Picato® (ingenol mebutate) gel: Case Study

Picato® is a prescription gel that treats skin actinic keratosis (potentially pre-cancerous sunspots). The journey to develop this product began in the 1970s when Queensland researcher, Jim Aylward, became interested in a local farming story about the healing properties of the sap of the radium weed Euphorbia peplus (E. peplus) when applied to sunspots on the skin.

**Origin**

Dr Jim Aylward began researching the sap of E. peplus in earnest in 1977. His early studies showed that the sap had a profound effect on melanoma cells in vivo. On this basis, he lodged a provisional patent application and established a company with his CSIRO manager which he named Peplin Biotech Pty Ltd. He had 12 months to find the active principle and complete the patent in August. His patent subsequently claimed a family of ingenol analogues including PEP005 (ingenol mebutate). Further research in collaboration with another QIMR Berghofer research team, led by Professor Peter Parsons.

In 1988, Aylward managed to extract and purify active compounds in the sap, including acetyl ingenol angelate, and completed the patent in 1998. Aylward’s new drug has led to more than $4.5 million in research funding to the Parsons and Suhrbier laboratories. E. peplus has been grown for commercial purposes on farms in Queensland. Outside of its native range it grows widely, including in Australia, New Zealand, North America and other temperate and sub-tropical regions.

**Grants and Investment**

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Dr Jim Aylward

**Professor Peter Parsons**

Professor Parsons holds a PhD in Organic Chemistry. He is the Group Leader of the Drug Discovery Group at QIMR Berghofer, and Honorary Professor, School of Medicine, University of Queensland. Professor Parsons has extensive knowledge and experience in preclinical drug development. His research focuses on preclinical research in tumour and on novel therapies for melanoma and other tumours. He has been a member of QIMR Berghofer’s National Cancer Drug Discovery Centre for Drug Development since it was established in 2001, and has been recognized as an expert in drug development for melanoma.

Dr Steven Ogbourne

Dr Steve Ogbourne is a Senior Research Fellow of Plant Biotechnology, University of the Sunshine Coast, with a background in plant science and molecular biology. His current research is focused on the use of plant cell culture technology to produce drugs and vaccine components. He has been involved with several product development and commercialization projects with both academic and industry partners.

**Professor Andreas Suhrbier**

Professor Suhrbier is Group Leader of the Information Biology Group at QIMR Berghofer, and Honorary Research Fellow with NHMRC and Adjunct Professor at Griffith University, James Cook University, and the University of Queensland. He has over 160 publications in international peer-reviewed journals, and on novel therapies for melanoma and other tumours. Professor Suhrbier has a strong background in drug development, having co-founded a medical research company and conducted collaborative R&D with, a number of international biotechnology and pharmaceutical companies, including Peplin (from 1999 to 2009) and LEO Pharma (from 2016-2020).

**Dr Sarah-Jane Cozzi**

Dr Sarah-Jane Cozzi is the Medical Scientific Liaison for Pfizer Biotechnology, University of the Sunshine Coast. In this role, she has worked closely with the Australian Therapeutic Goods Administration (TGA) to develop and manage the Picato® clinical trial programme and its associated regulatory requirements, culminating with the TGA approval and subsequent listing.

Dr Ogbourne’s pain management centre of excellence has been recognized as an industry leader in the field of pain management, with a number of international biotechnology and pharmaceutical companies, including Peplin (from 1999 to 2009) and LEO Pharma (from 2016-2020).