Biotech Daily

Monday September 18, 2023

Daily news on ASX-listed biotechnology companies

Biotech Daily Editorial: It's A Long Way To The Top

Accepting an award from the Victoria Governor many years ago, then CSL chief executive officer Dr Brian McNamee said: "In the glacial timelines of biotech, we have taken Gardasil from lab bench to blockbuster in 17 short years."

The approval of Glaxosmithkline's Ojjaara, formerly Cytopia's CYT387, raises the question, again, of why some Australian investors can't benefit from our drug know-how. I say some, because CSL is the exception to the rule, inventing drugs in Australia and returning dividends to investors.

On Friday afternoon in the US, the molecule first known as CYT387 - which was sold to YM Biosciences for $14 million, then to Gilead for $US510 million, then to Sierra for $US3 million upfront and finally to Glaxosmithkline for $US1.9 billion - was finally approved - and may well become a blockbuster for myelofibrosis, and potentially other blood cancers.

The last Australian drug to be taken to US Food and Drug Administration approval was Neuren's trofinetide, now Acadia's Daybue. Giaconda's antibiotic combination Heliconda was bought by Israel's Redhill Biopharma in 2010, renamed RHB-105 and later Talicia. It earned $US5.1 million in the six months to June 30, 2023.

Chemgenex took Omapro (Synribo) all the way through the regulatory process, apart from the final details shepherded by Cephalon-Teva. Like Clinuvel's Scenesse, although a great deal of development and regulatory progress was achieved by the Australian company, the original molecule was bought-in. Pharmaxis similarly won approvals for its mannitol-based Aridol and Bronchitol.

The only other original drugs we can recall that have gone all the way were the Acrux combinations of generic oestrogen and testosterone in generic alcohol and generic sun cream and Hatchtech's Xeglyze for headlice and their eggs.

The Adelaide-based FH Faulding & Co had FDA approval for its Eryc, Doryx and Kadian as modified release versions of erythromycin, doxycycline and morphine.

On the other hand, there are many devices and diagnostics with global approvals: Telix's Illucix, Sirtex Sir-Spheres, Nanosonics Trophon EPR, Cellestis Quantiferon-TB Gold, Compumedics brain diagnostics, Uscom's cardiac output monitor, Control Bionics Neuronode, Adherium's Hailie puffer monitor and Respiri's Wheezo asthma monitor.

But the FDA is finicky about drugs going into bodies and success has been few and far between.

While it is gratifying to know that Glaxosmithkline could take Cytopia's molecule all the way, how much better would it have been if the original team, including then chief executive officer Andrew Macdonald, Prof Andrew Wilks, Dr Chris Burns and the hundreds of investors – including this writer – could have had a share of the royalties.

The answer seems to be the need for much greater capital availability. Cytopia was sold to YM because it ran out of money and couldn't raise what it needed.

The sector was very young back then and even if we did know then what we know now, there was never a guarantee that CYT387 would be successful, which is why we have large, randomized, controlled trials.

And they aren't cheap.

David Langsam
Editor