Kibow's Pathway Through a Drug Like Validation for a Probiotic Dietary Supplement Targeted for Helping Maintain a Healthy Kidney Function

Natarajan Ranganathan, Ph.D[1], Usha Vyas, MS[1], Pari Ranganathan, MS, MT (ASCP)[1], Eli A. Friedman, MD[2].

[1]Kibow Biotech Inc., Newtown Square, PA, USA, [2]Downstate Medical Center, State University of New York, Brooklyn, NY.

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Background

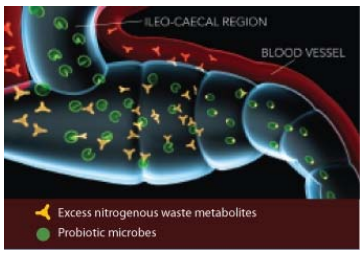
Probiotics are increasingly appearing in functional foods, beverages, supplements and complementary medicine. Occupying a middle ground between food and medicine, dietary supplements have been rapidly gaining popularity among Americans.

Probiotics can provide several health benefits ranging from lowering cholesterol and boosting immunity, to reducing the effects of lactose intolerance, constipation, diarrhea, Irritable Bowel Syndrome and even gum disease. Nonetheless, developing a probiotic product targeting kidney health has never been accomplished, until now.

Objective

In the US alone, 23 million Americans suffer from Chronic Kidney Disease (CKD) and more than 300 million individuals are affected worldwide. CKD is irreversible finally ending in End Stage Renal Disease (ESRD).

Kibow is interested in utilizing the properties of various probiotic bacteria for the removal of uremic toxins using an entirely novel but age old concept, utilizing the colon as a surrogate kidney to filter out the uremic toxins.



Methods

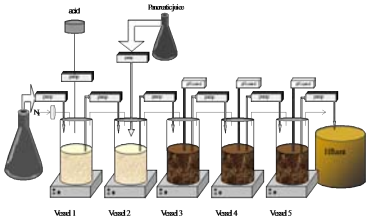
Large libraries of bacteria were screened for their ability to metabolize various uremic toxins. A blend of 3 different probiotic bacterial strains comprising of *S thermophilus* (KB19), *L acidophilus* (KB27) and *B longum* (KB31) was scientifically formulated from our extensive *in vitro* experiments.

Microbial counts, strain stability, and identification were performed by microbial methods and fatty acid via the SherlockR microbial identification system. Degradation of uremic toxins like urea was done colorimetrically using Diacetyl Monoxime and Thiosemicarbazide. An enteric coated formulation was designed to withstand gastric acidity and release viable microbes at the ileo-cecal pH of approximately 6.5 – 7.0. Additional simulation studies were carried out using a SHIME reactor at the Ghent University Belgium. This was followed by animal studies using 5/6th nephrectomized rats followed by mini-pigs. BUN levels, survival per se and creatinine levels were monitored.

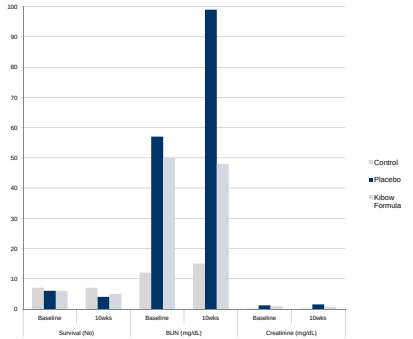
Based on the animal models, human trials were carried out in Canada, USA, Argentina and Nigeria. Outcomes were compared by measuring blood urea nitrogen (BUN), serum creatinine and uric acid. As an indication of inflammation C-reactive protein was also measured.

Results

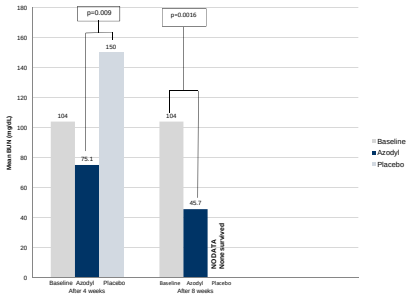
- In vitro lab data including the use of Simulated Human Intestinal Microbial Ecosystem (SHIME-a gastrointestinal 5 vessel biochemical reactor) demonstrated the disappearance of urea, uric acid, creatinine and production of short chain fatty acids.
- The same formulation in 5/6th surgically induced nephrectomized rats demonstrated a much longer survival (over 145 days with our product, 55-60 days with placebo).
- When nephrectomized minipigs were given this proprietary formulation, at the end of 8 weeks the BUN levels drastically reduced from 104mg/dL to 45mg/dL. All mini-pigs on the formulation survived whereas those on placebo died.
- Cats and Dogs with moderate to severe kidney failure also indicated reduction in Azotemia and substantial increased Quality of Life (QOL).
- This resulted in the licensing and commercialization of this company's veterinary product (Azodyl™) in USA and Canada by Vétoquinol (European based, publicly traded company).
- A human pilot scale clinical trial in 4 countries, in 5 different sites have been completed with enteric coated gel cap composed of a total of 15 billion CFU. Six gel caps (2 x 3 times) were taken after meals at breakfast, lunch and dinner times to a total dosage of 90 billion CFU/day. The data from this multisite pilot scale clinical study have shown positive indications for use in CKD 3 and 4 patients (see the additional poster being presented).



SHIME studies at Ghent University, Belgium

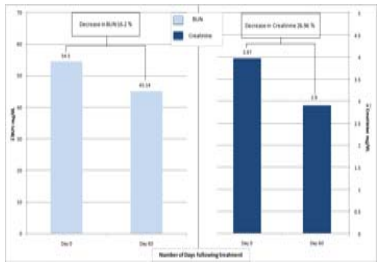


RAT studies at Thomas Jefferson University, Philadelphia



Supplement reduces azotemia in minipigs.

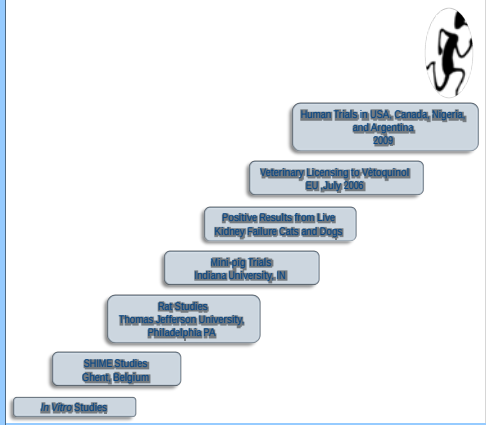
Studies carried out at Indiana University, Indiana.



Studies at Centinela Animal Hospital, Inglewood, California.

BUN and creatinine levels were reduced in feline azotemia

Summary



Conclusion

As discussed by the aforementioned technologies, it is distinclty apparent that a probiotic formulation for kidney or other applications needs to have a strong drug like validation for acceptance by the general consumer.

Source of support

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