic carcinoma with documented disease progression
   - not amenable to resection or locoregional radiation therapy with curative intent
   - failed approved standard therapies or for whom no standard therapy is available
   - at least 1 line of anti-cancer therapy for advanced disease (except adenoid cystic carcinoma)
2. Patients enrolled into Cohorts C and D (CV8102 in combination with anti-PD-1 therapy) must have:
   - histologically confirmed advanced melanoma or head and neck squamous cell carcinoma currently receiving SOC anti-PD-1 therapy
   - stable or slowly progressing disease after at least 12 weeks of anti-PD-1 therapy

    - intention to continue anti-PD-1 therapy
3. Presence of at least one injectable lesion that is measurable acc. to RECIST 1.1
4. Recovered from prior toxicities to grade ≤ 1
5. ECOG PS 0 or 1
6. 18 years of age or older
7. Adequate hematologic, renal, hepatic and coagulation function
8. Use of effective contraception

Key Exclusion Criteria:

1. Rapidly progressing multi-focal metastatic or acutely life threatening disease
2. Prior use of topical/localTLR-7/8 agonists within the past 6 months
3. Clinically active central nervous system metastases and/or carcinomatous meningitis (patients with stable brain metastases are eligible)
4. Ocular and mucosal melanoma
5. Prior anti-cancer therapy within 2 weeks (Cohort A) or 4 weeks (Cohort B) prior to the first dose of study drug
6. Tumors to be injected lying close to major blood vessels or nerves, or whose injection could potentially result in clinical adverse effects if post-treatment tumor swelling or inflammation were to occur
7. Lesions that are to be injected in previously irradiated areas unless progressive tumor growth has been demonstrated (no prior irradiation of injected lesions on patients with melanoma)
8. History of active coagulation or bleeding disorder or full dose anticoagulation within one week prior to enrollment; patients with melanoma and cutaneous squamous cell carcinoma with controlled oral anticoagulation are eligible
9. Treatment with any investigational anticancer agent within 4 weeks prior to the first dose of study drug
10. Acute hypophysitis or endocrinopathies that are not adequately controlled by hormonal replacement therapy or thyreostatic treatment
11. Use of immune modulating drugs or immunologically active topical therapies within 28 days of administration of the first dose of study drug
12. Systemic treatment with corticosteroids or other immunosuppressive medication within 28 days of the first dose of study drug (except physiological maintenance/replacement steroid doses, topical steroids outside the injected lesion or inhaled steroids); patients are eligible if steroid requirement is < 10 mg/day of prednisone (or equivalent) for at least 2 weeks

13. History of active autoimmune disease requiring immunosuppressive medication (except vitiligo)
14. Known malignancies or other types that have occured or reoccurred within the previous 5 years
15. Recent thromboembolic complications, or clinically significant cardiovascular disease, or any other uncontrolled illness that would pose a risk to patient safety
16. Severe infection or acute inflammatory state

Contacts and Locations

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03291002***

Contacts

Contact: Benjamin Weide, Prof. Dr. +49 7071 298 4555 benjamin.weide@med.uni-tuebingen.

Locations

Germany

Investigative Site **Recruiting**
Berlin, Germany

Investigative Site **Not yet recruiting**
Buxtehude, Germany

Investigative Site **Not yet recruiting**
Erlangen, Germany

Investigative Site **Not yet recruiting**
Hannover, Germany

Investigative Site **Recruiting**
Heidelberg, Germany

Investigative Site **Recruiting**

Lübeck, Germany

Investigative Site **Recruiting**
Münster, Germany

Investigative Site **Recruiting**
Tübingen, Germany

Sponsors and Collaborators

CureVac AG

Investigators

Principal Investigator: Benjamin Weide, Prof. Dr. benjamin.weide@med.uni-tuebingen.de

More Information

Responsible Party:	CureVac AG
ClinicalTrials.gov Identifier:	NCT03291002 History of Changes
Other Study ID Numbers:	**CV-8102-008**
First Submitted:	September 15, 2017
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Last Update Posted:	September 29, 2017
Last Verified:	September 2017

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Additional relevant MeSH terms:

Carcinoma
Melanoma
Carcinoma, Squamous Cell
Skin Neoplasms
Head and Neck Neoplasms
Carcinoma, Adenoid Cystic
Neoplasms, Glandular and Epithelial
Neoplasms by Histologic Type
Neoplasms
Neuroendocrine Tumors
Neuroectodermal Tumors
Neoplasms, Germ Cell and Embryonal
Neoplasms, Nerve Tissue
Nevi and Melanomas
Neoplasms, Squamous Cell
Neoplasms by Site
Skin Diseases
Adenocarcinoma