ASX ANNOUNCEMENT
24th August 2023

US nursing home study to pave way for FDA De Novo clearance

PainChek® Ltd (ASX: PCK) ("PainChek®" or "the Company"), developer of the world's first smart phone-based pain assessment and monitoring application, is pleased to announce it has signed an agreement for a clinical psychometric study of its PainChek® Adult software in the United States, which is scheduled to commence in September 2023.

The study will form the basis for PainChek®'s application to the US Food and Drug Administration (FDA) for De Novo regulatory clearance, which it expects to submit to the FDA in Q4 CY23. Based on a successful clinical study and standard FDA response times to De Novo submissions, regulatory clearance could occur for US market entry in Q1 or Q2 CY24.

The agreement for the study, to be conducted with Oaknoll Christian Retirement Services, will include recruitment at clinical sites in the states of Iowa, Illinois, and Missouri. The Clinical Research Organisation Donawa Lifesciences will oversee the project, conduct the data evaluation, and write the clinical report for submission to the FDA.

The study will be conducted at between 5 and 12 LeadingAge member nursing homes, who will recruit 100 residents living with moderate to severe dementia and are unable to self-report their pain. These residents will be of diverse racial and ethnic backgrounds to ensure the performance of PainChek® within the US population context. As was the case in previous studies the Abbey Pain Scale will be the clinical comparator. Residents will have their pain assessed simultaneously by two assessors, with the assessors blinded to each other's results. Performance will be evaluated based on the agreement of 600 matched paired pain assessments obtained using the two scales.

PainChek CEO Philip Daffas said: "This is a relatively short clinical study, but sufficient in size (100 participants) to generate high quality evidence, and it is the last step in completing the FDA requirements. We are confident that this will result in PainChek receiving FDA clearance as the protocol has been reviewed by the FDA multiple times over a one-year period and the clinical study process is consistent with our previous peer reviewed published Australia-based clinical studies that led to TGA and CE mark clearances. This next stage is important to the Company as the United States is the largest Aged Care market in the world and FDA regulatory clearance would provide PainChek with access to a market than is three times the size of our existing regulatory cleared markets in Australia, New Zealand, UK and Canada combined.

"In parallel to the FDA De Novo process, we continue to work with our existing US-based partners ensuring there is a pre-planned pathway for rapid entry into the US market upon receipt of FDA regulatory clearance."

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North America is the world's largest Aged Care market with 2,000,000 resident beds. As previously communicated, PainChek already has regulatory clearance in Canada where the first PainChek clients are in place and will enter the US when FDA clearance is received. In the US market PainChek has already signed a partnership agreement with Point Click Care Inc., which provides care management software to over 10,000 nursing homes and 1,000,000 resident beds in the US and Canada, a sales and marketing distribution agreement with Ethos Labs for the US market and a global partnership with InterSystems for the hospital market.

This release has been authorised for release by PainChek CEO Philip Daffas.

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About PainChek®

PainChek® Ltd is an Australian based company that develops pain assessment technologies.

Pain often goes unrecognised and under-treated in people with communication difficulties. PainChek Universal is a clinically validated smartphone-based medical device that enables best practice pain assessment for all people, everywhere.

PainChek Universal is a complete point-of-care solution that combines the existing PainChek® App with the Numerical Rating Scale (NRS). This enables best-practice pain management for all residents living with pain in any environment — from those who cannot verbalise pain to those who can, and those who fluctuate between the two.

The PainChek® App uses artificial intelligence and facial recognition to detect pain in those who cannot self-report. This gives a voice to those who cannot verbalise pain, whilst also driving objectivity and consistency in all assessments. For those who can self-report, PainChek Universal also includes access to the Numerical Rating Scale, a well-established standard used to document pain levels amongst these individuals. PainChek Universal also supports pain assessment using both tools at the point of care, for those people whose ability to communicate fluctuates.

PainChek® is being rolled out globally in two phases: first, PainChek® for adults who are unable to effectively verbalise their pain such as people with dementia, and second, PainChek® for infants who have not yet learnt to speak. Both the adult and infants products have received regulatory clearance in numerous markets including Australia, Europe, UK, NZ, Singapore and Canada.

The PainChek® Shared Care Program is a PainChek® licensing model which enables a professional carer to share their resident or patient data securely with other healthcare professionals or designated homebased family carers for ongoing pain assessments or clinical data review.

To find out more, visit www.painchek.com