dorsaVi receives FDA 510(k) clearance for ViMove2™

Key points:

- dorsaVi's ViMove2™ device has received 510(k) Clearance from the U.S. FDA
- Regulatory clearance paves the way for the device's anticipated U.S launch in Q4 FY18
- Low-back pain is a significant market in the U.S., with the condition costing an estimated US$100-$200 billion annually[i]

Melbourne, Australia – 19 July 2017: dorsaVi Ltd (ASX: DVL) today announced it has received 510(k) Clearance by the U.S. Food and Drug Administration (FDA) for the next generation ViMove2™ sensor designed to measure, record, and analyse movement and muscle activity of the lower back. The regulatory clearance comes ahead of U.S. launch scheduled for Q4 FY18.

ViMove2™ features the latest in wearable technology, including Bluetooth communication between sensors and a mobile app; personalised clinician and patient apps for real time access to data; an enhanced user interface as well as smaller movement and EMG (muscle activity) sensors with faster start up and longer battery life.

The device also features an accelerometer and gyroscope that precisely measures the range of movement in the sagittal (longitudinal) and coronal (vertical) anatomical planes. These enhanced capabilities allow clinicians to monitor patients outside the clinic and help deliver tailored treatment programs. Furthermore, ViMove2™ enables patients to track activity levels against goals set by their clinician via a patient app.

dorsaVi Chief Executive Officer, Andrew Ronchi, said the regulatory clearance marked a major milestone and that the Company remains on track to launch ViMove2™ in the U.S. in Q4 FY18.

"The FDA's 510(k) clearance for ViMove2™ is an important milestone for the Company as the product has a mass market clinical opportunity. ViMove2™ is highly intuitive, simple and a faster to use device that is patient-friendly. The addition of a patient app allows patient and therapists to monitor progress and improve adherence to treatment regimes; ultimately leading to better patient outcomes through quality movement data," said Dr Ronchi.

ViMove2™ was launched in Australia in May 2017 and will also be launched in the UK in Q2 FY18. This staged roll out has been designed to facilitate a smooth introduction into the U.S., our largest clinical market. dorsaVi is currently experiencing strong growth and high levels of customer satisfaction in the U.S. clinical market. dorsaVi is uniquely positioned to build a critical mass of devices in market.

ViMove2™ has been developed as an ongoing annuity revenue product, replacing the model of outright unit sale or short-term lease originally launched for ViMove™. The annuity model has been tested in the U.S. clinical market over the past 12 months and has been successful in facilitating sales and proving a steady revenue stream.

Watch the ViMove2 overview video: http://get.dorsavi.com/vimove2/.

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About dorsaVi

dorsaVi (ASX:DVL) is an ASX company focused on developing innovative motion analysis device technologies for use in elite sports, occupational health and safety, and clinical applications. dorsaVi believes its wearable sensor technology enables – for the first time – many aspects of detailed human movement and position to be accurately captured, quantified and assessed outside a biomechanics lab, in both real-time and real situations for up to 24 hours.

Our technology has applications across three sectors:

- **Clinical:** ViMove is transforming the management of patients by providing an objective assessment, monitoring outside the clinic and immediate biofeedback. ViMove is currently used by medical and physiotherapy practices in Australia, United Kingdom and the United States.

- **Elite Sports:** ViPerform is allowing coaches and medical teams managing elite athletes and teams to screen athletes and provide objective evidence for decisions on return to play, measure biomechanics and provide immediate biofeedback out on the field, tailor and track training programs and optimise technique and peak performance. ViPerform is being used by AFL and NRL clubs and the Australian Institute of Sport (AIS) in Australia. In the UK, Barclays Premier League (EPL), U.S. based sports clubs including the National Basketball Association (NBA) and the National Football League (NFL), and various Olympic teams and athletes internationally.

- **OHS**: We combine innovation, measurement and quality to reduce workplace incidents, costs, meet compliance and improve brand reputation. ViSafe enables employers to assess risk of injury for employees as well as test the effectiveness of proposed changes to workplace design, equipment or methods based on objective evidence. ViSafe has been used by major corporations including Sodexo, London Underground, Vinci Construction, Crown Resorts, Caterpillar (US), Monash Health, Coles, Woolworths, Toll, Toyota, Orora (formerly Amcor), Crown and BHP Billiton. Australian Workplace Compliance delivers risk mitigation through compliance to OHS, Quality Management Systems, Company Policy and Process.

  Further information is available at www.dorsavi.com.

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[i] Freburger JK, Holmes GM, Agans RP, Jackman AM, Darter JD, Wallace AS, Castel LD, Kalsbeek WD, Carey TS. The Rising Prevalence of Chronic Low Back Pain. Arch Intern Med. 2009;169(3):251-258.