

NEW CLINICAL TRIAL OPEN FOR INCLUSION

PROTOCOL TITLE

A multicenter, first-in-human, dose escalation and optimization Phase I/IIa study to investigate safety, tolerability, pharmacokinetics, and efficacy of the NaPi2b antibody-drug conjugate TUB-040 in patients with platinum-resistant high-grade ovarian cancer (PROC) or relapsed/refractory adenocarcinoma non-small cell lung cancer (NSCLC)

ALIAS	CTO NUMBER	SPONSOR
Napistar 1-01	CTO26015TUB	Tubulis GmbH

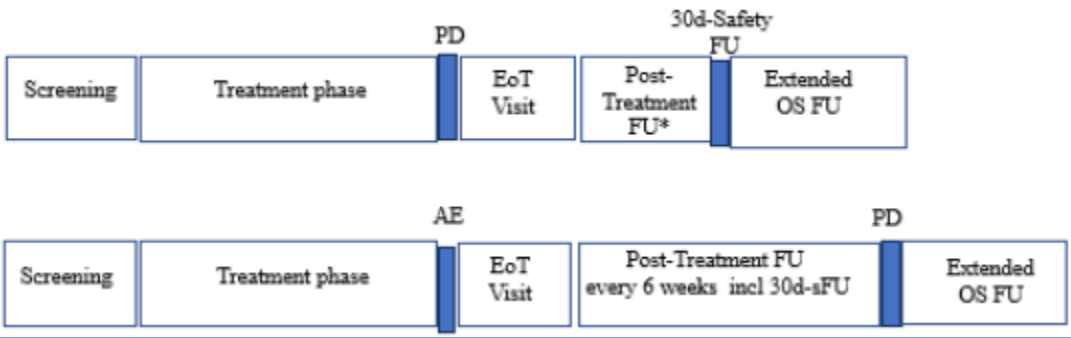
KEY INCLUSION AND EXCLUSION CRITERIA (PHASE IIB DOSE EXPANSION : PROC)

Patients w/ platinum-resistant ovarian carcinoma (measurable disease (RECIST)) that received 2-5 lines of prior systemic therapy and for whom single-agent therapy is appropriate as the next line of treatment, incl.:

a. ≥1 prior line of platinum therapy
b. Prior treatment with a bevacizumab containing regimen is required
c. Prior treatment with PARPi is required if indicated and locally available
d. Has had prior treatment with MIRV if indicated, medically appropriate, and locally available.
e. A weekly taxane-containing regimen either as a single-agent or in combination with BEV and/or pembrolizumab/relacorilant, if indicated, approved and locally available
f. Documented radiographic evidence of PD after the most recent line of therapy
g. Received a maximum of 3 prior lines of therapy in the platinum-resistant setting

DESIGN

Phase IIb: dose expansion PROC



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