Movember launches new Global Action Plan initiative:

The Unique Prostate Cancer Tissue microarray (TMA) project

17th December, 2012

Movember today announces the launch of a supplementary project under its Global Action Plan (GAP) prostate cancer biomarker initiative – **The GAP1 Unique TMA project**.

The **unique TMA project** will be a two year global project that will involve researchers from around the world collaborating to maximize patient cohorts to produce highly innovative, clinically valuable, and unique TMAs that can facilitate a better understanding of treatment response and resistance and can be utilized to further validate promising prostate cancer tissue-based biomarkers.

The most important component of the project is that samples for the construction of primary human TMAs should consist of tissue samples from patients with both pre and post biochemical recurrence AND/ OR pre and post treatment (either from biopsy or radical prostatectomy tissue). Post-treatment tissue samples could be from either primary local recurrence (post-radiation therapy or post-surgery) or metastasis (soft tissue mass or bone metastasis).

Movember will invest **AUD $1.2 million** into this project.

Project context and requirements

Movember acknowledges that there are many groups which can create prostate cancer TMAs and that many TMAs exist globally. The critical component of this initiative is that TMAs created as part of this project are from patient tissue samples that:

1) Meet a real unmet clinical need and answers a unique clinical question
2) Are very high quality
3) Are matched pre and post treatment
4) Have very well annotated clinical follow-up data, including:
    a. Treatment response and failure data
    b. A strict definition of aggressive disease – i.e. disease progression (biopsy-proven and as defined by commencement of initial therapy, patient relapse biochemically or there has been evidence of local cancer progression on MRI, or distant metastases seen on bone scan/other imaging modalities), Prostate Cancer Specific Mortality (as defined by WHO classification and recorded on death certificate)
5) Can be developed collaboratively as part of a global consortium

6) Have a well-defined governance structure that addresses ethical issues and facilitates access by the global prostate cancer community to validate promising prostate cancer tissue-based biomarkers that meet very robust biomarker assay performance characteristics with strong pre-validation data

TMAs should help answer clinical questions that address at least one of the following objectives of GAP1:

1. More accurately determine metastasis, disease progression and treatment options for individual patients

2. Determine mechanisms of treatment response and treatment resistance

As part of the initiative, it will be important for the GAP trans-regional project team to collaborate with biomarker assay developers (end users) to develop robust strategies that best utilize these precious samples.

A mandatory expectation for involvement in, and the appropriation of funds as part of the project, will be the sharing of material created throughout the project so that these TMA resources can be utilised by the wider prostate cancer research community as a global resource to further validate promising prostate cancer biomarkers.

EOI Information

To express interest in the project, please email Dr Mark Buzza, GAP Program Manager at **tmas@movember.com** outlining the relevant capabilities and patient resources that your group possesses (in 5 pages or less), including:

- Principal Investigators and Co-Investigators
- Research Institution
- Relevant research team (including pathologists, biostatisticians, technicians with TMA expertise, etc)
- Expertise in developing TMAs
- Clinical questions or hypotheses which could be addressed by constructing relevant TMAs as part of a global collaboration
- Number and details of patient cohorts and tissue samples
- Information regarding the robustness of clinical follow up data
- Whether the patients were recruited and samples collected as part of clinical trials
- *Number* of patients with clinical disease progression:
    - Biochemical recurrence

- Average years post RP
- Surgical margins positive
- Extra-capsular extension
- Seminal vesicle invasion
- Lymph node metastasis
- Distant metastasis (including bone)

- Information regarding relevant QC/QA processes
- Relevant normal controls (tissue-specific, biology-associated or organ system controls)
- Matched serum/plasma or urine (post DRE or no DRE) samples
- Current relevant collaborations with Investigators involved in both TMA construction and biomarker validation
- Capacity to obtain ethics approval in a reasonable timeframe to participate in such a project
- The ability to collaborate trans-nationally to:
  - Develop highly valuable and unique TMA resources
  - Share TMAs developed as part of a global collaboration with biomarker assay developers (end users)
- Indicative biomarker assay developers (end users) who may best able to utilise these precious samples.
- Details regarding how these samples have been funded to date and how this might logistically impact the sharing of TMAs in the future

After the EOI closes there will be a period of analysis to determine where potential synergies and collaboration opportunities exist at a trans-regional level before integrated project teams are assembled.

Key dates

Expression of interest launched – 17th December 2012.

Expressions of interest close at **5pm Thursday 28th February 2013 AEST.**

Movember expects to be in a position to appropriate funding for this project in **May 2013.**

Funding will be for a maximum of 2 years from the time of award.

The Movember Global Action Plan (GAP)

GAP is Movember's Global Action Plan. Launched in 2011, it was established to address critical challenges in prostate cancer research through global collaboration. As a result of working with our Men's Health Partners around the world, Movember identified an opportunity to accelerate research outcomes by providing researchers from around the world the opportunity to work together on specific projects that meet critical clinical questions.

By bringing together the leading international clinicians and researchers, GAP facilitates a new and unprecedented level of global research collaboration, not previously seen within the prostate cancer community.

About Movember

Since its beginnings in 2003 in Melbourne Australia, Movember has grown to become a global men's health movement inspiring millions of Mo Bros and Mo Sistas to participate.

During November each year, Movember is responsible for the sprouting of moustaches on thousands of men's faces around the world, the aim of which is to raise funds and awareness for men's health issues, specifically prostate cancer and male mental health.

In 2012, the global Movember community of over 1.1 million Mo Bros and Mo Sistas, raised over AUD $120 million for men's health programs.

Movember funds programs both directly and through its Men's Health Partners. The Movember Global Action Plan is a key initiative undertaken directly by Movember.