

Allarity Therapeutics

A new direction and name for Oncology Venture

Business outlook

Pharma & biotech

It has been approximately a year since the new leadership took the reins of the company and this time of unprecedented change is capped-off with a name change from Oncology Venture to Allarity Therapeutics. It has streamlined its operations, focused on its priority assets and recapitalised itself in preparation of the upcoming NDA for dovitinib and start of studies for Ixempra. We are providing our clinical and commercial outlook with a valuation of SEK1,029m or SEK5.18 per share.

Year end	Revenue (DKKm)	PBT* (DKKm)	EPS* (DKK)	DPS (DKK)	P/E (x)	Yield (%)
12/18	2.1	(22.5)	(0.44)	0.0	N/A	N/A
12/19	0.8	(174.9)	(2.08)	0.0	N/A	N/A
12/20e	0.9	(54.4)	(0.31)	0.0	N/A	N/A
12/21e	0.9	(192.8)	(0.91)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

A new name is the capstone for changes underneath

The change in name reflects all of the changes that have been undertaken at the company to make it more of a focused operation with a much clearer investment proposition. A year ago, Allarity had seven ongoing development programmes spread between three subsidiaries, each with a different ownership structure. The company has realigned between the three top programmes, stenoparib, dovitinib and Ixempra, which it now wholly owns.

Progress on multiple fronts

Although significant effort has been put into the company realignment, it has also made progress on development and regulatory fronts. Allarity is expected to submit its NDA for dovitinib to the FDA in 2021 (from Q420 previously following a manufacturing delay due to COVID-19), which will seek approval on the basis of non-inferiority to Nexavar. This is part of the strategy to first seek approval for the drug then seek supplemental NDA (sNDA) approval for the drug in combination with the company's drug response predictor (DRP) diagnostic platform. Also, the company is expected to initiate new clinical studies for Ixempra in early 2021 that will test it in combination with a DRP companion diagnostic for the first time.

Valuation: Lower on exchange rate effects

Our valuation is lower at SEK1,029m or SEK5.18 per share from SEK1,156m or SEK5.98 due to exchange rate effects and offset by increased net cash (estimated SEK20.2m from estimated SEK10.9m) following a recent offering through the company's equity facility with Global Corporate Finance (5.37m shares at SEK1.74). We have additionally rolled forward our NPVs and updated our clinical timelines. We expect the company to need DKK870m in additional capital to reach profitability in 2024, including DKK90m in near term cash needs, which we expect to be drawn from the company's existing financing agreements.

8 December 2020

Price **SEK0.92**

Market cap **SEK183m**

SEK8.88/DKK6.32/US\$

Net debt (DKKm) at June 2020 0.5

Shares in issue 198.7m

Free float 92.4%

Code ALLR

Primary exchange Nasdaq First North Stockholm

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (34.1) (44.2) (51.1)

Rel (local) (36.6) (47.9) (57.2)

52-week high/low SEK3.88 SEK0.90

Business description

Allarity Therapeutics is a Denmark-based biopharmaceutical company focused on oncology. Its patent-protected mRNA-based drug response predictor platform enables the identification of patients with gene expression highly likely to respond to treatment. The company is advancing the PARP inhibitor stenoparib (2X-121), the TKI dovitinib and microtubule inhibitor Ixempra.

Next events

Ixempra study initiation Early 2021

Dovitinib NDA submission 2021

Stenoparib OC Phase II results Late 2021

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Allarity Therapeutics is a research client of Edison Investment Research Limited

Investment summary

Company description: Reinvigorating drugs with better targeting

Allarity is a Danish pharmaceutical company that has developed the DRP diagnostic platform, a transcriptomic genetic test intended to predict which patients are most likely to respond to a particular drug. The goal of the company is to in-license drugs deprioritised by other companies but that have shown clinical activity and to use a DRP companion diagnostic to run trials in patient subgroups that are most likely to respond to treatment. The company is developing three assets: stenoparib, a PARP inhibitor being investigated for ovarian cancer; dovitinib, a tyrosine kinase inhibitor (TKI) for renal cell carcinoma (RCC); and Ixempra for breast cancer.

Valuation: Adjusted lower for forex effects and financing

We have lowered our valuation to SEK1,029m (SEK5.18 per share) from SEK1,156m (SEK5.98) due to exchange rate effects and new cash issued through the company financing agreements (estimated net cash SEK20.2m). This was offset by rolling forward our NPVs. We model dovitinib as the highest value asset at SEK723.3m and forecast a commercial launch of the product in 2024 or 2025, depending on the outcome from the upcoming preliminary NDA submission.

Financials: Costs to increase with increased development

Our financial assumptions for Allarity remain unchanged. Costs have been low through the transition period as the company realigns its business strategy and we expect an operating loss of DKK49m in 2020. We expect this to increase substantially in 2021 and beyond as the company increases its investment in the clinical development of its products. We forecast operational spending of DKK188m in 2021. We expect Allarity to need additional financing to support this development, which we include as DKK870m in illustrative debt (DKK90m in 2020, DKK400m in 2021 and DKK380m in 2022).

Sensitivities: Linked to DRP strategy

The risks faced by Allarity are somewhat unique, due to its particular development strategy. The drugs that it has in-licensed have all been vetted to various extents by their previous sponsors. Dovitinib, for instance, has shown non-inferiority in Phase III results, and Ixempra has been approved in the US. We believe this limits some of the risks associated with the development of these drugs. However, the company's regulatory and commercial strategy is dependent on coupling these drugs with DRP-based diagnostics. The DRP platform has been tested primarily in retrospective studies, and the company has yet to publish data gathered in a prospective fashion that support the use of the platform. We expect the company to need to perform these prospective studies to support the approval and/or marketing of each DRP diagnostic and drug combination. Even if the DRP platform can improve outcomes in one use case, it cannot be ensured this will translate to other circumstances and other drugs. The company also faces commercial risks once the drug/DRP combinations are approved. Stenoparib and dovitinib are drugs in well-established classes with multiple competitors already approved. Moreover, these competing drugs are sponsored by some of the biggest companies in the industry. A DRP companion diagnostic must increase the value proposition for these drugs substantially to gain market share. Finally, Allarity faces financing risk and we expect it to need an additional DKK870m before profitability. The company may face significant dilution if it seeks this on the capital markets.

Allarity: Technology and pipeline overview

Allarity's core goal is to use improved patient targeting to revitalise pharmaceutical assets that have been divested from other companies. Frequently in clinical development, patients will show varying responses to a drug for unknown or poorly understood reasons, which can limit the applicability of these drugs. During clinical development, these effects can potentially dampen the mean efficacy readouts in the aggregate data. The company has developed the DRP diagnostic platform in an attempt to identify those patients that are most likely to respond to a particular course of treatment beforehand. The business strategy is therefore to identify assets that show signs of efficacy in patient subgroups that have been deprioritised by other companies and develop these assets in combination with a DRP-based companion diagnostic.

Allarity underwent a change in management in mid-2019 and has subsequently been undergoing a business realignment to a more focused operation with a clear pathway towards commercialisation. This included selecting the highest priority assets from among the ongoing programmes, as well as consolidating ownership of these programmes. As of July 2020, the company owns 100% of its three lead assets: stenoparib (2X-121), dovitinib and European rights to Ixempra. Stenoparib is an orally bioavailable small molecule inhibitor of poly-ADP ribose polymerase-1/2 (PARP-1/2) and tankyrase-1/2 (TNKS-1/2) that is in Phase II clinical trials for ovarian cancer. Dovitinib is an oral TKI of fibroblast growth factor (FGF), vascular endothelial growth factor (VEGF) and platelet-derived growth factor (PDGF) receptors. Allarity intends to submit an NDA for dovitinib in 2021 for renal cancer and follow up with sNDA applications for use in combination with a DRP test. Ixempra (ixabepilone) is a chemotherapy that is approved in the US to treat metastatic and locally advanced breast cancer, but not yet been approved by the European Medicines Agency (EMA). The drug is expected to enter Phase II in early 2021.

Exhibit 1: Allarity pipeline

Drug	Indication	Stage	Mechanism
Stenoparib	Recurrent ovarian cancer	Phase II	PARP inhibitor
Dovitinib	Renal cancer	NDA	Multi-TKI
Ixempra	Metastatic breast cancer	Phase II	Microtubule disruptor

Source: Allarity

The DRP: Drug targeting with transcriptomics

The central premise of Allarity's business model is that the DRP platform in development by the company can be used to identify patients that will respond to a particular therapy. Allarity's strategy is to use the platform to develop companion diagnostics that can be used to revitalise divested assets, but in theory it could be used for any drug. The DRP platform is based on transcriptomics, meaning it measures which genes are being transcribed in a patient as the input for its algorithm. This differs from other genetic tests such as those for a critical mutation in a gene, because transcriptomics is focused on measuring RNA levels in patients, which provides a fingerprint of which genes are actively being read from the genome. This may provide an additional level of insight into a patient's profile that is not delivered by simply looking at a patient's DNA sequence information.

When a new test is developed using the platform, it starts with an established panel of 60 human tumour cell lines from the National Cancer Institute (NCI-60) to correlate the genetic expression profile of a tumour to either sensitivity or resistance to an anticancer drug. Gene expression profiles of the NCI-60 cancer cell lines are derived from a microarray (commercially available Affymetrix Gene Chips) to quantify the level of mRNA transcribed from a nucleic acid molecule that identifies biomarkers. A biological relevance filter is then applied such that only markers previously known to

interact are used to reduce the number of false positives. This process generates a list of genes characterising the cell lines that are sensitive and resistant to the drug in question, which is subsequently used to identify a subpopulation of cancer patients most likely to respond to the drug in vivo.

These cell panels are further validated using patient tumour samples or diagnostic formalin-fixed paraffin-embedded biopsies (note these are highly variable sample sets). Gene expression in patients' cells is determined in the same manner as in the cell lines previously described. The sum of the expression levels of the patient's biomarkers is compared to the training set population with the same tumour type to predict either sensitivity or resistance to the anticancer agent and provides an insight into how the drug will perform in the more variable clinical setting. In this way, a new diagnostic protocol can be developed for each disease/drug pair.

The DRP method is patented for more than 70 anticancer agents including vincristine, cisplatin, carboplatin, rituximab, etc.¹ The system has been tested in at least 35 retrospective studies for a variety of cancers and therapies. One such study evaluated the development of a gene expression score that predicts response to fulvestrant in patients with locally advanced oestrogen receptor-positive (ER+) breast cancer. The prediction score was based on baseline gene expression in the presence of fulvestrant where 103 genes showed increased expression in sensitive cell lines and 311 genes showed increased expression in non-responding cell lines.² A DRP test was then used to predict patient sensitivity to fulvestrant based on the expression of each gene in the response profile of pre-treatment tumour biopsies obtained from AstraZeneca's [Phase II study](#) that investigated neoadjuvant endocrine therapy for women with ER+ breast cancer. These data are combined to produce a predictor score. The patients who clinically responded (ie partial response) to fulvestrant demonstrated a significantly higher sensitivity predictor score than the non-responders (ie stable disease and disease progression) ($p=0.01$). Moreover, the addition of clinical covariates obtained from the study such as tumour stage and percentage of ER+ tumour cells demonstrated a significant difference ($p=0.003$) between responders and non-responders. Within this trial the positive predictive value was 88% and the negative predictive value was 100%. The company has subsequently performed a similar study examining the ability of a DRP-based diagnostic to predict the response to doxorubicin³ and epirubicin⁴ as neoadjuvants, with similar results.

In another test of the DRP system done in collaboration with the MD Anderson Center, the test was evaluated in three distinct datasets including patients treated with epirubicin monotherapy for breast cancer, ABVD (doxorubicin, bleomycin, vinblastine and dacarbazine) chemotherapy for Hodgkin's lymphoma and methotrexate for acute lymphoblastic leukaemia. MD Anderson independently selected datasets that satisfied specific conditions set by the company (ie at least 100 distinct patients receiving the same treatment and availability of treatment outcomes) and sent the list of drugs used to treat the patients to the company to develop a predictive model in vitro for each drug using the NCI-60 cell lines. MD Anderson then applied the model and compared the predictions with primary patient responses from existing records to evaluate the performance of the DRP diagnostic. The prediction score in all three cases significantly predicted patient response

¹ US Patent No. 8,445,198

² Knudsen S, et al. (2014) Development and Validation of a Gene Expression Score That Predicts Response to Fulvestrant in Breast Cancer Patients. *PLoS ONE* 9, e87415.

³ Buhl ASK, et al. (2019) Doxorubicin response prediction in neoadjuvant breast cancer therapy. *J Clin Oncol* 37, e12119.

⁴ Buhl ASK, et al. (2018) Predicting efficacy of epirubicin by a multigene assay in advanced breast cancer within a Danish Breast Cancer Cooperative Group (DBCG) cohort: a retrospective-prospective blinded study. *Breast Cancer Res Treat* 172, 391–400.

($p=0.02$).⁵ However, the study's sponsors concluded that although the sensitivity scores based on in vitro models predicted patient response better than chance, the results are not quite compelling enough to change clinical practice and there may be an opportunity to develop a DRP test for drug development purposes where existing clinical variables are not yet established, to predict the likelihood of patient response. Nonetheless, the platform also has its limitations. In one retrospective trial, a DRP test was developed to predict patient response (relapsed free survival) to irinotecan treatment for metastatic colorectal cancer. The irinotecan DRP test identified 38 positively correlated genes, but was unable to predict patient response to irinotecan ($p=0.450$).⁶ The study found that the test most likely failed in this case because no significant effect was found with irinotecan treatment and the population who did benefit from the drug may have been too small to detect using the available patient samples.

One limitation in our understanding of the platform is that all of the clinical data to date presented on the platform has been in the form of retrospective studies, where patients are evaluated with a DRP test after having received treatment. The company has completed a prospective study of the platform with its legacy asset, LiPlaCis, but to our knowledge the data from this study have not been made public. Prospective clinical studies provide a high level of clinical support and are often required for PMA approval. The company's strategy to date has been to run small Phase II studies to 'train' the DRP and determine the parameters of the test for that indication, and that these pilot studies would be followed by larger prospective clinical studies, but none of the drugs under development has yet reached this stage. The transcriptomic data probed by the platform are very rich and, in these circumstances, there is always the risk of overfitting. Overfitting is the case in which a test can accurately predict outcomes in the retrospective data used to determine its parameters, but fails to account for real-world variations outside of this initial dataset. A clinical benefit will need to be demonstrated using the DRP in a prospective study to support its inclusion on the label for these drugs, which would be a criterion for the company marketing these products in combination with the DRP. This being said, gathering and analysis of retrospective data are essential for the development of these products and an important piece of the clinical data that will be submitted to the FDA. We should note that the company is seeking initial PMA approval for the dovitinib DRP diagnostic on the basis of retrospective data (explained further below).

Dovitinib: A TKI going straight to the FDA

Allarity in-licensed dovitinib from Novartis in 2018. The product is a so-called multi-TKI that targets FGF, VEGF and PDGF, among potentially other tumour-associated receptors. Novartis has already completed pivotal Phase III studies of the drug in RCC but opted to not commercialise it when it was not shown to be superior to existing TKI treatments. The current strategy of Allarity is to seek approval of the drug under non-inferiority criteria and follow up this initial approval with additional clinical studies and submissions to support the use of the drug with a DRP test.

The mechanism of dovitinib is similar to those of other TKIs, which is to broadly inhibit a range of growth and proliferations signals that become aberrant in tumours. Signalling through the FGF pathway regulates cell proliferation and differentiation, angiogenesis, which is the development of new blood cells, as well as cell survival and wound healing.⁷ Abnormal FGF signalling plays a critical role in clinical tumour progression, effecting cellular proliferation, resistance to cell death and

⁵ Wang, W., et al. (2013). Independent Validation of a Model Using Cell Line Chemosensitivity to Predict Response to Therapy. *JNCI: Journal of the National Cancer Institute* 105, 1284-1291.

⁶ Buhl, I. K., et al. (2016) Cell Line Derived 5-FU and Irinotecan Drug-Sensitivity Profiles Evaluated in Adjuvant Colon Cancer Trial Data. *Plos One*, 11.

⁷ Lieu, C., et al. (2011) Beyond VEGF: Inhibition of the fibroblast growth factor pathway and antiangiogenesis. *Clinical Cancer Research*, 17, 6130-6139.

chemotherapies, as well as increased angiogenesis and metastases. Similarly, VEGF also modulates angiogenesis in cancer and is stimulated by cancer-causing genes, or oncogenes.⁸ Tumour vasculature promoted by VEGF is structurally and functionally irregular although it provides the tumour with nutrients and oxygen for growth. Correspondingly, hyperactive PDGF-receptor signalling via overexpression is associated with the development of malignant disease as well as benign diseases characterised by increased cell proliferation.⁹ Therefore, dovitinib may effectively inhibit the growth of highly vascularised cancers that are dependent on angiogenesis pathways such as RCC.

The safety of dovitinib was evaluated in a Phase I dose-escalating trial in heavily pre-treated (with VEGF and mTOR inhibitors) patients with advanced or metastatic RCC. The study showed the maximum tolerated dose (MTD) was 500mg/day on a five days on, two days off schedule in 28-day cycles and was generally well tolerated in this cohort.¹⁰ Two of 15 patients demonstrated a partial response, a median progression-free survival of 8.1 months and overall survival of 13.3 months. This dovitinib MTD was later tested in a Phase III trial in contrast to Nexavar, an oral multi-kinase inhibitor that was approved in 2005 for the first-line treatment of advanced renal cell liver and thyroid cancer with an expected patent expiry in January 2020. Bayer reported worldwide sales of \$841m for 2018.

In the randomised open-label Phase III trial, patients with metastatic RCC who previously received one VEGF-targeted therapy and one previous mTOR inhibitor received either dovitinib (500mg orally, five days on, two days off schedule) or Nexavar (400mg orally 2x daily). In total, 284 patients received dovitinib treatment and 280 patients received Nexavar. The median progression-free survival was 3.7 months in the dovitinib group compared to 3.6 months in the Nexavar group (p=0.063).¹¹ Adverse events were also similar in both treatment arms including fatigue and hypertension. Novartis ceased dovitinib development because it did not show efficacy or safety benefits over Nexavar.

Allarity's strategy is to seek initial approval submit an NDA to the US FDA for marketing approval of dovitinib on the basis of existing non-inferiority data versus Nexavar using existing Novartis data. The company's objective is that marketing approval for dovitinib in metastatic RCC (mRCC) on the basis of non-inferiority will pave the way for sNDAs for dovitinib in combination with a PD-1/PD-L1 and its unique DRP biomarker. Treatment of mRCC with PD-1/PD-L1 inhibitors is emerging as a new axis of treating the disease (in addition to TKIs) and approval of a combination would improve inclusion in this protocol. The NDA is planned to be submitted in 2021, following the announcement of some manufacturing delays (from prior guidance of Q420, due to COVID-19). The delay relates to the manufacturing of a registration batch of the drug (from a third-party contract manufacturer), which is a mandatory component of the NDA filing.

As part of the licensing agreement with Novartis, Allarity also received an ample amount of biopsy and gene expression data from previous studies by Novartis. Allarity received positive feedback from FDA biostatisticians to move forward with building the pre-NDA documents based on these data. However, if the standalone dovitinib NDA is not approved, the company may move forward with the dovitinib + PD-1/PD-L1 combination programme via a new NDA pathway and may require more time and more patients (and data) to fulfil NDA requirements. If the NDA is approved, the sNDA for consecutive trials may allow for smaller clinical studies.

⁸ Carmeliet, P. (2005) VEGF as a key mediator of angiogenesis in cancer. *Oncology* 69, 4-10.

⁹ Heldin, C. (2013) Targeting the PDGF signaling pathway in tumor treatment. *Cell Communication and Signaling* 11, 97.

¹⁰ Angevin, E., et al. (2013) Phase I study of dovitinib (TKI258), an Oral FGFR, VEGFR, and PDGFR inhibitor, in advanced or metastatic renal cell carcinoma. *Clinical Cancer Research* 19, 1257-1268.

¹¹ Motzer, R. J., et al. (2014) Dovitinib versus sorafenib for third-line targeted treatment of patients with metastatic renal cell carcinoma: an open-label, randomised phase 3 trial. *The Lancet Oncology* 15, 286-296.

The company is also planning on submitting an initial PMA for the dovitinib DRP companion diagnostic at the same time as the initial NDA, on the basis of Novartis biopsy data. Approvals for companion diagnostics have been made previously with retrospective data (for instance the cobas EGFR test, companion for Tarceva) but, to our knowledge, in all of these cases the biomarker was predefined and a different diagnostic was used against the same target in prior studies that supported approval of the drug. This is not the case with the DRP platform and dovitinib: the DRP is not testing a specific known biomarker and dovitinib has not been tested clinically in any biomarker subgroups yet. Although a PMA approval would clear the diagnostic for sales, we are sceptical that any marketing claims that could be made on the basis of retrospective data in this case would be sufficient to achieve reimbursement or market share. We believe that the biggest benefit from this initial PMA submission (for the companion DRP diagnostic) will be in the form of feedback from the FDA that will ultimately strengthen the forthcoming PMA/sNDA submission for a PD1/PD-L1 and dovitinib combination.

The company intends to use its new combination PD1/PD-L1 and dovitinib DRP biomarker to identify mRCC patients highly likely to respond to this treatment regimen. However, to run these trials successfully, it will need to partner with a PD-1/PD-L1 manufacturer. We assume Allarity and its future PD-1/PD-L1 partner(s) will be required to run at least a Phase Ib/II trial followed by a Phase III trial, most likely in patients with mRCC receiving second-line therapy.

Market and competitive environment

The National Cancer Institute estimates that 73,750 patients in the US will be diagnosed with RCC in 2020, or 16.3 per 100,000 adults on an age-adjusted basis.¹⁵ There will be an estimated 14,830 deaths in the US from the disease during the same year. Moreover, the disease is associated with a relative five-year survival rate of 74.1%. Treatment for localised RCC includes either partial or radical removal of the kidney followed by adjuvant therapy, such as Sutent (sunitinib, Pfizer). Pfizer reported \$1.0bn in sales of the drug for FY18. Management of advanced or metastatic RCC involves as many lines of targeted therapies that a patient may benefit from (Exhibit 2).¹² However, most patients develop resistance to TKIs via a number of mechanisms (ie genetic alterations, activation of other signalling pathways, or the increase in expression of a specific molecule in response to inhibition).¹³

Exhibit 2: RCC competitive landscape

Product	Mechanism	Indication	Notes
Nexavar (sorafenib, Bayer)	TKI of VEGF-1, -2 and -3, FLT3, KIT, and PDGFR- β as well as intracellular kinases	Advanced RCC	Median PFS: 5.6 months
Sutent (sunitinib, Pfizer)	TKI of VEGF-1 and -2, FLT3, KIT, and PDGFR- α and - β	Advanced RCC	Median PFS: 11.8 months (treatment-naïve patients)
Votrient (pazopanib, Novartis)	TKI of VEGF-1, -2, and -3, FGFR-1 and -3, KIT, and PDGFR- α and - β	Advanced RCC	Median PFS: 9.2 months
Inlyta (axitinib, Pfizer)	TKI of VEGF-1, -2, and -3	Advanced RCC after failure of systemic therapy	Median PFS: 6.7 months
Afinitor (everolimus, Novartis)	mTOR inhibitor	Advanced RCC following failure of one or more therapies (ie Nexavar, Sutent).	Median PFS: 4.9 months

Source: Company websites. Notes: PFS: progression free survival; FLT3: Fms-like tyrosine kinase-3; KIT: stem cell factor receptor; mTOR: mammalian target of rapamycin.

PD-1 and PD-L1 inhibitors have emerged as a new treatment options for patients with metastatic RCC and there have been multiple studies examining these agents in combination with TKIs. Keytruda is approved for use in combination with Inlyta for the treatment of first-line metastatic

¹² Ko, J. J., et al. (2014) First-, second-, third-line therapy for mRCC: Benchmarks for trial design from the IMDC. *Brit J Can*, 110(8), 1917-1922.

¹³ Bielecka, Z., et al. (2014) Mechanisms of acquired resistance to tyrosine kinase inhibitors in clear - cell renal cell carcinoma (ccRCC). *Current Signal Transduction Therapy*, 8(3), 219-228.

RCC. This combination was shown to reduce the risk of progression by 31% compared to Sutent. We expect this combination strategy to be the standard of care for advance disease in future.

Stenoparib: A new PARP inhibitor

Stenoparib (formerly 2X-121) is an orally bioavailable small molecule inhibitor of PARP-1/2 and TNKS-1/2 that was in-licensed from Eisai in July 2017 (previously named E7449). Allarity is advancing the drug for use in combination with a DRP companion diagnostic for the treatment of ovarian cancer, which is the first indication that was approved for other PARP inhibitors as well.

The PARP enzymes are a critical anticancer target due to their role in DNA damage repair, maintenance of genomic stability and functions in transcriptional regulation. More specifically, PARP-1 and 2 nuclear enzymes are responsible for the majority of PARP activity in the cell where they are recruited to, and triggered by, sites of DNA damage. PARP enzymes repair single-strand DNA breaks; as a result, PARP inhibition causes double-strand breaks, which require BRCA1/2 for repair. PARP inhibition is therefore particularly lethal to cancer cells containing BRCA1/2 mutations. TNKS enzymes also belong to the PARP family and are involved in Wnt/ β -catenin signalling, which plays a central role in cancer biology. Wnt overexpression contributes to tumour progression and, consequently, TNKS inhibition interferes with Wnt signalling.

In early clinical trials, stenoparib demonstrated antitumor activity in BRCA-deficient in vivo models and increased the effectiveness of radiotherapy and chemotherapy.¹⁴ The drug was well tolerated in a Phase I trial in 41 patients with solid tumours and demonstrated a 7.1% partial response. The DRP test for the drug was evaluated in a small 13-patient blinded retrospective trial using biopsy materials provided by Eisai. The assay predicted that seven patients would respond to stenoparib treatment and six would not respond; the median times to progression in these groups were 296 and 155 days, respectively, although the data did not reach statistical significance (HR=0.29, p=0.14).

The drug is being evaluated in a Phase II clinical [study](#) at the Dana-Farber Cancer Institute for recurrent ovarian cancer. The open-label study has a target enrolment of 60 and patients have been prospectively enrolled based on their DRP test results. The study has a target primary completion date of September 2021 (as shown at [clinicaltrials.gov](#)). The drug was previously in a separate Phase II study in metastatic breast cancer, but Allarity announced in August that it would be discontinuing the study due to complications regarding the biopsies used in the DRP diagnostic training set. The study used old biopsies taken at the time of diagnosis and found that these were insufficient for a proper assessment. However, we expect the drug if approved to be subsequently tested in breast cancer, similar to the other approved PARP inhibitors.

Market and competitive environment

Ovarian cancer is expected to account for 21,750 new cases and 13,940 deaths in the US in 2020.¹⁵ While worldwide incidence rates vary due to reporting discrepancies, the disease remains the seventh most common malignancy among women. It is particularly deadly since diagnosis occurs in the late stages due to the lack of disease-specific symptoms. A patient with a stage I tumour that is confined to the ovary has a relative five-year survival rate above 90%. However, most patients are diagnosed with stage III or stage IV tumours, and have five-year survival rates of 35% and 20%, respectively.¹⁶ Treatment plans typically involve surgical resection of the tumour, followed

¹⁴ McGonigle, S., et al. (2015) E7449: A dual inhibitor of PARP1/2 and tankyrase1/2 inhibits growth of DNA repair deficient tumors and antagonizes Wnt signaling. *Oncotarget* 6.

¹⁵ SEER database, National Cancer Institute.

¹⁶ Chornokur G, et al. (2013) Global ovarian cancer health disparities. *Gynecol Oncol* 129, 258-264.

by a platinum-based (paclitaxel or carboplatin) regimen. However, about 80% of women with advanced ovarian cancer are expected to have tumour recurrence and become resistant to platinum-based therapies.¹⁷

The space is evolving rapidly with the addition of new targeted therapies for the disease. PARP inhibitors, such as Zejula (niraparib, GSK) and Lynparza (olaparib, AstraZeneca/Merck) have recently changed the algorithm for the treatment of certain genetic subclasses of ovarian cancer. Additionally, the recent CDK4/6 inhibitors such as Ibrance (Palbociclib, Pfizer) have proved efficacious in breast cancer and are currently being tested for ovarian cancer. Finally, an assortment of checkpoint inhibitors such as Keytruda (pembrolizumab, Merck), are in late-stage clinical trials for platinum-resistant ovarian cancer.

There are several PARP inhibitors on the market and in development (Exhibit 3). Lynparza is the market leader (\$1.20bn worldwide sales 2019) and is approved for the treatment of BRCA1/2 mutated breast and ovarian cancers and is distributed by AstraZeneca and Merck such that both companies can potentially take advantage of the potential interaction between the PARP inhibitor and their respective immune-oncology drugs, Imfinzi (durvalumab, AstraZeneca) and Keytruda (pembrolizumab, Merck). Stenoparib is differentiated from the other PARP inhibitors on the market because it also inhibits TNKS-1/2 and Wnt signalling.

Exhibit 3: Select PARP inhibitors on the market and in development

Product	Status	Indication	Notes
Lynparza (Olaparib, AstraZeneca/Merck)	Market	Relapsed ovarian cancer, fallopian tube cancer, primary peritoneal cancer after response to platinum-based chemo. Advanced ovarian cancer with BRCA mutation and received three or more prior chemotherapy drugs. Metastatic HER2-breast cancer with BRCA mutation	Inhibitor of PARP1, PARP2 and PARP3
Rubraca (rucaparib, Clovis Oncology)	Market	Advanced ovarian cancer with BRCA mutation and have received 2 or more prior chemotherapy drugs	Inhibitor of PARP1, PARP2 and PARP3
Zejula (niraparib, GSK)	Market	Maintenance of recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer in complete or partial response to platinum-based chemotherapy	Inhibitor of PARP1 and PARP2
Talzenna (talazoparib, Pfizer)	Market	Locally advanced/mBC with BRCA mutation	Phase III trial demonstrated median PFS of 8.6 months in talazoparib treatment arm vs 5.6 months chemotherapy in patients with locally advanced/mBC with inherited BRCA mutation
Veliparib (AbbVie)	Phase III	NSCLC and TNBC	Two failed Phase III trials
Pamiparib (BeiGene)	Phase III	Gastric cancer, ovarian cancer	Inhibitor of PARP1 and PARP2, NDA submitted in China for ovarian cancer
Stenoparib (Allarity)	Phase II	DRP identified relapsed ovarian cancer	Inhibitor of PARP1, PARP2, TNKS1 and TNKS2

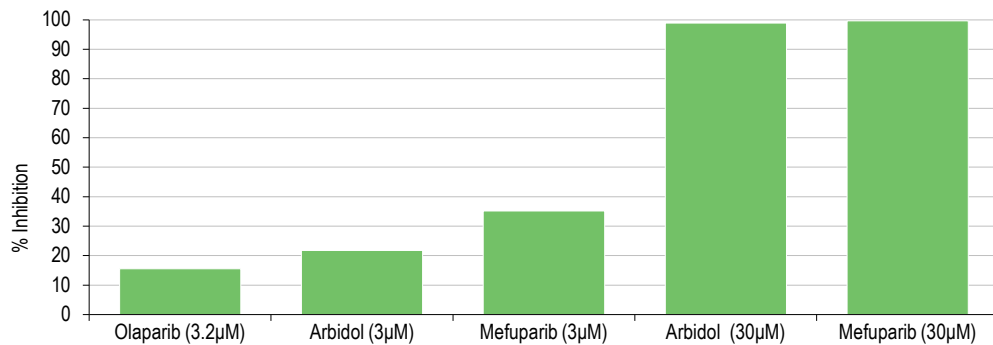
Source: Company websites. Note: PFS: progression-free survival, mBC=metastatic breast cancer.

PARPs for COVID-19?

The company is also investigating if stenoparib can have activity against the virus that causes COVID-19. The idea of testing stenoparib against COVID-19 comes from a study from Tsinghua University in Beijing that is available as a [preprint](#) (and thus has not been peer reviewed). The study tested two PARP inhibitors against COVID-19, olaparib and mefuparib (CVL218), and these were compared to a selection of antivirals including arbidol, an anti-influenza agent common in Russia and China that is being used in those countries for the treatment of COVID-19 (Exhibit 4). The study showed that mefuparib had higher activity than olaparib and arbidol, which has demonstrated a clinical effect in some early [studies](#), albeit it very high concentrations (30µM).

¹⁷ Luvero D, et al. (2014) Treatment options in recurrent ovarian cancer: Latest evidence and clinical potential. *Ther Adv Med Oncol* 6, 229-239.

Exhibit 4: Inhibition of COVID-19 in vitro with PARP inhibitors



Source: Ge et al. (2020)

Despite the limitations of this study, it did show the potential for antiviral activity in PARP inhibitors and we believe this avenue is worthy of further investigation. The company has stated that a preclinical test showed some antiviral activity of stenoparib, but no data has been provided so we cannot comment on how meaningful these findings are. The company stated it intends to immediately seek financing to start clinical studies of stenoparib for COVID-19 and it has applied for a grant from the Biomedical Advanced Research and Development Authority.

Ixempra: A last-line chemo for breast cancer

On 4 April 2019, Allarity announced it had obtained an option to in-license the European rights to Ixempra (ixabepilone) from R-Pharm, which previously acquired it from Bristol-Myers Squibb in 2015. Ixempra is a chemotherapy that received FDA approval in 2007 (and 18 other markets worldwide) for the treatment of metastatic or locally advanced breast cancer with tumours that are resistant/ refractory to anthracyclines, taxanes and capecitabine. However, Ixempra is not approved by the EMA. Bristol-Myers Squibb withdrew its marketing authorisation application in 2009 following negative feedback on safety, specifically the number of patients developing severe neuropathy, from the EMA Committee for Medicinal Products for Human Use.

The drug is a chemotherapy that operates by disrupting microtubules in the body, similar to the taxane class of agents. Both Ixempra and taxanes operate by stabilising the microtubule structure, preventing its depolymerization. Microtubule assembly is important for cell division, and by inhibiting this axis these drugs decrease the growth rate of rapidly dividing cells, such as those in tumours.

The drug was evaluated by Bristol-Myers Squibb in a 752-patient pivotal study, which examined the drug in combination with capecitabine against capecitabine alone. Patients on that study were those that had progressed on taxanes or anthracyclines. The drug increased progression free survival to 5.7 months compared to 4.1 months on capecitabine alone (HR=0.69, p<0.0001). The drug was also examined as a monotherapy for metastatic breast cancer in patients that had progressed on two or more previous chemotherapies or on high-dose anthracyclines. In these patients of last resort, the drug had a 12.4% response rate and a six-month median duration of response.

Based on previous treatment results and tumour gene data published by Bristol-Myers Squibb, the company has evaluated the potential ability of its DRP companion diagnostic to identify the patients most likely to benefit from Ixempra therapy. According to the agreement, Allarity will evaluate Ixempra with its DRP test in new European clinical trials in patients with metastatic breast cancer and, if these results are positive, Allarity will have the option to exclusively in-license European

commercial rights. The financial terms of this agreement have not yet been disclosed. The company has guided towards starting a clinical study for Ixempra in early 2021.

Market and competitive environment

Breast cancer has one of the highest disease burdens of any malignancy and is expected to impact 276,480 women in the US in 2020 or 128.5 per 100,000 women according to the National Institutes of Health.¹⁵ The disease is stratified by a range of different biochemical markers, such as hormone receptor positive (HR+) cancers or HER2 positive (HER2+) cancers, which heavily guides the treatment for metastatic disease and there are a range of targeted therapies available depending on biomarker status. Despite the availability of targeted therapies, chemotherapy remains an important treatment methodology in the adjuvant setting and in patients with advanced disease. Ixempra is positioned as a therapy for patients that progress on other chemotherapy regimens, where there are few other treatment options and patients would otherwise go on palliative care.

Other assets out-licensed

On the other side of Allarity's efforts to focus its clinical strategy, it has out-licensed two of its deprioritised assets, 2X-111 and LiPlaCis, to Smerud Medical Research. Smerud was the contract research organisation (CRO) that was previously engaged by the Allarity to run clinical studies of LiPlaCis, which are still ongoing. The transaction includes up to \$30m in regulatory milestones to Allarity and undisclosed royalties on future sales. Additionally, Smerud plans to continue to develop the two assets in combination with the DRP diagnostic, which may provide additional future revenue streams to Allarity if the products reach the market. Allarity previously returned the rights for its other deprioritised asset APO010, leaving a single asset, Irofulven, in its legacy portfolio.

Sensitivities

Allarity has a unique strategy of acquiring the rights to deprioritised assets and coupling them with its DRP diagnostic platform. This limits many risks to the company, while exposing it to others that are unique to this strategy. For instance, concerns surrounding the individual efficacies of dovitinib and Ixempra can be largely set aside, as both drugs have demonstrated efficacy in pivotal clinical studies. Stenoparib has also shown positive previous clinical results thus far (albeit at an earlier stage). However, the company's regulatory and commercial strategy hinges on the ability of the DRP platform to provide diagnostic information for these drugs that can improve clinical outcomes in the identified patient subgroups. There are numerous studies that have been published using retrospective data with the platform, but none for the three drugs in question. Moreover, because only retrospective data have been published, it is difficult to evaluate whether the DRP platform can actually be used in a clinical setting to identify patients. Although the current plan is to seek initial PMA approval for the dovitinib DRP companion diagnostic on the basis of retrospective data, we expect the company will need to demonstrate the prospective utility of this and all of its DRP companion diagnostics to support their marketing.

Moreover, if and once these drugs are approved, we expect them to face commercial competition. All of the indications being targeted are rapidly evolving and there is already existing competition within the same drug classes. We believe the DRP will uniquely position these therapies among those in the same class, but the algorithm may change.

Finally, Allarity faces financing risk, as it will need significant additional capital to advance its development programmes. We expect it to attempt to address these capital needs at least in part

through the out-licensing of these assets in part of in whole, but we forecast a DKK870m shortfall if it was to bring these assets to market itself.

Valuation

Our valuation is slightly lower than previous estimates at SEK1,029m or SEK5.18 per share from SEK1,156m or SEK5.98 per share due to exchange rate effects and updated new cash.

Additionally, we have accounted for delays in the initiation of the Ixempra clinical program, which is now expected in early 2021 (from 2020 previously). Our valuation is based on a risk-adjusted NPV analysis of the future earnings potential of the company's assets. These are made with a series of assumptions outlined in Exhibit 5. In each case we assume the DRP will be used to select the top 20% of responders to the test, which will go on to receive the drug, although this value may eventually be higher or lower based on the results of Phase II clinical studies. We model commercialisation in the US and Europe for stenoparib and dovitinib and commercialisation in Europe alone for Ixempra. We assume pricing 25% lower in Europe than the US for stenoparib and dovitinib. We assume COGS of 10% for stenoparib and dovitinib and 15% for Ixempra, which includes undisclosed royalties payable to the licensors. We include \$10m in marketing overhead and a 10% cost of selling for each product once approved.

Exhibit 5: Valuation assumptions

Value driver	Indication	Incidence for subgroup (per 100,000)	DRP (top % most likely to respond to treatment)	Penetration
Stenoparib	Recurrent ovarian cancer with BRCA gene mutations	1.2	20	45%
Dovitinib	Second line metastatic RCC in combination with PD-1 or PD-L1 inhibitor	2.6	20	50%
Ixempra	3+ line metastatic breast cancer	9.6	20	25%

Source: Edison Investment Research

For dovitinib, our valuation is based on a scenario analysis of the upcoming NDA submission for the product. We do not expect the product to be commercially viable until after it is approved for use with the DRP, but the initial approval under the current NDA may streamline the process for a follow-up sNDA. We assume a 50% probability of success for the first NDA and a 75% to 85% probability of success on the subsequent submission (sNDA or NDA depending on the initial outcome).

We estimate pro forma net cash of SEK6.1m, which includes the SEK0.7m (DKK0.5m) in net debt at the end of Q320 (DKK0.2m cash offset by DKK0.7m in bank loans), and SEK6.9m in increased net cash from subsequent transactions (post-Q3) with Negma and Global Corporate Finance through the company's financing agreements. As explained below, these transactions raised SEK16.9m in added gross cash in the form of SEK10m in debt and SEK6.9m in equity.

Exhibit 6: Dovitinib scenario analysis

Step 1	Value/cost (SEKm)	Decision	Probability	Step 2	Decision	Probability	NPV for stage (SEKm)	Total adjusted NPV (SEKm)
NDA Novartis data	(16.29)	Approved	50%	sNDA	Approved	50%	931.53	457.38
				Not approved	50%	0.00	(4.20)	
		Not approved	50%	New NDA	Approved	35%	567.92	275.57
				Not approved	65%	0.00	(5.45)	
Total								723.29

Source: Edison Investment Research

Exhibit 7: Valuation of Allarity

Development Program	Indication	Clinical stage	Prob. of success	Launch year	Launch pricing	Peak sales (\$m)	rNPV (SEKm)
Stenoparib	Recurrent ovarian cancer	Phase II	25%	2025	\$138,000	51.3	131.8
Dovitinib	Renal cancer	NDA	35–50%	2024–25	\$145,000	176.4	723.3
Ixempra	Metastatic breast cancer	Phase II	50%	2025	\$41,000	56.4	167.5
Total							1,022.6
Net cash (Q320 + subsequent transactions, SEKm)							6.1
Total firm value (SEKm)							1,028.8
Total shares (m)							198.7
Value per basic share (SEK)							5.18
Dilutive warrants and options (m)							15.2
Fully diluted shares in issue (m)							214.0
Fully diluted value per share (SEK)							4.92

Source: Allarity reports, Edison Investment Research

Financials

Allarity recently reported an operating loss of DKK35.1m for the first nine months of 2020 (9M20) (vs DKK46.0m in 9M19). The biggest change to our financial projections is that we have delayed some of the costs associated with the initiation of the Phase II study of Ixempra to 2021 (from 2020 previously), which has reduced our expected 2020 operating loss to DKK49m from DKK97m. Additionally, we have adjusted for exchange rate effects and the company's recent financing. Other changes are small and include other minor adjustments to align the R&D timeline, such as moving the dovitinib NDA into early 2021. We expect Allarity to be a loss-making company in the near term as it finances its clinical development programmes. We expect an increase in operating costs in 2021 (DKK188m forecast operating loss) and thereafter as the company advances its development programmes.

Allarity has been supporting its capital needs recently through two financing agreements: a convertible debt agreement with Negma Group and Park partners (the Negma agreement) and a separate equity facility with Global Corporate Finance (the GCF agreement). Allarity announced in November 2020 that it had drawn a SEK10m convertible debt tranche with Negma. In October 2020, the company announced a share-based financing with Global Corporate Finance (5.37m shares at SEK1.74 per share).

We expect the company to need additional capital to complete its clinical programmes, but the recent financings have reduced our expected financing to DKK870m from DKK915m previously. We expect the company to need additional capital in 2020 to avoid running a deficit. We include this financing in our forecasts as illustrative debt (DKK90m in 2020, DKK400m in 2021 and DKK380m in 2022). We expect Allarity will try and meet some of these financial needs through licensing its assets either in part or in whole, but it may face dilution if it seeks this cash on the capital markets.

Exhibit 8: Financial summary

	DKK000s	2018	2019	2020e	2021e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		2,147	801	901	901
Cost of Sales		0	0	0	0
Gross Profit		2,147	801	901	901
EBITDA		(32,258)	(66,502)	(55,042)	(187,051)
Operating Profit (before amort. and except.)		(32,471)	(148,102)	(56,100)	(188,109)
Intangible Amortisation		0	0	0	0
Exceptionals/Other		0	0	7,099	0
Operating Profit		(32,471)	(148,102)	(49,001)	(188,109)
Net Interest		(192)	(26,822)	1,680	(4,666)
Other		10,146	0	0	0
Profit Before Tax (norm)		(22,517)	(174,924)	(54,420)	(192,775)
Profit Before Tax (IFRS)		(22,517)	(174,924)	(47,321)	(192,775)
Tax		6,973	36,792	5,225	3,671
Deferred tax		0	0	0	0
Profit After Tax (norm)		(15,544)	(138,132)	(49,194)	(189,104)
Profit After Tax (IFRS)		(15,544)	(138,132)	(42,095)	(189,104)
Average Number of Shares Outstanding (m)		33.8	63.4	161.2	208.7
EPS - normalised (DKK)		(0.44)	(2.08)	(0.31)	(0.91)
EPS - IFRS (DKK)		(0.44)	(2.08)	(0.26)	(0.91)
Dividend per share (ore)		0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets		237,096	158,895	176,482	175,443
Intangible Assets		236,733	155,978	169,150	169,150
Tangible Assets		363	2,917	2,072	1,033
Other		0	0	5,260	5,260
Current Assets		14,401	22,306	86,151	307,864
Stocks		0	0	0	0
Debtors		5,262	5,937	3,019	18,966
Cash		1,547	10,176	75,104	277,197
Other		7,592	6,193	8,028	11,700
Current Liabilities		(35,407)	(31,497)	(17,930)	(27,707)
Creditors		(16,515)	(27,919)	(17,228)	(27,005)
Short term borrowings		(18,892)	(3,578)	(702)	(702)
Long Term Liabilities		(34,234)	(8,370)	(106,747)	(506,747)
Long term borrowings		0	0	(98,865)	(498,865)
Other long term liabilities		(34,234)	(8,370)	(7,882)	(7,882)
Net Assets		181,856	141,334	137,956	(51,148)
CASH FLOW					
Operating Cash Flow		(31,392)	(54,511)	(54,016)	(197,888)
Net Interest		(2,391)	(26,846)	648	0
Tax		6,159	8,942	4,187	0
Capex		0	(56)	(19)	(19)
Acquisitions/disposals		9,855	0	(13,365)	0
Financing		198	62,715	24,832	0
Dividends		0	0	0	0
Other		(3,299)	(4,253)	(423)	0
Net Cash Flow		(20,870)	(14,009)	(38,155)	(197,907)
Opening net debt/(cash)		(3,326)	17,345	(6,598)	24,463
HP finance leases initiated		0	0	0	0
Exchange rate movements		(199)	(98)	(230)	0
Other		398	38,050	7,324	0
Closing net debt/(cash)		17,345	(6,598)	24,463	222,370

Source: Allarity reports, Edison Investment Research

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Management team	
CEO: Steve Carchedi Steve has served as CEO and a director of Allarity Therapeutics since September 2019. He was previously president and chief executive officer of Apexian Pharmaceuticals, an early-stage oncology discovery and development company focused in novel targets to treat cancer, and earlier served as chief executive officer of Raphael Pharmaceuticals (formerly Cornerstone Pharmaceuticals), an oncology company focused in cancer metabolism. Earlier in his career, Steve served as the senior vice president and president, commercial operations (North America) for Mallinckrodt Pharmaceuticals leading the company listing on NYSE. In addition, he previously held senior leadership positions at General Electric, Johnson & Johnson, Eli Lilly & Company, and Bristol Myers Squibb. In addition to his executive experience, Steve serves on the board of directors of Sunesis Pharmaceuticals and Bionumerik Pharmaceuticals.	CFO: Henrik Moltke Henrik joined the executive team in 2019. The primary focus in his career has been in venture financing, including IPOs as well as follow on capital increases in the public markets, investor relations, finance, project management, and strategic development. Henrik has formerly served in such senior roles with companies like Scandinavian Micro Biodevices, Astion Pharma, NeuroSearch, Novo and Ferrosan. He has also a broad financial and managerial experience from several listed and unlisted companies as member of their Boards of Directors. Henrik holds a master's degree in international economics and strategic management from Copenhagen Business School, Denmark. Henrik is a member of the board of directors of Initiator Pharma and Hartmanns.
CSO: Steen Knudsen Steen is the founder of Oncology Venture (now Allarity Therapeutics) and the inventor of DRP, which is Allarity's core technology and science platform. Knudsen is a professor of systems biology with extensive expertise in mathematics, bioinformatics, biotechnology, and systems biology.	CMO: Marie Foegh Marie leads clinical development of the company's precision medicine oncology pipeline. She previously led the successful development and regulatory approval of more than 10 novel drug products in the US and UK, within oncology, endocrinology and cardiology. Marie has fluency in regulatory interactions with the FDA and EMEA, including INDs, NDAs, IDEs (for predictive biomarkers and/or companion diagnostics), and product issues. She also manages interactions with the oncology key opinion leaders that sit on the scientific advisory board. She holds both Medical Doctorate and Doctorate of Science degrees, and is a member of the American College of Physicians, American Medical Association, the American Society of Clinical Oncology, and the American College of Obstetricians and Gynecologists.
Principal shareholders	(%)
UBS	5.9
Sass & Larsen	18.6
Steen Meier Knudsen	3.1

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