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Australian Securities Exchange Limited
Companies Announcements Office
SYDNEY

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Bioxyne reports the results from the Phase IIb study

- **Analysis of the full patient population indicates that there was no significant benefit of the immunotherapeutic across the study group as a whole.**
- **Subset analysis in patients under 65 years old indicates that there were significant benefits in the group treated with HI 164 OV. This group represented approximately 30% of the patients in study 005.**
- **Patients under the age of 65 years of age showed a 50% reduction in hospitalization, with a >50% reduction in duration of stay in the active treatment arm.**
- **The study confirms that the immunotherapeutic is safe for use in COPD patients**
- **Commercialisation program commenced with Torreya**
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SYDNEY Australia 28 June 2012: Australian immunotherapeutics business, Bioxyne Limited (ASX: BXN), has received the preliminary analysis of the study 005 which examines the efficacy and safety of the immunotherapeutic, HI 164 OV in patients with chronic obstructive pulmonary disease (COPD). The study recruited 320 patients from 21 sites around Australia. At study's end 287 patients completed the study. From previous, much smaller studies, particularly study 002, the immunotherapeutic suggested it reduced the exacerbations common in this disease, and the risks of hospitalization in patients with more severe disease.

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The Company, together with the Clinical Research Organisation managing the clinical study, and other professional advisers, has undertaken an extensive assessment of the data pack emerging from the study. The outcome is complex, and that has required the company, and its professional advisers, to undertake a number of additional analyses to better understand the results.
The findings from the study were:

- When the complete patient cohort is analysed there was no benefit in reducing either exacerbations or hospitalisations for the active group.
- A subset of the test group, patients under the age of 65, however, demonstrated significant benefits attributable to HI 164 OV. These included-
    - Hospitalisations associated with exacerbations were reduced by 50%
    - Days in hospital associated with exacerbations were reduced by 65%
    - Time to the first exacerbation was extended by a significant time
    - Number of corticosteroid treatments were reduced by a significant amount
- HI 164 OV was a safe product when used in this group of COPD patients

It is the Company's belief that the study was well designed and managed, building on initial earlier indications from both pre-clinical and Phase 2a data. The data generated from the sub group of patients under the age of 65 is supportive that HI 164 OV may have a place in the management of COPD patients. It should also be noted that there appears to be lower incidence of H.influenzae infections during the study which may account for the decreased incidence of exacerbations across both groups., and explain the difference between the Studies 002 and 005.

Bioxyne has considered the implications of these results and determined the following:

- As previously communicated, the Company is currently engaged in active dialogue with a number of external companies exploring their commercial interest in HI 164 OV.

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- The company will embark upon a targeted marketing plan in conjunction with Torreya Partners, with initial approaches to additional partners commencing early in July.
- Some external parties with which the Company has commenced commercialization discussions have expressed interest in the use of the immunotherapeutic for indications other than COPD and these options will also be considered for licencing.
- Probiotics, inherited from the PCC merger, will continue to be a cash generating asset. The company will continue to look for monetization opportunities for this asset, including global licensing opportunities.
- In parallel with the above, the Company will actively work to control and constrain costs.

Bioxyne will continue to provide more information to the market as the commercialization efforts continue.

Why was the outcome of HI-H005 different from the earlier study HI-H002?

1) The current study,HI-H005, analyzed data in over 300 patients, while the earlier positive study, study HI-H002, included only 38. It is not uncommon for a much larger study to give a different clinical outcome to previous smaller studies. The current study validated the safety and points towards potential value in a sub set of patients under the age of 65

2) The data from the Under 65 age group as a subset analysis is supportive of the initial data from study 002. This patient cohort accounted for approximately 30% of the study group. The significant differences in this group would have been offset by data arising from the over 65 year age group. This may drive the lack of statistical difference in the overall study.

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3) It may be that there was a difference between the 002 and 005 studies due to an underlying difference in the colonization rate for *Haemophilus influenzae* in the patients (being lower in the HI-H005 study). This organism was the target of the immunotherapeutic.. Further studies would be required to validate this assumption.

Why did Hunter Immunology embark upon the study HI-H005 and the associated expense?

1) Extensive pre clinical research and clinical study strongly supported the decision to proceed

2) The earlier, small study HI-H002 provided indications as to the potential benefit of HI-164OV. The HI-H005 study was designed to provide statistical clarity around the data. From the study HI-H005 it appears that there is more value in the therapy within the under 65 year old age group. The reason for this discrepancy would be the subject of further investigations. However, from publicly available data, the under 65 year old age group accounts for approximately 27% of the COPD patients, which still represents an attractive market opportunity.

3) A number of pharmaceutical companies have been awaiting the HI-H005 outcome, supporting the decision to have proceeded.

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About Bioxyne

Bioxyne Limited (ASX:BNE) is an Australian immunotherapeutics business created in April 2012 through the reverse takeover of Probiomics (ASX: PCC) by privately held Hunter Immunology. The Company's lead therapy, HI-164OV is based on the Company's proprietary technology that uses the application of mucosal immunology to treat common human diseases such as Chronic Obstructive Pulmonary Disease (COPD). The global incidence of COPD, which includes common diseases like bronchitis and emphysema, is growing rapidly and is a substantial burden on health budgets. Bioxyne also makes and sells consumer food supplements, based on a proprietary probiotic compound, generating a source of revenues. For further information please visit **www.bioxyne.com**