

## Pharmaxis appoints Gary Phillips as new CEO

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**Singapore:** The Pharmaxis board has appointed Mr Gary Phillips to the position of chief executive officer with immediate effect. Mr Phillips has served as the company's chief operating officer for five years, having started with Pharmaxis when it listed on the Australian Securities Exchange in 2003.

Dr Alan Robertson steps down and will leave the company after 13 years of service as the founding chief executive officer. He has agreed to assist Pharmaxis in a consulting capacity to help the company generate value from its pipeline of early-stage assets.

Mr Malcolm McComas, Pharmaxis chairman, said, "Pharmaxis is facing likely delays in the commercialization of Bronchitol in the US. Gary Phillips will review the current business model and implement a number of changes aimed at securing Pharmaxis' position as a commercially successful pharmaceutical company and maximise shareholder value. Gary has more than 30 years experience in the pharmaceutical sector and was previously a CEO of Novartis group of companies in Europe, Asia and Australia. He has an exceptional knowledge of all aspects of the Pharmaxis business worldwide and a strong relationship with all of our major stakeholders."

"We thank Alan Robertson for his contribution to Pharmaxis since its inception as a venture capital funded start-up. He has created a substantial business and has led the development of a much needed, novel treatment for cystic fibrosis. The Board acknowledges his vision and tenacity in steering Bronchitol and Aridol through complex clinical trials, regulatory approvals and reimbursement processes in global markets."

Dr Alan Robertson said, "The company is on a solid footing with a strong cash position and with both Aridol and Bronchitol approved in many countries and generating revenue. The path to regulatory approval for Bronchitol in the US is still to be resolved; however, I remain optimistic that a satisfactory outcome will be reached. I look forward to the continued success of the company and to turning my attention to new challenges and horizons, especially providing advice and support in development of the potential new drugs in the Pharmaxis pipeline."

Mr Phillips said: "We have overcome a number of hurdles to bring Bronchitol to cystic fibrosis patients in Europe and Australia and recently secured additional funding through a financing agreement with NovaQuest. It is vital that we now focus our resources on maximising the growth of Bronchitol's sales while at the same time accelerating the addition of new territories." Mr Phillips also outlined some of the key initiatives to be undertaken in the near future:

### **US Food and Drug Administration (FDA) response**

The company is expecting to receive a response from the FDA next week concerning its application for marketing approval for Bronchitol in cystic fibrosis patients aged 6 and above. Pharmaxis anticipates it will need to request a meeting with the FDA in the second quarter of calendar 2013 to clarify any additional requirements the FDA may have. The company remains committed to making Bronchitol available to the world's largest cystic fibrosis market.

### **Bronchiectasis**

Bronchitol remains the only airway clearance product worldwide in phase 3 clinical trials for bronchiectasis. There are no products currently approved for this serious respiratory disease affecting many hundreds of thousands of people. The company's current trial (B305) is the largest and longest study ever conducted in bronchiectasis, and reached a major milestone last week when the last patient in the study had their last clinic visit. The primary endpoint of the study is a reduction in exacerbations. The data from the study will soon be collated and analysed. Pharmaxis expects to report the top line results in the second quarter of calendar 2013. The result from B305 will have significant implications for Bronchitol - potentially providing access to significant markets. The outcome is, therefore, central to the company's review of its business model.

### **Growth of Bronchitol**

Pharmaxis is approaching a 10 percent market share of adult patients in Germany and continues to make steady progress month by month. The company is learning more about how the product is being used and has a number of initiatives planned for the months ahead to improve growth rate and patient adherence. Clearing reimbursement hurdles in the remaining EU countries is a challenge given the current economic climate and fast changing regulations. Pharmaxis has, however, succeeded in England which perhaps has the most rigorous process and is pushing as fast as possible into other EU markets.

Restrictive entry criteria for reimbursement has led to a slower than expected uptake of new patients. The company is continuing to work with the Australian government to refine the wording of these restrictions.

The company aims to leverage the approvals it has in Europe and Australia to enter new markets in Eastern Europe, the Middle East and South America. Progress in this regard will be reported in the second quarter of calendar 2013.

The outcome of the likely meeting with the FDA regarding Bronchitol and the outcome of the B305 trial are key to determining any necessary changes to the company's business model. There will be clarity around both issues in the second quarter of calendar 2013 and more specific guidance on the changes will be provided at that point.

### **Generating value from pipeline of early stage assets**

The company has a number of new projects in various stages of development. In the coming six months, it will be assessing a range of options to fund some or all of these programs through to clinical trials. Assets that fall into this category are Oligonucleotide portfolio; Orbital; PXS4728  $\mu$ V; LOX / LOXL2 Inhibitor Program; and PXS64/PXS25.

Mr Phillips concluded: "I look forward to reporting on the outcomes of discussions with the FDA and the results from the bronchiectasis trial in coming months. Further updates on the initiatives outlined above will be provided as matters progress. I am confident that we have both the team and resources to successfully navigate the challenges facing the company."

Mr Phillips has been appointed to the Pharmaxis board of directors effective March 14, 2013. The company is in the process of finalising details of his appointment terms which will be disclosed to the market when concluded.

