The Office of Orphan Product Development at FDA, has granted Kre-Celazine® Orphan Drug status in the treatment of Juvenile Idiopathic Arthritis.

A pivotal pilot study, submitted to the FDA in 2012 has won All American Pharmaceutical Orphan Drug designation for **Kre-Celazine®** in 2013*.

Juvenile Idiopathic Arthritis (JIA) is a physiologically complex, chronic childhood autoimmune–related inflammatory disease of unknown origin. Like adult rheumatoid arthritis, joint and soft tissue destruction is relentless, except that this inflammation can begin when the victim is as young as a one-year old infant in the crib.

The study sponsored by All American Pharmaceutical was able to demonstrate that 16 children/juveniles – ranging in ages 7 to 17 years, who had been suffering from longstanding JIA, despite their use of chronic antiinflamatory prescription medication, experienced: (a) significant reduction or elimination of palpable inflammation, (b) renormalization of range of motion, (c) reduction/absence of perceived pain, (d) renormalization of blood values for C-reactive protein and Erythrocyte Sedimentation rate.

In the open label clinical study, participants received **two** 750 mg capsules (total, 1,500 mg) of an **Kre-Celazine®** to be taken daily (one in the morning, and one in the evening, on an empty stomach, and with water only) for a period of 30 consecutive days. Efficacy of this nutritional supplement was determined by the juvenile's treating physician. Attending physicians reported that, "*Almost all visible/palpable inflammation had disappeared*," in all but three individuals. Range of motion was rated as 'normal' in all individuals. Two of the participants reported feeling, "*Fully recovered*" and began playing basketball at their school.

Based on the experiences reported in this study, as well as those of a previous study using arthritic adults (Golini J, et al. 2009)**, individuals with arthritic inflammation of the knee, ankle, and foot, as well as shoulder, elbow, wrist and hand all appeared to benefit from the use of this nutritional supplement.

*It must be noted that as of January 1, 2014 – **Kre-Celazine®** **<u>has not yet</u>** been licensed for the treatment of any disease condition in the United States. FDA licensing is a lengthy process for any product.

Golini J, Beeson M, ND, Angersbach D, ND, Moore J, ND, Holl P, DC, Amicone C, ND, Jones W. **A Single-Center, Double-Blind Placebo Controlled Study to Evaluate the Efficacy of Kre-Celazine®, an Oral Buffered Creatine-Cetylated Fatty Acid Compound, in its Ability to Reduce Site-specific Inflammation and Pain. JANA. Vol. 12, No. 1, 2009: 20-25. ISSN-1521-4524. [www.ana-jana.org]