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ASX Announcement

Technology License and Clinical Development Program for Injectable Vertebral Disc Repair Therapy

Today we are pleased to announce that Medigard Ltd has entered into a binding exclusive worldwide license agreement with Kunovus Pty Ltd, the owners of the experimental KT009 injectable product to treat intervertebral disc degeneration (IVDD), debilitating Degenerative Disk Disease (DDD) and chronic lower back pain.

As communicated recently, Medigard seeks to invest carefully in a small number of medical projects that are close to clinical trials and could compliment the company's syringe technology trials.

The initial development program for KT009 is clear – make clinical grade recombinant KT009 (GDF-6), conduct preclinical testing of the clinical grade agent and then run a small scale human trial in Australia with patents suffering intervertebral disc degeneration or degenerative disc disease.

Degeneration of the intervertebral disk (IVD) is a common yet major pathological process linked to lower back pain and disk herniation – both major unmet medical needs. Disk degeneration can be detected in 90% of individuals >50-year-old. Globally, lower back pain is among the top three causes of disability, ranking above diabetes and mental health as a contributor to years lost to disability. The costs of back pain treatment, absenteeism and disablement exceed all other musculoskeletal conditions, estimated at ~US$100 billion in the USA. Conservative DDD management is unsuccessful in ~25% of individuals, therefore, the potential KT009 market is ~30 million patients in the US alone (based on a population of 320 million). Population growth coupled with the aging population is likely to have a positive impact on sales prospects. The Lancet Back Pain Group in March 2018 called for action to address the scourge of back pain and identified the disc as a putative source.

Under this license agreement, Medigard has the worldwide exclusive rights to commercialise two granted US patents and associated patent applications. The IP has been demonstrated in an international prize winning animal study. The results presented at Banff in May 2018 by the University of California San Diego team led by Professor Koichi Masuda, describe the use of an injection recombinant endogenous human protein (i.e. a biologic drug KT009) to treat disc degeneration and resultant chronic lower back pain.

As an alternative to surgery or implants, the KT009 treatment seeks to harness the natural biological activity of an endogenous protein to regenerate the IVD tissue. Whilst KT009 has demonstrated reversal of disc tissue destruction in sheep and in rabbits, it has also shown pain relief in a rat model.

The License requires that Medigard make mainly back-ended payments to the licensors. After initial upfront fees of $35,000 over 60 days, payments consist of defined fees based upon clinical trial milestones, a royalty on net sales, an annual license maintenance fee of $25,000 p.a., capped reimbursement of past IP costs in CY '19 and a share of sublicense fees. Medigard also has an option to purchase the KT009 IP from the licensor and reduce certain fees otherwise payable.

Dr Ian Dixon, Executive Director of Medigard, said "Partnering to commercialise KT009 is a logical yet important step in the history of Medigard and our investment will be directed at bringing the invention through manufacture, preclinical testing and into clinical trials. An injectable KT009 product could transform the lives of millions of people suffering intervertebral disc degeneration and Degenerative Disk Disease, and become a big-selling drug."

Sydney-based Dr Ashish Diwan PhD FRACS FAOrthA, a spinal and orthopaedic surgeon has been closely involved with the development of KT009. He states that the development arises from interactions with globally recognised DDD specialist physicians and scientists and is the subject of numerous peer-reviewed publications. Dr Ashish Diwan, said "Translating medical scientific discoveries into a drug used to treat millions of people is something that every medical doctor dreams of. The collaboration with Medigard is the next phase in solving the problems in my patients that I see every day. The data we have points to likely safety and efficacy in treating intervertebral disc degeneration and Degenerative Disk Disease with KT009, but the next step requires an investment to conduct proper clinical trials."

Dr Dixon said, "Once we demonstrate that KT009 can be made, is safe, and patients benefit from its injection – we anticipate that a Pharmaceutical company may partner with us to take KT009 through Phase III clinical trials, registration and marketing." A future partnering transaction with a Pharmaceutical company could involve upfront fees, milestone fees and royalties on sales for the duration of the patent life (till around 2030) and beyond.

Further information will be made available as it comes to hand.

Please feel free to contact me any time at ian.dixon@medigard.com.au.

Yours sincerely

Ian Dixon

Executive Director

30th October 2018