

## CHOSA Oncology AB publishes results from clinical phase 2 trial of liposomal formulation in breast cancer, using predictive marker for cisplatin

### Abstract 3130: First predictive biomarker for cisplatin in prospective phase 2 of liposomal cisplatin in metastatic breast cancer

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#### Background/Methods

- Heavily pretreated late-stage breast cancer patients of any subtype represent a huge treatment challenge.
- Cisplatin may work in selected patients but is often disqualified because of toxicity.
- LiPlaCis is a liposomal formulation of cisplatin in development utilizing a lipase-triggered targeted release of cisplatin.
- The statistically significant Drug Response Prediction (DRP) of cisplatin efficacy with a 205 mRNA profile has previously been demonstrated in two NSCLC cancer patient cohorts receiving adjuvant cisplatin<sup>1</sup>.
- The DRP % is the 205 gene profile converted to a 0-100% sensitivity score.

#### Methods

The dose-escalation part of a phase 1/2 study, of 20 patients with a variety of locally advanced or metastatic solid tumors, suggested a phase 2 dose of LiPlaCis to be 75mg on day 1 and 8 q 3 wks. In this phase 2 part, the cisplatin DRP was used to select metastatic breast cancer (mBC) patients with response likelihood scores from FFPE diagnostic or later biopsies. Patients were treated until progression or unacceptable toxicity. Halfway through phase 2 part, the dosing was changed to a per-body surface schedule (40 mg/m<sup>2</sup>) after a fatal event with the flat dosing (in effect 51 mg/m<sup>2</sup> for this patient). Among the 52 patients included in the phase 2 part, we here, report data from the 37 patients with mBC, being platinum naïve, with the highest DRP scores of 34-100%, and with RECIST-defined response outcomes. Within this subgroup, we conducted a post hoc analysis of possible DRP cut-off values that could identify patients with a clinically meaningful response to treatment.

#### Main findings:

- ✓ The first clinical study to prospectively validate a method to identify responders to cisplatin.
- ✓ Cisplatin prediction could be useful in neoadjuvant decisions.
- ✓ LiPlaCis shows efficacy in heavily pretreated mBC patients when using the prediction method as a companion diagnostic.

We thank participating patients, Danish Regions' Breast Cancer Sites, and Danish Breast Cancer Cooperative Groups (DBCG). Contact: Peter Buhl Jensen, pbj@buhloncology.com



#### Results

mBC patients had received a median of 7 previous treatment lines. A DRP score >80% (DRP80+) identified the responders and non-responders to liposomal cisplatin. All 4 partial remissions in the study were in the DRP80+ group, and other key efficacy endpoints were also in favor of the DRP80+ versus the lower scores (DRP80-).

		Total	DRP80-	DRP80+	p-value <sup>†</sup>
N		37	21	16	
Tumor response	ORR	4 (10.8%)	0 (0%)	4 (25.0%)	0.0276
	CR	8 (21.6%)	2 (9.5%)	6 (37.5%)	0.0554
PFS [in weeks]	median [95%CI]	15 [7,24]	8 [6,23]	19 [13,30]	0.155
OS [in weeks]	median [95%CI]	50 [33,60]	44 [21,60]	56 [17,62]	0.554

<sup>†</sup>DRP80+ vs DRP80-

#### Tolerability

Only 1 SAE (pyelonephritis) was reported and considered related to treatment. One patient died whilst on treatment, but due to disease progression. From a total of 164 treatment cycles, 18 of the patients reported 1 grade 4 and 41 grade 3 AEs considered possibly related to treatment.

#### Future Directions for Research

- Selection for treatment with LiPlaCis in neoadjuvant mBC

**CEO Peter Buhl comments:** "CHOSA presents these important findings that have crystallized by deep clinical knowledge and years of dedication to developing LiPlaCis and its response prediction test DRP".

We welcome interaction and look forward to discussing this at the ASCO poster session that opens today:

**Abstract number and title:** 3130; *Predictive biomarker for cisplatin in prospective phase 2 of liposomal cisplatin in metastatic breast cancer*

**Session:** Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology

**Poster Board:** 328

**Date and time:** Saturday 3 June 2023; 8:00-11:00 CDT

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**CHOSA in short**

CHOSA Oncology AB is an oncology biotechnology company led by a proven international team with veteran specialists in oncology; drug development; running clinical trials; regulatory expertise; and business development. CHOSA intends to enter into agreements for partnership or sublicensing of iCIP™.

**About iCIP™ - LiPlaCis® and DRP®**

CHOSA is focused on late-stage clinical development of iCIP™ (LiPlaCis® and its DRP® companion diagnostic together) to which it has worldwide rights. The cisplatin DRP is the only proven test to foresee and thereby select who to treat and who will benefit from cisplatin. In essence, iCIP™ combines the identification of patients that will benefit from cisplatin treatment with the ability to treat them with higher efficacy and less toxicity.

**Breast:** We have strong phase 2b data in metastatic breast cancer, demonstrating that patients selected by DRP® responded better to treatment; have longer progression-free survival; and maybe even an overall longer total survival than those patients who were identified as unlikely to respond well to the treatment.

**Lung:** The cisplatin DRP has previously shown its ability to foresee the value of cisplatin therapy in lung cancer. Cisplatin therapy after surgery is a gold standard that clearly increases lung cancer cure, but not always, and until now the doctors do not know who will benefit from cisplatin and who should have something else. This is where the cisplatin DRP is a potential game changer especially in new neoadjuvant treatment where immunotherapy obtains high efficacy rates when combined with cisplatin-doublets.

Cisplatin DRP was validated in a blinded retrospective study in two lung cancer patient cohorts receiving cisplatin after surgery to kill remaining tumor cells. Thus, patients with the 10% highest scores had a 3-year survival of 90% whereas the patients with the lowest 10% score had much lower survival with only 40% surviving 3 years<sup>1</sup>.

<sup>1</sup>) Buhl et al PLOS One doi: 10.1371/journal.pone0194609

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