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Special Edition

US FDA Approves GSK Ojjaara (Cytopia's CYT387) For Myelofibrosis

Prof Andrew Wilks says that after 20 years of development, the US Food and Drug Administration has approved Ojjaara (Cytopia's CYT387) for myelofibrosis.

Prior to founding Cytopia, Prof Wilks and his team at Melbourne's Ludwig Institute for Cancer Research discovered and developed a suite of patents around JAK1 and JAK2 which were licenced by Cytopia, which he led with and Dr Chris Burns, now the chief executive officer of Amplia Therapeutics and Andrew Macdonald.

A media release from Prof Wilks said the JAK enzymes were the protein targets of Ojjaara, formerly known as momelotinib and CYT387.

The announcement said that Cytopia was founded in 1999 and listed on the ASX in 2004.

Prof Wilks said he was currently a managing-director at Synthesis Bioventures.

Dr Burns told Biotech Daily that "originally JAK was 'just another kinase' but it was formally named a Janus kinase for the Roman god of doorways".

"Like Janus, the kinase has two faces - binding to growth factors and cytokine receptors," Dr Burns said.

Dr Burns said that the "mel" in momelotinib was a reference to the Melbourne invention of the drug. Glaxosmithkline changed the name to Ojjaara.

In 2009, the then ASX-listed Cytopia said it would be acquired by the Toronto-based YM Biosciences for 16.59 cents a share or $14 million (BD: Oct 6, 2009).

In 2011, YM Biosciences said that raised $US46 million for Cytopia's CYT387, having acquired the company in January 2010 (BD: Mar 18, 2011).

YM said at that time that data suggested that CYT387 was able to significantly improve the symptoms of patients with myelofibrosis, a frequently fatal bone marrow disorder.

In 2012, Gilead Sciences said it would acquire YM Biosciences for $US510 million, whose lead drug was the Melbourne-developed CYT387 (BD: Dec 13, 2012).

It has been widely reported that in 2018, Gilead sold the drug to Vancouver's Sierra Oncology for $US3 million up-front; and last year Sierra sold CYT387 to Glaxosmithkline for $US1.9 billion ($A2.9 billion).

This week, Prof Wilks said that CYT387 or momelotinib "was the only asset of Sierra Oncology which was ultimately acquired by GSK in 2022 for US$1.9 billion in an all-cash deal, making it the highest acquisition amount paid for a drug invented in Australia".

In June, Glaxosmithkline said that FDA Prescription Drug User Fee Amendments (PDUFA) date for momelotinib had been delayed by three months "to provide time to review recently submitted data" with a new date of September 16, 2023.

This week, the media release said that while Ojjaara was approved initially as a treatment for the bone cancer myelofibrosis, the molecule had "the potential to gain additional approvals for treating a number of inflammatory diseases".

Prof Wilks said that FDA approval for Ojjaara was "not only a personal victory but a triumph for the many scientists and clinicians with whom he worked across Australia".

"Australia punches above its weight in terms of life science discoveries," Prof Wilks said.

"And whilst government support drives the scientific sector, there needs to be a culture change for scientists to understand the commercial opportunities," Prof Wilks said.

"Despite Melbourne boasting one of the world's leading biomedical precincts in Parkville, Australian scientists often face a shortage of experience and capital required to maximize the value of their inventions," Prof Wilks said.

Prof Wilks said that Synthesis Bioventures is a fund focused on early-stage therapeutics, investing in projects from discovery through pre-clinical proof-of-concept and FDA investigational new drug application-enabling studies.

He said the fund invests in small molecule therapeutics, biologics, and cell and gene therapies for indications with significant unmet needs.

Biotech Daily editor David Langsam held shares in Cytopia at the time.