4th CIMAvax EGF Global Meeting
November 22-23th, 2011

CIMAvax EGF in advanced stages NSCLC patients unfit for chemotherapy

Phase II/III Clinical Trial

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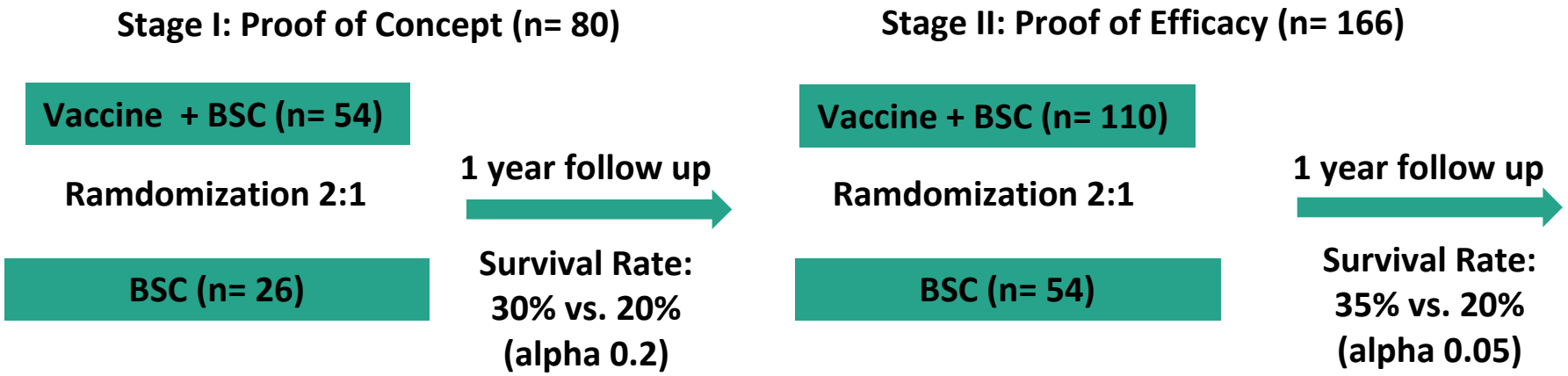
Design

Adaptive & Seamless Phase II/III Clinical Trial

- Open
- Controlled
- Multicentric



- Regulatory Status: Approved by Cuban Regulatory Office - CECMED

Hunsberger S., Zhao Y. A comparison of phase II study strategies. Clin Cancer Research; 15(19) October 1, 2009.
Royston P., Babiker A. "A menu driven facility for complex sample size calculation in randomized controlled trials with a survival or a binary outcome". The Stata Journal 2002 2(2):
Lakatos, E. Sample sizes based on the log-rank statistic in complex clinical trials. Biometrics 1988 44: 229–241.
Fine, et al. Drug Information Journal 41:535-539. 2007

Eligibility Criteria

Inclusion criteria

- Cytologically or histologically confirmed IIIb/IV NSCLC
- Aged >18 years
- Both genders
- Ineligible for onco-especific therapy without other therapeutic options
- Adequate bone marrow, liver and renal function
- Signed a voluntary written informed consent form
- ECOG ≤ 3

Eligibility Criteria

Exclusion criteria

- Previous receiver of another investigational drug such as CIMAvax EGF of Nimotuzumab
- Previous receiver of another onco-especific therapy
- Uncontrolled or unstable infectious or chronic disease
- Not agree to use double-barrier contraception (males and females alike)
- Pregnancy
- Personal history of severe or life-threatening hypersensitivity reaction
- Another active concurrent malignant disease except non- melanoma skin lesions or cervix cancer.
- Brain metastases (Only if detectable by radiological image scan previous sign or symptoms)
- ECOG > 3

CIMAvax EGF combined with adjuvant chemotherapy in the resectable setting of NSCLC patients (Ib- II- IIIA stages)

Phase II/III Clinical Trial

Design

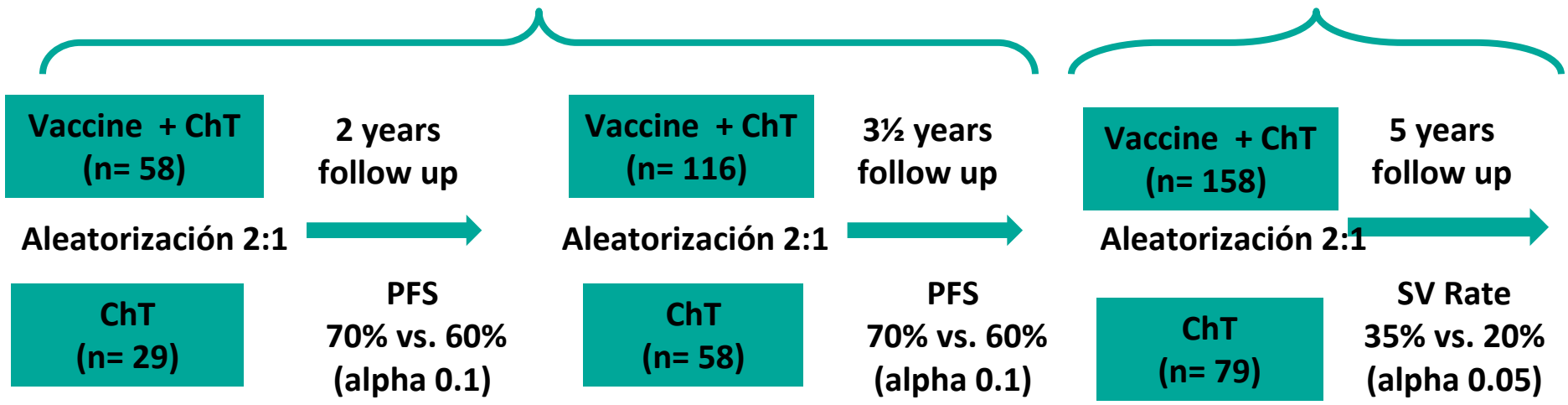
Adaptive & Seamless Phase II/III Clinical Trial

- Open
- Controlled
- Multicentric

Randomization balanced:
- Tumor localization
- Surgery borders clean

Stage I: Proof of Concept (n= 171)

Stage II: Proof of Efficacy(n= 237)



- Regulatory Status: Investigators & Ethics Committee Review

Hunsberger S., Zhao Y. A comparison of phase II study strategies. Clin Cancer Research; 15(19) October 1, 2009.
Royston P., Babiker A. "A menu driven facility for complex sample size calculation in randomized controlled trials with a survival or a binary outcome". The Stata Journal 2002 2(2):
Lakatos, E. Sample sizes based on the log-rank statistic in complex clinical trials. Biometrics 1988 44: 229–241.
Fine, et al. Drug Information Journal 41:535-539. 2007

Eligibility Criteria

Inclusion criteria

- Cytologically or histologically confirmed Ib/II/IIIa NSCLC
- Aged >18 years
- Both genders
- Post- surgery time $\leq$ 4 weeks
- Eligible for first line onco-especific therapy
- Adequate bone marrow, liver and renal function
- Signed a voluntary written informed consent form
- ECOG 0-2

Eligibility Criteria

Exclusion criteria

- Post- surgery time > 4 weekss
- Inelegible for first line onco-especific therapy
- Uncontrolled or unstable infectious or chronic disease
- Not agree to use double-barrier contraception (males and females alike)
- Pregnancy
- Personal history of severe or life-threatening hypersensitivity reaction
- Another active concurrent malignant disease except non- melanoma skin lesions or cervix cancer.
- ECOG > 2

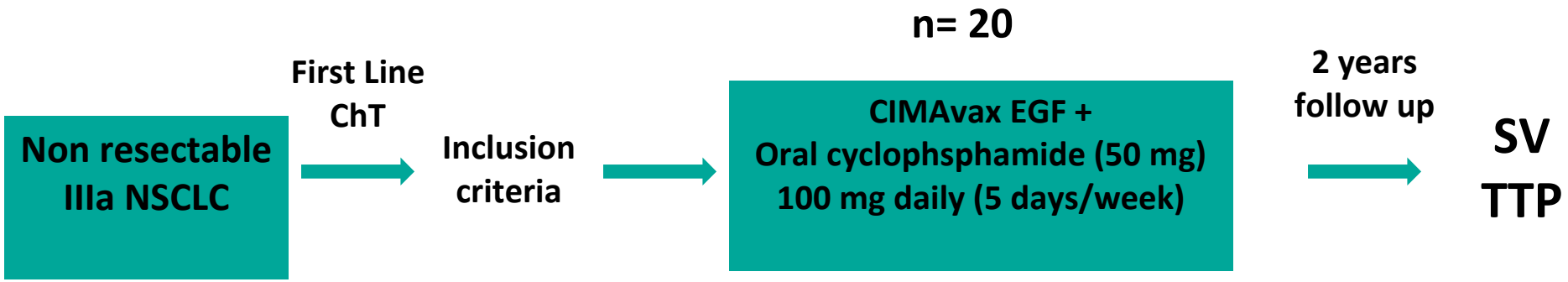
CIMAvax EGF combined with metronomic cyclophosfamide in non-resectable IIIA stages NSCLC patients

Exploratory Physician Lead Clinical Trial

Design

Exploratory Physician Lead Clinical Trial

- Open
- Non Controlled



- Regulatory Status: Approved by Ethics Committee Review & Active Recruiting

Eligibility Criteria

Inclusion criteria

- Cytologically or histologically confirmed NSCLC
- Not eligible for tumor surgery IIIa stage
- Aged >18 years
- Both genders
- Adequate bone marrow, liver and renal function
- Signed a voluntary written informed consent form
- ECOG 0-2

Eligibility Criteria

Exclusion criteria

- Acquired surgery criteria during or after first line chemotherapy
- Eligible for tumor surgery
- Disease progression or brain metastasis during first line onco-especific therapy
- Uncontrolled or unstable infectious or chronic disease
- Not agree to use double-barrier contraception (males and females alike)
- Pregnancy
- Personal history of severe or life-threatening hypersensitivity reaction
- Another active concurrent malignant disease except non- melanoma skin lesions or cervix cancer.
- ECOG > 2

¡Muchas gracias!