Next Generation Companion Diagnostics for Kinase Inhibitor anti-cancer therapies

Key benefits

- **Accurate ranking of the kinase activities in a patient's tumour**
- **Patient specific therapies identified that can effectively treat haematological and other cancers**
- **Three patent families that cover unique algorithms for KinoScan™ platform**
- **End result is a greater market size of likely drug responders compared to that achieved by current companion diagnostic tests**
- **First product biomarker panel test kit for AML therapy**

Executive Summary

Kinomica Ltd operates as an R & D and contract for services company in the field of stratified medicine for cancer. Kinomica is a spin out company from Barts Cancer Institute, Queen Mary University of London. **KinoScan™** is based computational tools that extract clinically relevant information from mass spectrometry based phosphoproteomics data following analysis of tumour biopsies. Using **KinoScan™** clinicians can tailor a personalised treatment regime with greater chance of sustained response.

Economic incentives for superior companion diagnostics are compelling: (i) drug developers can achieve faster time to market with less expensive clinical trials; (ii) regulators see the potential for more directed regulatory submissions with fewer adverse events; (iii) patients are more appropriately treated; and (iv) payers see the potential reduced cost of unnecessary treatments.

Although Kinomica will initially focus on cancer, the approach can also be applied to other therapeutic areas such as autoimmune diseases, rheumatoid arthritis and neurological diseases.

"The kinase inhibitors market is expected to see a staggering growth with the current market valued at $15 billion in 2012 and anticipated to reach $36 billion in 2018 with a CAGR of 8 to 9 % from 2012 to 2018."

(http://www.transparencymarketresearch.com/kinase-inhibitors.html)

Background

- Kinases are involved in key signalling pathways that regulate cell replication, growth, metabolism and death
- Signaling pathways dysregulated in cancer, autoimmune and inflammatory diseases
- Aberrant phosphorylation profiles associated with diseased state and progression
- Kinase inhibitor drugs can reduce cancer cell viability where tumour cells are dependent on or addicted to the targeted kinase for proliferation and spreading
- Precision medicine approach to stratify patients based on the kinase addiction for the tumour

The Market- the case for accurate protein kinase profiling

- Important drug targets (Gleevec $4.7B in 2014, Mekinist predicted $2.4 billion by 2020)
- Oncaspar used to treat ALL(acute lymphoid leukaemia) costs $146,000 per patient – Trametenib costs $200,000 p.a.

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- US Food and Drug Administration (FDA) has approved Rydapt® (midostaurin, formerly PKC412) for two indications. The first indication is for the treatment of acute myeloid leukemia (AML) in newly diagnosed patients who are FMS-like tyrosine kinase 3 mutation-positive (FLT3+), as detected by an FDA-approved test
- Rydapt sales 2018 est. $351M
- 42 drugs targeting kinases approved (100+ in pipeline) - indications in cancer, autoimmune and inflammatory diseases
- A wider market exists for some kinase inhibitors in additional cancer types

Patents Summary

- Unique method of providing automated, rapid analysis of kinase activities - important molecules involved in cell cycle regulation by phosphorylation
- Platform technology has identified panel of novel biomarkers that can identify AML patient response to Kinase inhibitors
- Unique drug characterization capacity – including elucidation of mode of action and identification of resistance mechanisms
- Significant pharma pipeline of kinase inhibitor drugs that can be tested using this technology for pharma/biotech customers - includes CfS offering under business model
- AML biomarkers. Prognosis for most patients with AML is poor. Current therapies are ineffective in many patients; only a minority of patients achieve a durable remission, and the overall five-year survival rate is low at around 25%. Method for predicting whether AML can be effectively treated with one or more kinase inhibitors selected from different kinase inhibitors including those that target FLT3, PAK, MAPK and RAS downstream kinases

Patent references

1. Method of systematic identification of regulatory protein kinases (KSCORE) (PCT) Application No: PCT/EP2016/077845 Cutillas et al

2. Method WO 2013/132075 A1; Kinase Substrate enrichment analysis (KSEA)

3. A method of assessing protein modification status and identifying biomarkers linked to cell signalling pathways PCT/GB2016/0516319

What is the title of the AML patent?

Link to inventor's website; https://www.bci.qmul.ac.uk/en/staff/item/pedro-cutillas

Inventors:

- World leading specialists & facilities – Barts Cancer Institute (BCI)
- Close ties with Barts Health Trust - serving over 3M people
- BCI - largest recruiter in clinical trials in UK - world leaders in Cancer Research
- Access to the large bio-bank of cancer tissues
- Team with clinical oncology, proteomics and commercial management experience

Kinomica is seeking to establish additional partnerships with pharma companies and investors to support core resources and planned R&D programmes. The Kinomica Business Plan is available on request.

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