Immune Suppression Monitoring: A breakthrough approach to measuring the therapeutic effect of calcineurin inhibitor drugs

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ImmunoMetrix, Inc.

Emory OTT Breakfast Club
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Market

• There were approximately 50,000 solid organ transplants in 2005 (US, Europe and Japan, only)

• It is estimated that the number of persons living with a functioning organ transplant is over 230,000 worldwide (about 65%, or 150,000, in the U.S.)

• The majority of these patients are prescribed calcineurin inhibitors for life.
Clear Benefits of Calcineurin Inhibitors

<table>
<thead>
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<tbody>
<tr>
<td>Patient survival:</td>
<td>1yr 5yr</td>
<td>1yr 5yr</td>
</tr>
<tr>
<td>Kidney</td>
<td>62% 42%</td>
<td>95% 81%</td>
</tr>
<tr>
<td>Heart</td>
<td>18% -</td>
<td>85% 75%</td>
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</tbody>
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### Significant Risks with Calcineurin Inhibitors

<table>
<thead>
<tr>
<th>Post Transplant Complications</th>
<th>Long-term risk (5+ years):</th>
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<tbody>
<tr>
<td>Viral Infections</td>
<td>44%</td>
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<tr>
<td>Chronic Renal insufficiency</td>
<td>26-86%</td>
</tr>
<tr>
<td>End-stage renal disease</td>
<td>8%</td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>11-31%</td>
</tr>
<tr>
<td>Cancer</td>
<td>34%</td>
</tr>
<tr>
<td>Cancer</td>
<td>30%</td>
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A Novel Fluorimetric Enzyme Activity Assay for the measurement of therapeutic immunosuppression

Unmet Medical Need

Lifelong Immunosuppressive Regimens

Surrogate Marker Testing

Solid Organ Transplant

Emory Tech IDs 505075, 07075, 07133 and 09031
**Development**

**Figure 2. Fluorimetric method to detect CaN activity.** A peptide substrate is prepared with a phospho-Ser residue and an N-terminal fluorescent tag. The substrate is incubated with lysate and reaction buffer and then loaded onto TiO₂-coated wells. The phospho-peptide substrate binds to the TiO₂ while the non-bound peptide is decanted to a black plate for fluorimetry. Fluorescence is compared to a standard curve of CaN activity run simultaneously.

**Next Steps**

SBIR application under review: “Establish the clinical role of a novel calcineurin enzyme activity assay and determine its applicability as a method to monitor therapeutic immunosuppression”
Intellectual Property (Emory OTT)
• “Methods for determination of protein phosphatase activity and the uses in predicting therapeutic outcomes”
• Provisional Patent – August 2007
• PCT – July 2008

Scientific and Clinical Expertise
• Jennifer Gooch, Ph.D. – Emory University School of Medicine
• Alan Kirk, M.D. Ph.D – Emory University Transplant Center
• Stuart Knechtle, M.D. – Emory University Transplant Center
The Future

Improved Monitoring......
Leads to reduced side effects......
Leads to wider use an effective therapeutic....

Autoimmune Diseases....
  Rheumatoid Arthritis, MS, Myasthenia gravis,
  Lupus, Crohn’s Disease, etc.

Chronic Inflammatory Disease......
  Long-term Allergic Asthma control

Potentially other Immune System Disorders.....