Prana presents new benchmark test to assess Huntington's Disease patients in clinical trials

New testing method created by clinical investigators in Prana's REACH2HD trial highlighted at the *17th Annual Congress of Parkinson's Disease and Movement Disorders*

Wednesday, 19 June, 2013: Melbourne-based Prana Biotechnology (ASX:PBT / NASDAQ:PRAN) has unveiled a world first, patient-reported outcomes study for Huntington's Disease (HD) in a poster presentation at the *17th Annual Congress of Parkinson's Disease and Movement Disorders* being held in Sydney this week.

The Poster entitled: *"The Huntington's Disease patient-reported outcome of problems: feasibility and applicability in clinical research (HD-PROP)"* details a new benchmarking system to assess the problems experienced by people with HD. The HD-PROP test aims to overcome some of the challenges associated with assessing clinically relevant outcomes in HD where progressive motor, cognitive and psychiatric symptoms can interfere with comprehension of lengthy patient self-report questionnaires and communication of responses. The HD-PROP test may be a useful tool to evaluate Prana's clinical trial results.

The HD-PROP test asks trial participants three questions in relation to their HD at the commencement of the trial. What problem is most bothersome? In what way is this problem bothersome? How severe is this problem?

The HD-PROP test was created by clinical investigators involved in Prana's Phase 2 clinical trial of PBT2 known as the REACH2HD Study. This 109 patient trial is fully recruited and nearing completion.

Professor Ira Shoulson, one of four authors of the Poster and an internationally renowned clinical investigator, said: "This is the first time this type of patient response testing has been applied to HD, and we expect it will form an important part of future trials in HD."

"Patient-reported outcomes are an important area of focus for the US Food and Drug Administration (FDA) and along with clinical measures provide a more complete understanding of the relevance as well as safety and effectiveness of potential treatments."

At the commencement of Prana's Phase 2 trial, 97% of participants reported at least one bothersome problem, 87% reported at least two problems, and 67% reported at least three problems. Motor symptoms, cognitive symptoms, functional decline, and behavioral symptoms were the most commonly reported first, second and third problems.

Geoffrey Kempler, Chief Executive Officer of Prana Biotechnology added: "This new assessment gives us great insight into the issues and concerns of people with HD and has established an important benchmark that we can consider when assessing the final clinical results of our REACH2HD trial."

The full Poster is attached.

About Prana Biotechnology Limited

Prana Biotechnology was established to commercialise research into Alzheimer's Disease and other major age-related neurodegenerative disorders. The Company was incorporated in 1997 and listed on the Australian Stock Exchange in March 2000 and listed on NASDAQ in September 2002. Researchers at prominent international institutions including The University of Melbourne, The Mental Health Research Institute (Melbourne) and Massachusetts General Hospital, a teaching hospital of Harvard Medical School, contributed to the discovery of Prana's technology.

For further information please visit the Company's web site at www.pranabio.com.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934. The Company has tried to identify such forward-looking statements by use of such words as "expects," "intends," "hopes," "anticipates," "believes," "could," "may," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements. Such statements include, but are not limited to any statements relating to the Company's drug development program, including, but not limited to the initiation, progress and outcomes of clinical trials of the Company's drug development program, including, but not limited to, PBT2, and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to the difficulties or delays in financing, development, testing, regulatory approval, production and marketing of the Company's drug components, including, but not limited to, PBT2, the ability of the Company to procure additional future sources of financing, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug compounds, including, but not limited to, PBT2, that could slow or prevent products coming to market, the uncertainty of patent protection for the Company's intellectual property or trade secrets, including, but not limited to, the intellectual property relating to PBT2, and other risks detailed from time to time in the filings the Company makes with Securities and Exchange Commission including its annual reports on Form 20-F and its reports on Form 6-K. Such statements are based on management's current expectations, but actual results may differ materially due to various factions including those risks and uncertainties mentioned or referred to in this press release. Accordingly, you should not rely on those forward-looking statements as a prediction of actual future results.

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The Huntington disease patient-reported outcome of problems (HD-PROP): feasibility and applicability in clinical research

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Advancing Health Through Research

Introduction

- In HD, the assessment of patient-reported outcomes is challenging because progressive motor, cognitive, and psychiatric symptoms can interfere with comprehension of lengthy self-report questionnaires and verbalization of responses.
- Conventional quality of life questionnaires are not customized to capture the unique perspective of the individual that affect treatment choices and satisfaction. This may be particularly important in progressively degenerative diseases such as HD because clinical concerns may change over the course of illness.
- The HD-PROP was developed to allow for verbatim expression of problems facing the individual with HD, and includes three key questions:

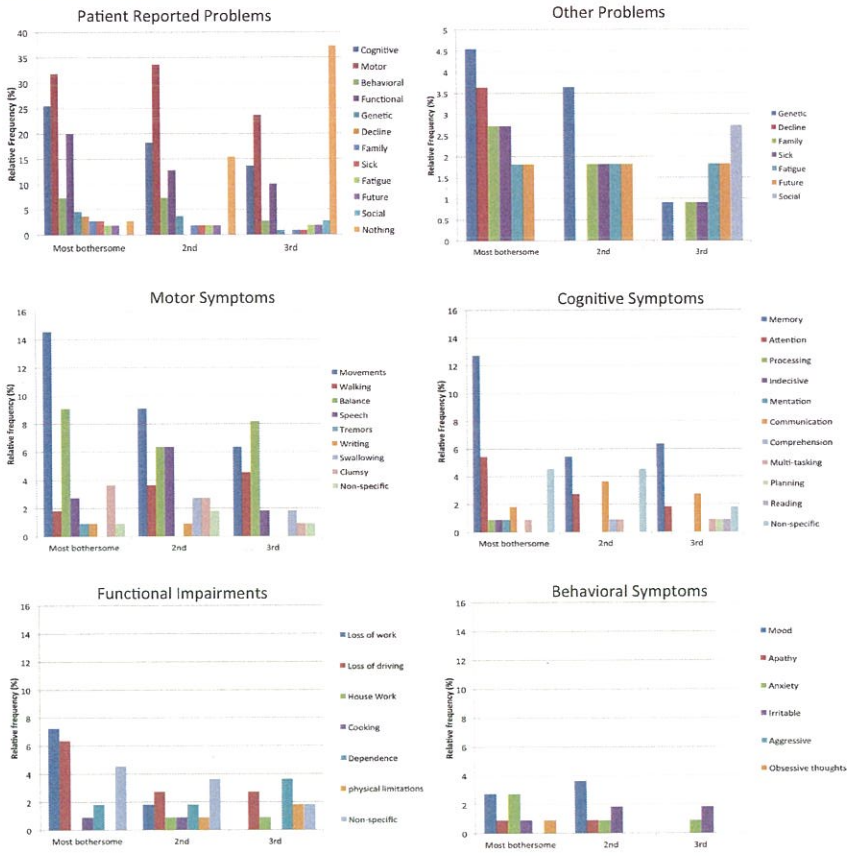
  (1) What problem is most bothersome?
  (2) In what way is this problem bothersome?
  (3) How severe is this problem?
- This open-ended, hierarchical, and problem-oriented tool may offer an alternative to conventional self-reported patient-questionnaires that are longer, usually involve clinical assessments, and require calculation of a score.
- The purpose of this study was to explore feasibility and analytic approaches of the HD-PROP in a randomized clinical trial involving ambulatory HD research participants.

Methods

- Participants included 110 adults with clinical features of HD and CAG repeat ≥ 36, who consented to participate in the REACH2HD study, a multi-center, randomized clinical trial. Eligible subjects were over age 24, and had cognitive (Montreal Cognitive Assessment score ≥ 12) and functional (Total Functional Capacity score ≥ 6) impairments.
- At the baseline evaluation, subjects were administered the HD-PROP questions in a semi-structured interview. Open-ended, verbatim responses were recorded. Participants were asked what is their most bothersome HD problem, in what way the problem is bothersome, and how severe the problem is (on a 0 to 4 scale of not to very bothersome).
- Data were anonymized. Patient responses were entered into EZ-Text software developed by the Center for Disease Control for analysis.
- A clinical neuropsychologist (SFL), not involved in the trial or interviews, coded all responses. Categories paralleled the motor, cognitive, behavioral and functional domains of the Unified Huntington's Disease Rating Scale (UHDRS) as well as problems not captured by this investigator-reported research tool.
- Frequency tables displayed the categories of reported problems.

Support: This research was supported by Prana Biotechnology (Melbourne, Australia), sponsor of the Huntington Study Group REACH2HD trial.

Results



- 97% of participants reported at least one bothersome problem, 87% reported at least 2 problems, 67% reported at least 3 problems, 6% reported at least 4 problems, and 4% reported having 6 problems. Three subjects did not report having any bothersome problems related to HD.
- Motor symptoms, cognitive symptoms, functional decline, and behavioral symptoms were the most commonly reported 1st , 2nd , and 3rd problems. For the 1st problem 85% of subjects responded in one of these 4 UHDRS categories while 17% identified other complaints, for the 2nd problem 72% versus 15%, and for the 3rd problem 51% versus 17%.
- Other reported problems included concern for genetic inheritance of HD, general clinical decline, issues related to family, being sick, fatigue, concern for the future, and impact on social functioning.

Conclusion

- The HD-PROP was feasibly administered in a randomized clinical trial to research subjects who reported verbatim their most bothersome problems. The reported motor, cognitive, behavioral and functional symptoms were in keeping with the domains assessed in commonly used investigator-reported research tools, such as the UHDRS.
- The open-ended format of the HD-PROP allowed for identification of relevant clinical problems that identify unmet needs and may potentially be targeted for treatment or constitute treatment outcomes.
- This study lacks assessment of inter-rater reliability of the coded responses. Ongoing research in these subjects will examine the relationship of HD-PROP responses to demographic features, genetic burden and UHDRS investigator ratings as well as the consistency of responses after a 6-month follow-up assessment. The HD-PROP is also being examined in other clinical research cohorts that include a wide range of disability and the corresponding perspectives of care providers about the most bothersome problems affecting individuals with HD.