Race Oncology Ltd

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Specialty Pharma company focused on fast-to-market opportunities

Race Oncology is a specialty pharmaceutical company focused on rediscovering or repurposing overlooked drugs that can deliver early commercial milestones.

The Company's business model is to pursue later stage drug assets with an opportunity to bring them to market quickly.

Drug Asset - Bisantrene

Race Oncology's first asset is Bisantrene, a small molecule chemotherapy drug that can be used for Acute Myeloid Leukaemia (AML).

Bisantrene is related to the anthracyclines, the most frequently prescribed cancer drugs and first line of treatment for many cancers, and has been shown to have greatly reduced cardiac toxicity.

Bisantrene was tested in more than 40 phase II clinical studies before it was lost in a series of pharmaceutical mergers in the 1990s. It showed activity in several cancers, notably AML, where in five studies it produced an average CR rate (complete clinical response) of 48% in heavily pre-treated and/or refractory patients. The initial clinical opportunity for Bisantrene is for such relapsed/refractory AML patients.

Race has filed two patents on the drug and has been granted an Orphan Drug Designation in the USA for AML – conferring 7 years of market exclusivity in US from date of FDA approval.

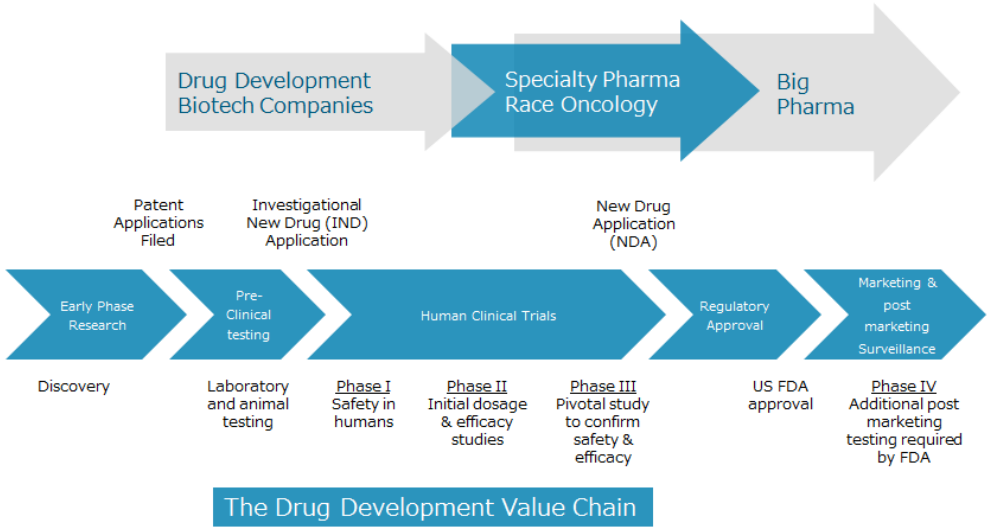
Commercialisation Strategy

Race is pursuing two pathways simultaneously, both of which are expected to deliver value in the short term.

General marketing approval in the US

FDA approval would allow Race to market Bisantrene in the US and provide the springboard for approval in all other markets. The Company aims to file an IND (Investigational New Drug application) within the next few months to re-enter the FDA clinical trials and approvals process.

In a pre-IND meeting, the FDA confirmed that the proposed development of Bisantrene qualifies for the 505(b)(2) accelerated development pathway. This allows Race to use the large database of historical preclinical and clinical data on Bisantrene. Bisantrene could potentially be approved in the US after a single pivotal study.



The Drug Development Value Chain

European Named Patient Program (NPP)

Race plans to start selling Bisantrene in a small number of qualifying European countries under a Named Patient Program ("NPP"). NPP is essentially 'compassionate use', where a patient has exhausted available treatment options. In certain countries, like France, Italy and Turkey, it is possible to sell a drug to those patients (or to the treating hospitals) and make sales. For Race, these sales of Bisantrene should not only provide operating cash flow, but also help establish commercial proof of principle for the drug while Race prosecutes the US FDA approval pathway.

Race has signed an agreement with CarthaGenetics, a European NPP specialist, to manage its European NPP sales. Recently, Race also signed a license and sales agreement with BL&H for NPP sales in South Korea. The Company intends to seek licensees for other countries where profitable NPP sales can be made.

A closer look at Bisantrene

Bisantrene is a chemotherapy drug used for Acute Myeloid Leukaemia (AML). AML is a blood cancer (leukaemia):

- Caused by proliferation of immature immune cells from bone marrow
- Orphan disease - around 20,000 new patients a year in the US
- Disease mainly of the elderly and incidence growing as population ages
- AML progresses rapidly and has a poor long-term prognosis once patients relapse

The primary treatment of AML has not changed in over 30 years and there is no approved or effective treatment for relapsed/refractory AML.

Bisantrene is also active against breast cancer, lymphoma & ovarian cancer.

Race Oncology key investment highlights

- Specialty pharmaceutical company with low risk business model
- Low base operating cost and expedited path to market
- World-class team with deep oncology and commercial experience
- Bisantrene: late-stage clinical asset that could be approved in the US after a single pivotal trial
- Early sales under NPP in Europe and Korea