Chosa Oncology

Making headway in precision oncology

Chosa Oncology is a Scandinavian biotech looking to progress the clinical development of its cisplatin-based technology, iCIP, which consists of two core technologies: an AI-powered drug response predictor (DRP) that aims to identify the patients most likely to respond to cisplatin treatment and LiPlaCis, a liposomal cisplatin formulation with potential to improve both the safety and efficacy of conventional cisplatin. iCIP has demonstrated encouraging clinical proof-of-concept data from a Phase IIb study in metastatic breast cancer (mBC) patients, where patients with higher DRP scores were found to respond more effectively to LiPlaCis compared to those with lower DRP scores. In our view, iCIP is likely to interest pharmaceutical companies investigating novel cisplatin combination treatments. Chosa is looking to identify and secure strategic partnerships or buyers to advance iCIP into follow-on clinical studies.

iCIP: A two-in-one solution to today's cisplatin

Cisplatin is one of the most widely prescribed drugs in oncology, with c 10–20% of newly diagnosed cancer patients expected to receive cisplatin treatment. The drug continues to be the subject of many novel exploratory treatment regimens and is active in 1,372 ongoing clinical studies. However, the major drawbacks of cisplatin remain its extremely toxic, off-target side effect profile, as well as treatment resistance in certain patient populations. iCIP aims to provide a tool that can identify the patients most likely to respond to cisplatin therapy (DRP) including a potentially safer and more efficacious liposomal version of the treatment, LiPlaCis.

A potentially expedited development pathway

Chosa reported results from a Phase IIb study at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2023, which included mBC patients (n=37) screened using the DRP tool and subsequently treated with LiPlaCis. Only patients with a DRP score of more than 80 (n=16) responded to treatment with a reported median progression-free survival (mPFS) of 4.4 months and median overall survival (mOS) of 13 months, compared to 1.8 months and 10.4 months, respectively, with a DRP score of less than 80. Chosa believes there is an opportunity for iCIP to receive FDA breakthrough therapy designation (BTD) following completion of a follow-on study with fewer than 40 patients. BTD would allow greater guidance from the FDA in the design of future clinical development programmes including potential to apply for accelerated approval. Additionally, the company has stated the DRP tool may act as a predictor of carboplatin treatment response, a prodrug to cisplatin, expanding the potential clinical opportunity for the device.

Cash runway guided through Q224

At end March 2023, Chosa Oncology reported a gross cash position of SEK17.5m. Management has guided that with the expected receipt of a SEK7.7m tax credit in Q423, the company should have sufficient cash on hand to fund operations through Q224.

Pharma and biotech

2 June 2023

Price	**SEK1.59**
Market cap	**SEK100m**

Share price graph

Share details

Code	CHOSA
Listing	Spotlight Stockholm
Shares in issue	62.8m
Gross cash at end March 2023	SEK17.5m

Business description

Chosa Oncology (previously RhoVac) is a Danish biotech focused on the development of iCIP, a technology consisting of a cisplatin drug response predictor and a liposomal formulation of conventional cisplatin. iCIP has demonstrated encouraging clinical proof of concept from a Phase IIb study in breast cancer patients and Chosa is now looking for strategic partnerships to progress clinical development of the technology.

Bull

- A potential first-in-class genetic screening tool to predict cisplatin treatment response.
- Exclusive global rights to both the DRP and LiPlaCis technologies.
- DRP may serve as a valuable screening tool for selecting suitable clinical trial participants.

Bear

- Generic cisplatin reduces barriers to entry for potential competitor technologies.
- Significant clinical benefit will need to be demonstrated to support premium pricing of LiPlaCis.
- Clinical data, to date, has been generated on small patient numbers.

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iCIP: A wholly owned Chosa technology

Chosa Oncology AB (CHOSA) was formed in January 2023 following the reverse merger acquisition of the Danish biotech Chosa ApS by RhoVac AB, a cancer vaccine-focused biotech. In March 2022, Chosa ApS secured the exclusive rights to iCIP (including both the DRP and LiPlaCis) through a three-party licensing agreement with the owners of the technology, Allarity Therapeutics and LiPlasome Pharma, and a buyout agreement with the previous licensee of iCIP, Smerud.

As part of the three-party agreement, Allarity and LiPlasome are entitled to receive regulatory milestone payments associated with the approvals of iCIP in the United States or EU as well as commercial milestone payments if iCIP reaches net sales of $50m in each region. The value of the milestone payments are currently undisclosed.

The buyout deal with Smerud includes a clause stipulating that Chosa will use Smerud as a service provider to conduct the follow-on iCIP clinical study in services worth up to $2.5m. The agreement also requires Chosa to pay milestone payments of up to $1m to Smerud related to the follow-on trial. None of the agreements in place with Allarity, LiPlasome or Smerud include back-end royalties on net sales of iCIP, with Chosa entitled to receive the full amounts of any future revenues generated.

Importantly the deals mean that Chosa has the exclusive worldwide rights to develop, manufacture and commercialise iCIP for any indication. It also grants Chosa all associated know-how, trademarks and patents associated with iCIP. The major patents granted (including US) protect the combined product, iCIP, and standalone DRP tool until 2038, while standalone LiPlaCis has patent protection until 2030. However, the company believes this could be extended by five years depending on development timelines.

Improving the cornerstone of cancer treatment

Despite major advancements in the development of new treatments in oncology, cisplatin continues to be one of the most commonly employed therapies for the treatment of a range of solid tumours including non-small cell lung cancer, breast, ovarian, bladder and head and neck cancer. Despite being almost 50 years old cisplatin remains one of the more widely used oncology therapies and it is likely to continue to be a mainstay in cancer treatment, particularly with evidence of its ability to improve efficacies of certain novel immunotherapeutic agents. However, as a rudimentary chemotherapy agent, cisplatin is associated with significant off-target treatment-related side effects. These include vomiting, neurotoxicity, gastrointestinal toxicity, kidney toxicity and ototoxicity (drug-related hearing or balance problems) resulting in poorer patient adherence to treatment. In our view, this highly unfavourable safety profile is one of the major limitations of conventional cisplatin therapy. Additionally, cisplatin response rates tend to range significantly depending on the cancer. In breast cancer (BC), an indication of interest for Chosa, the historical mOS reported in mBC patients treated with cisplatin combined with chemotherapy ranges from 4.3 to 10.8 months depending on whether patients have triple-negative (10.8 months) or non-triple-negative breast cancer (non-TNBC, 4.3 months). In our view, sub-optimal responses to treatment in some cancer forms, such as in non-TNBC, may provide scope for Chosa to differentiate with LiPlaCis.

Furthermore, certain patient populations may be inherently resistant to platinum-based chemotherapy. This is particularly true for some indications like certain forms of breast cancer, where cisplatin response rates can range between 10% and 20%, as well as non-small cell lung cancer, with c 21% response rates for cisplatin monotherapy and 20–40% with particular cisplatin combination treatments. However, platinum chemotherapy resistance is often not apparent until

after a patient has begun treatment. The ability to avoid exposing patients to potentially unnecessary and highly toxic cisplatin would be beneficial for patients.

Altogether, the company has started to demonstrate the potential improvements in treatment response that can be realised through application of the iCIP technology in BC patients, as discussed in the Phase II data described later in the note.

iCIP equipping cisplatin to improve patient outcomes

Chosa Oncology is aiming to develop a product that aims to overcome the existing issues associated with cisplatin called iCIP, which is comprised of two core technologies:

- **Drug response predictor (DRP):** a test that uses an AI-powered predictive algorithm to identify patients most likely to respond to cisplatin treatment based on their genetic profile. The DRP analyses 205 genes (more than 900 are linked with platinum resistance) that Chosa believes are the most important in predicting cisplatin utility, irrespective of tumour type. Importantly, Chosa has a patent granted (including in the United States) that provides protection over the 205 cisplatin response predictor genes. The DRP has received CE marking in Europe, allowing commercialisation in 32 European countries and an investigational device exemption (IDE) by the FDA allowing its use in clinical studies.
- **LiPlaCis:** a liposomal formulation of cisplatin designed to be specifically degraded by enzymes over expressed in tumours. This is expected to allow for the preferential release of cisplatin at the tumour site, which is thought to decrease off-target toxicity and improve efficacy.

Existing methods of determining patient eligibility for cisplatin treatment are primarily based on various physiological parameters such as comorbidities, renal function or pre-existing hearing impairment. However, these eligibility criteria are mainly related to safety rather than potential response to treatment. To our knowledge, there are currently no genetic screening tools designed to predict the efficacy of cisplatin prior to treatment initiation.

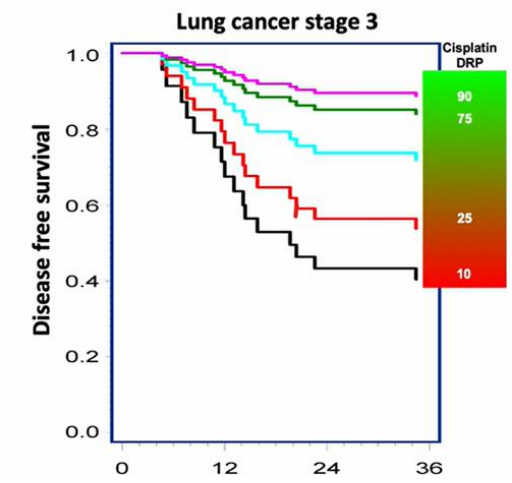
Building proof-of-concept evidence for iCIP

The iCIP platform has now been utilised in several studies and has started to generate encouraging initial data for both the DRP and LiPlaCis technologies. In our view, the most compelling clinical evidence to date are the positive results that Chosa presented at ASCO in June 2023 from a Phase IIb study where heavily pre-treated BC patients were assessed using the DRP tool before being treated with LiPlaCis. Those patients with a higher DRP score were found to respond better to LiPlaCis therapy compared to those with lower scores. We note that these are the first major results reported publicly from the study.

A compelling correlation with DRP score

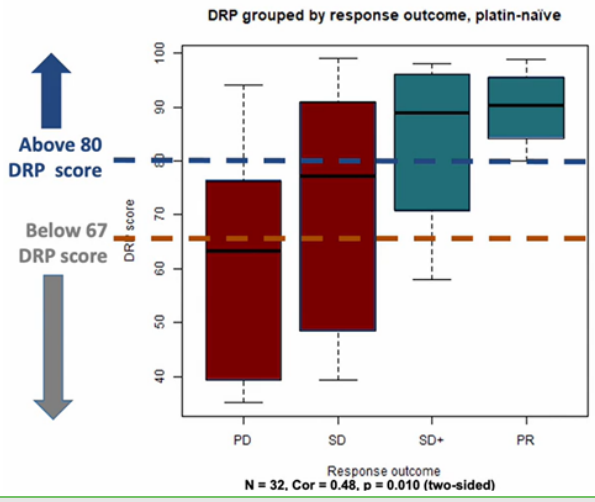
Chosa has reported data from two studies where the DRP technology has been employed: a retrospective lung cancer study as well as data from the Phase IIb trial noted above from patients enrolled with mBC. The lung cancer study assessed historical tumour samples from patients with stage 3B non-small cell lung cancer (NSCLC) who had undergone surgery and were subsequently treated with cisplatin adjuvant therapy. There was found to be a direct correlation between tumour DRP scores and disease-free survival (DFS) rates, with higher scores corresponding to patients experiencing extended DFS following cisplatin treatment, Exhibit 1.

Exhibit 1: DRP scores from retrospective lung cancer study



Source: Chosa Oncology

Exhibit 2: DRP scores from Phase II breast cancer study



Source: Chosa Oncology

In our view, the most supportive clinical evidence to date demonstrating the potential clinical utility of the DRP tool are the results reported at ASCO 2023 from the blinded Phase IIb study in mBC patients. Of the 37 patients assessed with the DRP tool, 16 had a DRP score greater than 80 and 21 had a DRP score less than 80, with each group subsequently treated with LiPlaCis. The overall response rate (ORR) in the DRP score >80 group was 25% compared to 0% in the DRP <80 cohort, a statistically significant result. Notably, mPFS was 4.4 months in DRP >80 patients compared to a mPFS of 1.8 months for DRP <80, a 2.5-fold improvement. This translated into mOS of 13 months versus 10.4 months in DRP >80 and DRP <80 patients respectively. We note that the historical mOS reported in mBC patients treated with cisplatin combined with chemotherapy ranges from 4.3–10.8 months depending on whether patients have triple-negative or non-TNBC.

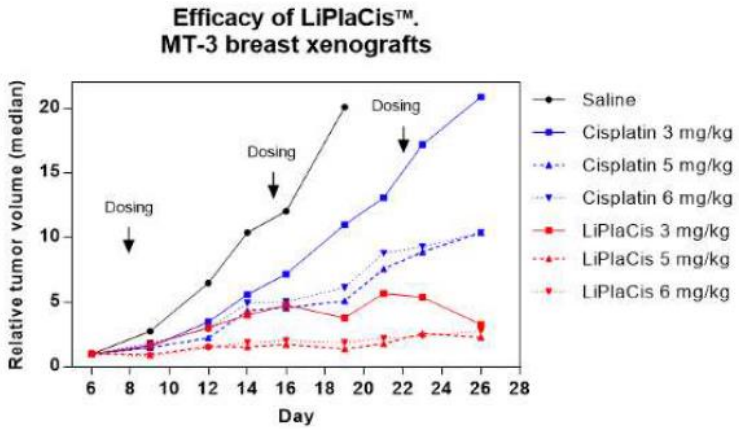
However, we acknowledge that the data generated, to date, represent only a small number of patients and that the study was not statistically powered. Nonetheless we see these initial correlations between DRP scores and survival rates as an encouraging initial clinical proof of concept. Additionally, Chosa has communicated that it believes iCIP may be able to receive BTD from a follow-on trial with fewer than 40 patients. However, we note the company has communicated that in the absence of partnerships it does not intend to initiate additional clinical studies independently until Q224, at the earliest.

In our view, these results also highlight the DRP's potential as a clinical trial companion diagnostic with the ability to delineate those patients most likely to benefit from LiPlaCis treatment and serve as a tool to recruit suitable patient populations into clinical studies. To our knowledge, the DRP tool is one of the only devices under development to assess the expression of multiple genes linked with cisplatin resistance. The most common single mutation individuals are often screened for to assess eligibility for platinum-based chemotherapy is the BRCA mutation. However, in cancers such as TNBC, BRCA mutations are only present in c 9–15% of the patient population, and methods of more expansive genetic profile screening to determine platinum therapy resistance could be of significant value, in our view. The BC market represents a potentially sizable opportunity with global estimated sales of BC drugs estimated to reach $42bn by 2028 (EvaluatePharma). Notably, sales of the immune checkpoint inhibitor (ICI) pembrolizumab (Keytruda) in BC are expected to be $3.6bn by 2028. Chosa views the iCIP technology as a potential companion technology that could complement ICIs, opening up strategic opportunities within ICI combination treatment regimens (see further details in the ICI section below).

LiPlaCis showing signs of trumping cisplatin

The second component of the iCIP technology is Chosa's liposomal cisplatin formulation, LiPlaCis, which the company believes may provide both safety and efficacy benefits over conventional cisplatin. There are currently no approved liposomal formulations of cisplatin, meaning LiPlaCis has potential to be a first-in-class product, should it receive approval. While there was no control arm allowing for a direct clinical comparison between cisplatin and LiPlaCis in the Phase IIb study, Chosa has reported preclinical mouse model data where LiPlaCis was found to have a greater impact in reducing tumour volumes, Exhibit 3.

Exhibit 3: Preclinical mouse model data of LiPlaCis versus cisplatin



Source: Chosa Oncology

In our view, improvements in safety is where LiPlaCis could potentially offer significant market differentiation over cisplatin. To date, up to 100 patients have been treated with LiPlaCis across clinical studies conducted by Chosa with no reported cases of severe and debilitating side effects commonly associated with cisplatin including neurotoxicity, kidney toxicity, hearing loss and bone marrow toxicity. Bone marrow suppression represents one of the most significant and common dose-limiting side effects associated with conventional chemotherapy, including cisplatin; it reduces the production of blood cells leading to conditions such as anaemia. The absence of bone marrow toxicity associated with LiPlaCis means that the treatment may have potential to be used in combination with existing chemotherapeutic regimens.

Notably, a recent positive clinical result highlighting the potential benefits of liposomal formulations of conventional chemotherapeutic agents came from Ipsen's Phase III NAPOLI-3 study investigating Onivyde (liposomal irinotecan) for the treatment of first-line metastatic pancreatic cancer. The trial found that patients treated with NALIRIFOX (liposomal irinotecan, plus 5-fluorouracil, leucovorin and oxaliplatin) had an mOS of 11.1 months compared to standard of care nab-paclitaxel and gemcitabine with an mOS of 9.2 months. Ipsen had previously acquired Onivyde from Merrimack Pharmaceuticals in April 2017 in a deal worth up to $1bn. In our opinion, additional LiPlaCis studies will need to compare the treatment against a conventional cisplatin control arm to be able to draw effective conclusions on the drug's potentially enhanced safety and efficacy.

Potential to extract further value in the neoadjuvant setting

Some of the major limitations of cisplatin that have excluded its use as an earlier-line therapy, such as in the neoadjuvant setting for breast and lung cancer, are its poor bioavailability and significantly toxic side-effect profile. In our view, if LiPlaCis can continue to demonstrate a beneficial safety profile in clinical studies, Chosa may be able to position the drug as a neoadjuvant treatment. Management has communicated it expects to price LiPlaCis at c $40k per treatment course in BC, a significant premium over generic cisplatin treatments, which cost c $800–1,100 per treatment cycle; however, we believe LiPlaCis could justify higher pricing as a neoadjuvant therapy provided it can demonstrate a significant cost patient-benefit ratio in future studies to secure payor coverage.

With the conclusion of the Phase IIb trial Chosa is now looking to identify potential strategic partnerships with pharmaceutical companies to finance and progress clinical development of iCIP. Over the next 12 months Chosa intends to engage in close discussions with regulators (the FDA and European Medicines Agency) to determine the most appropriate next clinical steps for iCIP and its potential route to market, as well as to prepare the scale-up manufacturing of LiPlaCis. The company believes that it may be possible for iCIP to receive FDA BTD after completion of a follow-on study with fewer than 40 patients, which would allow for greater interaction with the FDA including the potential to apply in the future for accelerated approval. Chosa has communicated that it does not intend to independently initiate a follow-on study in FY23 in the absence of a partner or acquirer for the iCIP technology.

Providing checkpoint companies with a competitive edge

Since the FDA's approval of the first ICI in 2014, ipilimumab (Yervoy), the ICI market has continued to grow exponentially, and the discovery of ICIs has had one of the most significant impacts on the oncology treatment landscape in recent decades. To date, the FDA has approved eight standalone ICIs: Keytruda (Merck), Opdivo (BMS), Libtayo (Regeneron/Sanofi), Tecentriq (Roche), Bavencio (EMD Serono, Merck), Imfinzi (AstraZeneca), Yervoy (BMS) and Jemperli (GSK); as well as an ICI combination therapy, Opdualag (nivolumab/relatlimab, BMS). In 2022 combined global sales for ICI therapies reached c $39bn and are expected to reach $64bn by 2028 (according to EvaluatePharma).

While ICIs have made a major impact, they still suffer from relatively low response rates and in 2018 it was estimated only 12% of eligible patients would respond to ICI monotherapy. However, we acknowledge that this number may have increased since then. In our view, combination therapies will be key for developing new ICI treatment protocols to demonstrate clinically meaningful improvements in patient outcomes and disrupt existing standards of care. There is a growing body of clinical evidence to suggest cisplatin can work synergistically with ICIs to provide efficacy enhancements. This has been exemplified by Keytruda's (pembrolizumab) approvals in combination with platinum chemotherapy, which includes cisplatin, as first-line treatments for NSCLC, head and neck squamous cell cancer and oesophageal cancer.

A clinical development strategy commonly employed for many blockbuster ICIs is a broad-spectrum approach, with attempts to reposition treatments across a range of different cancers. As such, while the only combinations approved by the FDA, to date, have included Keytruda, there are currently c 365 active studies aiming to expand the clinical utility of ICIs through ICI/cisplatin treatment regimens, Exhibit 4.

Exhibit 4: Number of active ICI trials being investigated in combination with cisplatin

Source: Edison Investment Research, Clinicaltrials.gov

iCIP a potential clinical trial companion

The challenges associated with drug development in the pharmaceutical industry are well documented and clinical failure rates continue to sit at c 90%. In our view, such challenges are only set to continue, if not become further compounded, as FDA drug approvals in 2022 were down c 25% from 2021, bringing them to their lowest levels since 2016. Today, it is estimated that clinical development failures can cost c $700m. We therefore believe this provides opportunities for new technologies to potentially disrupt and improve the traditional way in which companies approach trial development.

Chosa Oncology's iCIP technology may become a valuable screening tool with its ability to potentially help select clinical trial participants who are most likely to respond to cisplatin therapy prior to study recruitment. Additionally, those patients identified through the DRP tool of iCIP could potentially benefit from treatment with LiPlaCis, provided it can demonstrate robust efficacy and safety benefits over cisplatin in future studies. While the DRP tool within the iCIP platform could theoretically find application across any form of trial that includes cisplatin, we believe that, given the expanding market and continued interest in ICIs, its positioning within the cisplatin/ICI treatment market could provide a significant opportunity.

A hypothetical example of where the DRP tool could have been applied is the Phase III CHECKMATE-816 study (n=358), which investigated Bristol Myers Squibb's nivolumab (Opdivo) in combination with cisplatin for the treatment of NSCLC. The study reported a complete response rate of 24%; however, the DRP technology could have potentially been utilised to identify these treatment responders prior to trial initiation.

Financials

At end March 2023, Chosa Oncology (previously RhoVac) reported a gross cash position of SEK17.5m. The company previously had an outstanding SEK14.98m (10% interest) convertible loan facility, which was repaid in full, plus interest, in Q223 following receipt of an undisclosed payment from Horizon 2020 (a key EU funding programme for research and innovation). Chosa Oncology reported a Q123 net cash outflow from operating activities (before changes in working capital) of SEK2.0m, which compares to an outflow of SEK33m in FY22. Management expects to receive an R&D tax credit payment of SEK7.7m in Q423, which the company has guided, together with its current cash position, will provide an operating cash runway through Q224. Additionally, the company has stated that it does not intend to conduct any additional clinical studies in the absence of a pharmaceutical partner. If this is the case, the operating cash burn rate would not be expected to increase significantly from current levels.

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