5th October 2016

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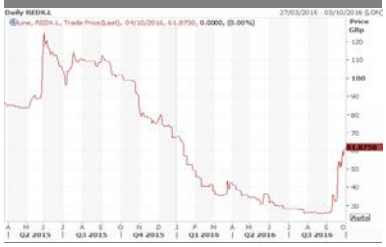
Pharmaceuticals & Biotech



Source: Eikon Thomson Reuters

Market data

EPIC/TKR	REDX
Price (p)	61.3
12m High (p)	102.9
12m Low (p)	23.0
Shares (m)	93.6
Mkt Cap (£m)	57.4
EV (£m)	45.6
Free Float*	57%
Market	AIM

**As defined by AIM Rule 26*

Description

Redx Pharma is a drug discovery and development company, focused on creating best-in-class new drugs in the areas of cancer, infection and autoimmune disease. The company's work has been endorsed by partnerships with global pharma companies and the NHS

Company information

CEO	Neil Murray
CFO (interim)	Andrew Booth
Chairman	Frank Armstrong
	07491 651 406
	www.redxpharma.com

Key shareholders

Directors	11.7%
Seneca Partners	11.4%
Jon Moulton	10.7%
AXA Framlington	9.8%
Aviva	7.2%
Alderley Park Holdings	4.7%

Events

Aug-16	Hardman update
Oct-16	Trading update
Jan-17	Finals

Analysts

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Redx Pharma

Porcupine inhibitor enhances anti-PD-1 effect

Although Redx has only been in operation since late-2010, it has already created several valuable drug candidates that are about to begin clinical development. Progress into the clinic will enhance significantly the value of these drug candidates as well as providing further technical validation of the company's approach. Redx recently announced that its porcupine inhibitor (RXC004) has a potential role in cancer immunotherapy. Redx has now confirmed that RXC004 enhances the effect of a PD-1 checkpoint inhibitor in animal studies.

- **Strategy**: To discover 'best-in-class' drugs in therapeutic areas of significant commercial interest and, on a selective basis, to take those assets through early clinical development. Redx is focused on licensing out assets to drug major(s) for late-stage development and commercialisation to secure optimal returns.
- **Porcupine (PORCN) inhibitor:** With RXC004, Redx is targeting a cell signalling pathway that controls the spread and recurrence of cancer as well as resistance to other treatments. In pre-clinical studies, Redx has demonstrated the implication of PORCN inhibitor in the field of immuno-oncology.
- **First-in-man trial:** In early 2017, Redx is planning to commence a first-in-man study with RXC004 for hard-to-treat cancers such as pancreatic, gastric and biliary cancers. This will also represent the first project that Redx has brought into the clinic since its creation in 2010.
- **Valuation:** Redx has established itself as a well-run company, building a broad portfolio of pre-clinical assets. Out-licensing at the pre-clinical stage generates on average $17-20m in up-front payments and milestones. Taking some of these assets into early clinical development moves the asset up the value chain significantly, where up-front payments of $40-50m are common, accompanied by better milestones and higher long-term royalty streams.
- **Risks:** Clearly not without financial risk, however, Redx's strategy and breadth of portfolio reduces the binary risk seen with single product companies. Also, timing of licensing deals is difficult to predict, but management has established already a track record of securing deals (including AstraZeneca, NHS, Horizon, Pierre Fabre). There is clear precedent that pharma/biotech is willing to pay high prices for assets, reflecting the level of de-risking undertaken by the developer.
- **Investment summary:** Redx offers investors access to a highly versatile and successful discovery engine, geared specifically towards clinically differentiating its assets to achieve potentially best-in-class and first-in-class status, which in turn should translate into highly valuable assets. The market reacted quickly and positively to this announcement that the PORCN inhibitor programme is moving up the value chain, as evidenced the ca50% jump in the share price.

RXC004 – porcupine inhibitor

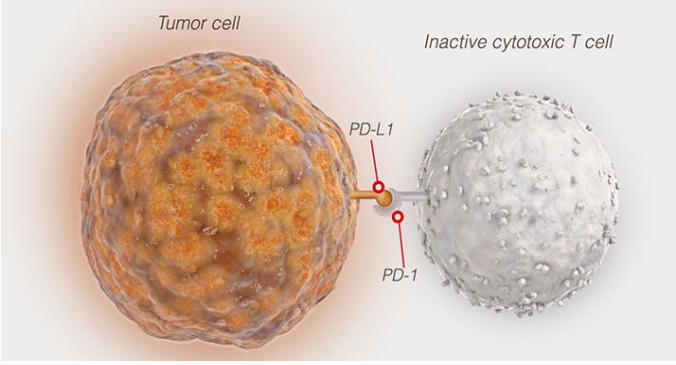
Enhances effect of PD-1 checkpoint inhibitors

On 19th September, Redx announced that RXC004, its lead Porcupine (PORCN) inhibitor, enhances the immune system response when used in combination with a PD-1 checkpoint inhibitor in animal studies. With this *in-vivo* experiment, Redx has confirmed further the assumption that the Wnt pathway, and more specifically, a PORCN inhibitor, has a role in cancer immunotherapy.

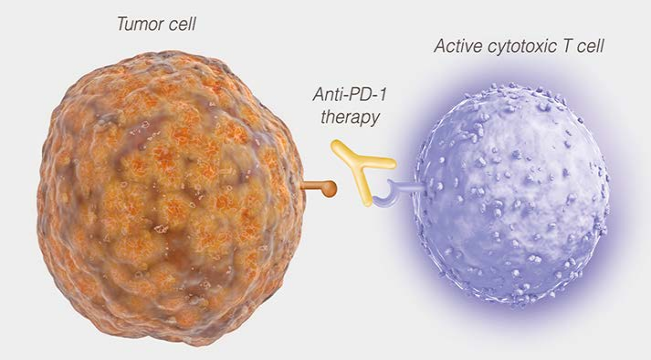
This pre-clinical experiment demonstrated that RXC004 improves the effect of a checkpoint inhibitor in a colon cancer model. Combination therapy with a PD-1 checkpoint inhibitor increased significantly the ratio of cytotoxic T-cells (which attack tumours) to the regulatory T-cells (that downregulate the immune system) in the tumour micro-environment, when compared to using anti-PD-1 therapy alone.

Role of PD-1 in immuno-oncology

Inactivation of T-cells reduces tumours cell death and elimination



Blocking PD-1: active T-cells, tumour cell death and elimination



Source: Dako website

Checkpoint inhibitors prevent the ability of cancer cells to interfere with these checkpoints and make them visible to killer T-cells. Clinical studies on different checkpoint inhibitors have shown notable therapeutic effects against a wide range of cancers. However, with response rates in the region of 20-40% range, many cancer patients clearly do not respond to treatment. Moreover, they have also been associated with numerous severe side effects, some of which are use limiting.

The experiment performed by Redx suggests that a combination of RXC004 and an anti-PD-1 could potentially improve the rate of patient rate response, expanding the use of checkpoint inhibitors.

Porcupine inhibitor RXC004

RXC004 is Redx's small molecule inhibitor of the Porcupine protein. This patented reagent is the lead development candidate to be used in hard-to-treat cancers such as pancreatic, gastric and biliary cancers.

Pre-clinical results

Pre-clinical results demonstrated that RXC004, an orally bioavailable small molecule, was shown to be as effective as a stand-alone therapy in a hard to treat cancer model, such as pancreatic cancer.

- Improved potency and oral once-daily dosing regimen
- *In vivo* proof-of-concept has been achieved in only 14 months – Efficacy was achieved in a pancreatic cancer xenograft model
- RXC004 was well tolerated in rat tolerance studies

Phase I clinical trial

RXC004 first-in-man trials are expected to start early in 2017. This will represent a considerable achievement by the company, taking less than 38 months to reach this stage from concept, meaningfully quicker that the industry average. It represents also an important milestone as it will be the first programme Redx brings into the clinic since its creation in 2010. Consequently, Redx is evaluating the opportunities for a clinical trial using a combination of RXC004 and a checkpoint inhibitor.

RXC004 manufacture agreement for first-in-man trials

Redx has entered into an agreement with Quay Pharma to manufacture the small molecule RXC004. Quay pharma is a UK-based specialist GMP contract development, manufacturing and packaging organisation that will formulate and produce the capsules for Phase I trials. Its regulatory approved facilities can support clinical development from Phase I to Phase III.

Oncology pipeline

Redx has developed a portfolio of small molecule inhibitors to receptors/targets that are of significant commercial and scientific relevance. These include SMO, PORCN, BTK, and pan-raf inhibitors, three of which have reached candidate nomination stage (SMO, BTK and PORCN).

Oncology pipeline	
Programme	**Description**
SMO inhibitor (RXC001)	Implicated in skin, brain and blood cancer. Achieved preclinical proof-of-concept (POC). Candidate topical drug identified with focus on Basal Cell Carcinoma (BCC)
Porcupine (PORCN) inhibitor (RXC004)	Implicated in pancreatic, gastric and biliary cancers. Achieved pre-clinical POC and development candidate drug identified
BTK (reversible) inhibitor	Aimed at treating ibrutinib resistant Chronic Lymphocytic Leukaemia (CLL)
IDO inhibitor	Implicated in solid tumours such as skin and lung cancer
Pan-raf inhibitor	Implications in colorectal cancer

Source: Company reports

Porcupine

The porcupine protein is a key target implicated in the maintenance of cancer stem cells in multiple cancer types that lead to the recurrence of tumours. It is a key target within the Wnt pathway, an embryonic signalling pathway linked with maintenance of cancer stem cells (CSC), which leads to the recurrence of tumours after successful initial treatment, as well as the resistance of tumours to potential cancer therapies. The target is also believed to have an emerging role in the field of immuno-oncology with the potential to be combined with checkpoint inhibitors. There is strong evidence that the Wnt pathway is also involved in immunity and Redx is assessing whether RXC004 can also directly stimulate the immune system to tackle the cancer.

The PORCN protein within the Wnt pathway has generated substantial external interest given that Novartis has taken its lead compound (WNT974) into Phase I/II trials. Redx believes this could potentially result in a best-in-class drug, given its improved potency and pharmacokinetic (PK) profile.

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