ASX ANNOUNCEMENT
22 JANUARY 2021

Successful completion of PainChek® Infant Face-Only clinical study for regulatory clearance filings

HIGHLIGHTS

- Findings validate the use of PainChek Infant for procedural pain assessment
- Publication submitted to peer-reviewed scientific journal
- Study compared PainChek assessments to leading pain scales used world-wide
- Results support regulatory clearances and market launch of PainChek Infant in Australia & Europe during Q2 CY21
- Total market opportunity is 400 Million pre-verbal children worldwide[1]

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 that the PainChek Infant Face-Only clinical study to support CE Mark and TGA regulatory clearance has been successfully completed with findings supporting the use of PainChek Infant for procedural pain assessment with infants. A publication detailing the findings of the study has been written and submitted to a scientific journal for peer review.

PainChek is on schedule for Australian (TGA) and European (CE Mark) regulatory clearance of the PainChek® Infant product in Q2 calendar 2021 followed by market launch in these territories. The clinical study results will support these market launches.

The PainChek Infant Face-Only study was developed to test the feasibility of using PainChek® Infant's face domain alone as an indicator of pain, and evaluate it using video recordings of infants undergoing painful procedures.

The study, which received ethics approval from Curtin University, involved PainChek infant face domain scores being compared with assessments conducted using the Revised Neonatal Facial Coding System (NFCS-R) and the Observer Visual Analogue Scale (ObsVAS). Both NFCS-R and ObsVAS are well known and validated scales used in assessing procedural pain in infants, such as vaccinations, finger and heel pricks, dressing changes or more invasive procedures such as biopsies. Assessment of procedural pain occurs in various settings, from hospitals to home care environments.

Using the face only automatic assessment, PainChek Infant demonstrated effectiveness in procedural pain assessment, with comparison against the NFCS-R and ObsVAS demonstrating the psychometric properties of the technology i.e. validity, reliability and internal consistency. The findings showed that PainChek Infant (Face Only) has excellent correlation with NFCS-R and ObsVAS, and detailed results of the study will be made available following the peer-review and publication in a scientific journal.

PainChek continues with next steps to broaden the clinical applications of PainChek Infant, including research at the Royal Children's Hospital (RCH) in Melbourne, which was put on hold due to COVID-19.

ABN 21 146 035 127
401, 35 Lime Street,
Sydney, NSW, 2000

P: +61 8 9388 8290
E: info@painchek.com
W: painchek.com

PainChek® CEO Philip Daffas said:

"This is an excellent outcome for the PainChek Infant technology, as it demonstrates its ability to assess procedural pain with infants to the same accuracy as current pain scales used by health professionals globally. We look forward to the peer-reviewed publication which we expect will provide further validation of the technology.

With 400 million pre-verbal children[1] worldwide at any one time, including an estimated 100 million with first time parents each year, there is an outstanding market opportunity for PainChek Infant across various settings including hospital, home care and primary care."

[1] see PainChek ASX release Company presentation 28th November 2019.

This release has been authorized for release by CEO Philip Daffas.

For more information:

Ian Hobson
Company Secretary, PainChek
ianhobson@bigpond.com
+61 8 9388 8290

Philip Daffas
CEO, PainChek
philip.daffas@painchek.com
0406 537 235

About PainChek®

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

PainChek® is a smart phone based medical device using artificial intelligence to assess and score pain levels in real time and update medical records in the cloud. PainChek® records a short video of the person's face and analyses the images that indicate pain and records them.

Next, the caregiver uses PainChek® to record their observations of other pain related behaviours that complete the assessment. Finally, PainChek® calculates an overall pain score and stores the result allowing the caregiver to monitor the effect of medication and treatment over time.

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 Children who have not yet learnt to speak.

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