

## 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/m<sup>2</sup> concentrate for infusion  
Cisplatin EBEWE 75 mg/m<sup>2</sup> 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:**

<i>Site #</i>	<i>Principal Investigator</i>	<i>Address</i>	<i>Status of the site</i>
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 <sup>st</sup> 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.*

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