CHOSA Oncology AB presents clinical phase 2 results of LiPlaCis and its Drug Response Predictor test at ASCO 2023

CHOSA Oncology AB today publishes results from the prospective phase 2 study of LiPlaCis® (a liposomal formulation of cisplatin) in previously heavily treated patients with metastatic breast cancer as the abstract is being released on the ASCO website on May 25, 2023, at 5:00 PM (ET) / 23:00 CET (please see a link to ASCO's website below). This patient group was tested using the diagnostic tool Drug Response Prediction (DRP®), which is a 205 mRNA biomarker signature, that assesses whether the patient is likely to respond to cisplatin treatment - or not. The results show that patients who get high scores in the DRP reading (DRP 80 +) are the only ones that respond and show 2.5x longer median PFS (Progression Free Survival).

CEO Peter Buhl comments: "I am very proud and happy to present these excellent results, which demonstrate our ability to identify and select patients who will benefit from treatment with our cancer drug, LiPlaCis®. LiPlaCis is a new formulation of cisplatin, and our tumor gene test, used to predict the individuals who will respond positively to the platinum-based drug, has shown clear efficacy in heavily treated breast cancer patients. This further supports previous data indicating that the test is also highly effective in identifying lung cancer patients who will benefit from cisplatin."

This metastatic breast cancer group, which has received several other treatments in the past, presents a major challenge as they may have developed 'treatment resistance'. Many times, physicians would like to choose cisplatin treatment, but opt out of this as it has a strong side effect profile. Results from this prospective and predictive study show that DRP can facilitate the decision-making process for the doctor when cisplatin treatment may be relevant. With the help of DRP, the doctor has a better basis for decision-making, it is cheaper for healthcare to provide the right treatment at the right time, and above all a benefit for the patient.

Data from the current study is pointing towards a new treatment opportunity for 20% of heavily pretreated breast cancer patients with metastatic disease. In the study the patients had received a median of 6,6 therapies for their disease before they received LiPlaCis, and they were otherwise out of treatment options. We believe that a progression free survival advantage increase of 250 % in the sensitive 20% provides a potential break-through designation and a route for LiPlaCis approval.

The current data also point to other opportunities. We believe that similarly it is very likely that there is a large or small fraction of patients with early lung and breast cancer who may benefit from precision use of cisplatin.

Here below are the results in summary – more details can be found at the ASCO website (please follow link below) and **will be presented at a poster session at the ASCO conference on June 3rd, 2023.**

		Total	DRP80-	DRP80+	p-value[2]
N		37	21	16	
Tumor response	ORR	4 (10.8%)	0 (0%)	4 (25.0%)	0.0276
	CBR	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

37 metastatic breast cancer patients had received a median of 7 previous treatment lines before treating with LiPlaCis. A DRP score ≥80% (DRP80+) discriminated well between 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 in favor of the DRP80+ vs the lower scores (DRP80-).

DRP® is proprietary to and a registered trademark of Allarity Therapeutics (Nasdaq:ALLR). These data are from a clinical study previously run by Allarity (formerly Oncology Venture). CHOSA Oncology AB has licensed

worldwide rights to LiPlaCis® and its DRP® companion diagnostic (together referred to as iCIP™) from Allarity Therapeutics Inc.

Link to ASCO website for electronic abstracts: http://meetings.asco.org/abstracts-presentations/226582

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
Presenter: Peter Buhl Jensen

This disclosure contains information that Chosa Oncology AB is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 25-05-2023 23:01 CET.

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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[1].

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