

## Imugene progresses Vitamin D development program

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### Highlights

- **Selected Linguet™ Vitamin D products to commence human trials in 2013**
- **New patent application filed to protect Linguet™ formulations**

**Melbourne, 23 May 2013:** Australian drug development and pharmaceutical company Imugene (ASX.IMU) is pleased to provide an update on its Vitamin D development program.

Since completing feasibility testing and formulation development on its novel Linguet form of Vitamin D, Imugene has now progressed to laboratory testing of the drug to monitor the transport of the Vitamin D molecule across the membrane of the mouth (buccal mucosa), which is due for completion in Q3 2013.

Following the laboratory testing, Imugene will commence a clinical study later this year to assess the relationship between two preparations of Linguet Vitamin D in the same dosage form (bioequivalence study). Based on this progress, Imugene expects to file for regulatory approval in the UK in the first half of 2014.

Imugene's novel Linguet™ technology enables the active ingredient of drugs to be absorbed straight into the bloodstream when placed inside the cheek (via the buccal mucosa) or under the tongue (sublingual). The proprietary tablet can improve the efficacy and safety of a range of prescription and over the counter medicines.

"Imugene has repositioned itself as a drug development pharmaceutical business and has consequently assembled a board and management with experience in developing and commercialising pharmaceutical products with an initial focus on Vitamin D," said Dr Nick Ede, Executive Director of Imugene.

"We continue to make steady progress in the development of our first product, an application of the Linguet technology in Vitamin D, passing the key milestones of feasibility and formulation testing as we advance into further testing and initiate licensing discussions."

While global sales of Vitamin D supplements are rapidly growing there are serious limitations with the existing treatments. Oral Vitamin D supplements are absorbed through the gastro-intestinal tract erratically and lead to transient surges of Vitamin D in the blood stream, limiting the effectiveness of the treatment and in some cases resulting in toxicity.

### Intellectual property portfolio extended

Imugene has also announced the extension of its patent family for Linguet™ with a new provisional patent filed this week (2013901834). The patent protects the innovative new drug formulations designed to deliver both colecalciferol (Vitamin D3) and 25-hydroxy vitamin D (calcidiol) more efficiently into the bloodstream.

"Strengthening our international IP is a key milestone in maintaining the competitive position of Linguet and any future improvements, drug formulations and clinical uses. We are extremely

pleased with the progress we have seen in our Vitamin D development program so far, and expect to see the product approved in the UK in 2014,” said Dr Ede.

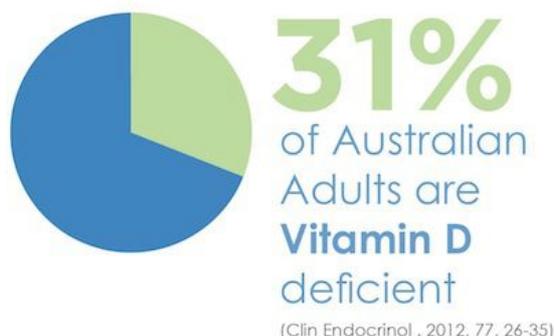
## Vitamin D and the wider community

Several pivotal studies published by Australian medical and academic institutions in 2012 point to the seriousness of Vitamin D deficiency in the Australian population. The first study, published in the international journal *Clinical Endocrinology*<sup>1</sup> and headed by Professor Robin Daly, Chair of Exercise and Ageing within the Centre for Physical Activity and Nutrition Research at Deakin University, and honorary fellow in the Department of Medicine (Northwest Academic Centre) at the University of Melbourne, highlights vitamin D deficiency as a major public health issue for Australia that requires urgent attention.

“Vitamin D deficiency is emerging as a major health problem worldwide. It is clear from the results of our study that, despite an abundance of vitamin D rich sunlight, Australians are not immune from this issue,” said Professor Daly.<sup>2</sup>

“Low levels of vitamin D can contribute to a number of serious, potentially life-threatening, conditions such as softened bones; diseases that cause progressive muscle weakness leading to an increased risk of falls, osteoporosis, cardiovascular disease, certain types of cancer and type 2 diabetes,” said Professor Daly.<sup>2</sup>

The study revealed that 31 per cent of the population was vitamin D deficient and nearly three quarters (73 per cent) had levels considered by many experts as below the optimal for musculoskeletal health.



In a second study, published in the same internationally renowned journal, Professor Steven Boyages from Sydney Medical School and his PhD student Kellie Bilinski published similar and concerning findings related to the extent of Vitamin D deficiency in the Australian population.<sup>3</sup>

“Vitamin D deficiency is implicated in a number of serious diseases including diabetes and cancer so improving our understanding is critical”, said Professor Boyages.<sup>4</sup>

1 *Clinical Endocrinology* (2012) 77, 26–35

2 <http://www.deakin.edu.au/news/2012/160112vitamindeficiency.php>

3 *Clinical Endocrinology* (2012) 77, 515–523

4 <http://sydney.edu.au/news/84.html?newsstoryid=10124>

For more information please visit [www.imugene.com](http://www.imugene.com) or follow Imugene on [Facebook](#)

**Ends**

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### About Imugene

Imugene Limited (ASX:IMU) is commercialising drug delivery applications based on its novel buccal (drugs administered via the cheek) Linguet™ technology. Linguet™ is a patient friendly and cost effective system used to deliver established pharmaceutical and nutraceutical products.

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