

Clinical Trial Results:

Protocol Title: A phase II study of Vinorelbine, cisplatin, disulfiram and copper in CTC_EMT positive refractory metastatic breast cancer.

Sponsor Protocol Code: BREAST-SK-001

ClinicalTrials.gov Identifier: NCT04265274

EudraCT number: 2019-001957-16

Sponsor: Národný onkologický ústav, Klenová 1, 833 10 Bratislava, Slovakia

IMP: Disulfiramum 400 mg *effervescent tablet*
Vinorelbin 25 mg/m² concentrate for infusion
Cisplatin EBEWE 75 mg/m² concentrate for solution for infusion

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Start Date of Recruitment: 17 August 2020

Global End of Trial: 13 December 2021

Reason for termination of the trial: .
Early termination due to insufficient recruitment.

List of the investigators and sites:

Site #	Principal Investigator	Address	Status of the site
01	Prof. MUDr. Michal Mego, DrSc.	Národný onkologický ústav, Klenová 1, 833 10 Bratislava, Slovakia	closed 13.12.2021

Number of trial subjects:

Worldwide: 6

Country: 6

6 subjects were screened in Slovakia, all 6 subjects did not meet Inclusion/Exclusion criteria and were Screen failures.

Site #	Site Initiated	1 st Subject Screened	Total Screened	Screen failure	Total Enrolled
01	04-Dec-2020	17-Aug-2020	6	6	0

Adverse events/ Serious Adverse Events :

None Adverse or Serious Adverse Events have been reported in this clinical trial in Slovak republic. None SUSARs have been reported.

Other information:

New clinical trial Protocol, version 2.0 from 30.08.2019 was approved.

Summary of changes:

- *Study Title and Table of Content were modified*
- *List of abbreviation was added*
- *Section 8: Screening period was specified*
- *Schedule of activities was amended*
- *Secton 12.1 Statstical design was amended*
- *Minor administrative updates and typographical errors were corrected throughout.*

Ing. Tomáš Alscher, MPH
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prof. Juraj Pechan, MD., CSc.
Medical Director NOÚ

Prof. Michal Mego, MD., DrSc.
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