



MEDIA RELEASE

iCeutica Commences Clinical Program for Metaxalone SoluMatrix™

- *iCeutica's reformulation of metaxalone is designed to create an improved lower dose product, with distinct advantages over other muscle relaxants.*
- *This trial is the 14th to be conducted on SoluMatrix products and the 5th product to commence clinical trials for iCeutica and its partners.*
- *Company is pursuing additional clinical programs with new partners to be announced shortly.*

Philadelphia PA: iCeutica Inc. ('iCeutica'), a rapidly growing pharmaceutical company focused on creating new and improved drugs for patients, today announces that it has commenced the clinical program for Metaxalone SoluMatrix™ tablets.

iCeutica's investigational Metaxalone SoluMatrix™ tablets are a reformulation of the popular muscle relaxant sold by King Pharmaceuticals® (owned by Pfizer®) as Skelaxin®. The current metaxalone product contains 800 mg of the active ingredient and the amount of drug absorbed by patients can vary dramatically, depending on whether or not it is taken with a meal. iCeutica's Metaxalone SoluMatrix™ product has the potential to significantly reduce the dose of metaxalone required to be given to patients, reduce the variability of existing metaxalone products to ensure consistent absorption and demonstrate fewer of the side effects of other muscle relaxant products.

iCeutica plans to compare its metaxalone reformulation with a cyclobenzaprine hydrochloride muscle relaxant product, which is the dominant molecule prescribed in the muscle relaxant class. Cyclobenzaprine hydrochloride products are closely related to the tricyclic antidepressants and are known to cause drowsiness, dizziness and dry mouth in some patients.

iCeutica has been able to successfully reformulate metaxalone by utilizing its proprietary SoluMatrix™ technology, which reduces the particle size of the active drug by more than 100-fold. These submicron particle formulations dissolve much more quickly than traditional formulations, which dramatically improves absorption and requires less drug to achieve the target therapeutic exposure.

"We are very pleased to commence the clinical program for Metaxalone SoluMatrix™," iCeutica CEO Matt Callahan commented. "This represents the 14th clinical trial to be undertaken using the SoluMatrix technology and the 5th development program to enter the clinic."

Metaxalone is a muscle relaxant which is used with rest, physical therapy and other measures to relax muscles and relieve pain and discomfort caused by strains, sprains and other muscle injuries. Currently sold by King Pharmaceuticals® and CorePharma®, the product had sales of more than \$350 million in the USA during 2011. Along with

sales of the dominant cyclobenzaprine, the muscle relaxant market was worth more than \$1 billion in 2011, despite the limitations of many of the products in that market.

"The development plan for Metaxalone SoluMatrix™ is relatively fast and is very cost effective," Mr Callahan commented. "We plan to utilize the 505(b)(2) approval pathway with the FDA and ensure that our improved branded product becomes available to patients as quickly as possible."

"There has been little innovation and very few new products in the muscle relaxant market for some time," said iCeutica Vice President of Clinical and Regulatory Affairs Dr. Paul Nemeth. "Creating a new product which provides effective muscle relief, but which avoids the somnolence and other side effects of cyclobenzaprine products and other similar products is an important goal for patients."

The first clinical trial for Metaxalone SoluMatrix™ is scheduled to be completed before the end of the year and the second trial required for registration is planned for Q3 2013. A Phase 4 comparison trial comparing Metaxalone SoluMatrix™ with a cyclobenzaprine product is scheduled to commence thereafter and will likely overlap with the NDA review period.

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About iCeutica Inc.

iCeutica is a clinical stage pharmaceutical company focused on the development and commercialization of innovative therapeutic products which utilize its proprietary SoluMatrix™ technology. The SoluMatrix™ technology has been used in 5 different product candidates which have completed 14 clinical trials to date. The company has a robust pipeline with several late stage pain and inflammation candidates which have been partnered and a number of in-house clinical assets that are being developed by iCeutica. For more information, visit www.iceutica.com.