

Report : Clinical Program Update

News Title :

Headline	Company
<p>Madeira Therapeutics looking to secure USD 2m Series A round for liquid statin; currently partnered with CRO Camargo, CEO says</p>	<p>Shionogi Pharma, Inc. (FKA:Sciele Pharma, Inc.)</p>
<p>2010-01-26 Pharmawire</p>	<p>Company</p>
<p>Intelligence Details</p>	<p>Shionogi Pharma, Inc. (FKA:Sciele Pharma, Inc.)</p>
<p>Madeira Therapeutics, a privately held, Kansas-based specialty pharmaceutical company, is seeking USD 2m for the development of liquid statin for children, CEO Peter Joiner said.</p>	<p>Intelligence Type(s)</p>
<p>The company is currently working with Cincinnati, Ohio-based Silverstone Advisors, a business strategy consultancy and investment banking firm. The company has secured initial funding of USD 1.2m from Maverick Angels and is looking to use additional funding towards Phase I studies of liquid statin for children.</p>	<p>Product Development</p>
<p>Joiner said that the company recently spoke with Landmark Angels, a private, angel group located in Greenwich, Connecticut.</p>	<p>Intelligence Grade</p>
<p>Madeira Therapeutics is focused on reformulating adult drugs for better dosage control in children. The company utilizes the FDA's 505(b)(2) approval method, which relies in part on the regulatory agency's findings for a drug previously approved for adults, Joiner said. Thus, the development timeframe is shortened and previous data can be submitted as part of the NDA.</p>	<p>confirmed</p>
<p>Madeira's lead product is a liquid version of a statin (MT001) that is generic. Having a statin formulation in liquid form for oral dosing allows for the necessary ability to customize the dose and individualize therapy according to the child's specific recommended goal, Joiner added. According to the current timeline, the NDA submission is expected in Q3 of 2011, with a projected launch in Q2 of 2012. The second compound in development is a liquid analgesic, which is a synthetic opioid for children for mild to moderate acute pain. An additional USD 8m will be required to advance this compound into the clinic, Joiner added.</p>	
<p>Joiner said that the company is looking to further develop the liquid statin in the US and bring it to the market on its own but will likely seek a partner for commercialization. Joiner said that companies such as Shionogi Pharma (formerly Sciele Pharma) and Kowa Pharmaceuticals America may find Madeira Therapeutics of interest. Additionally, Japanese or Korean companies looking for "inroads" into the US may also be interested in Madeira Therapeutics.</p>	
<p>In the EU, however, Maderia is in active discussions for a partnership. Joiner noted that Madeira is seeking a company with a large presence in the pediatric space for exclusive rights in the EU. Joiner said that he prefers a larger upfront payment and less on the backend due to the current need for capital to</p>	

advance clinical trials.

Joiner noted that there is an immense need for children's products that have been tested and approved specifically for use in the pediatric population. He added that between 1973 and 1997, 71-81% of approved drugs contained no labeling information for children. He added that two-thirds of drugs prescribed for children have not been specifically studied and labeled for pediatric use.

Joiner added that the American Academy of Pediatrics (AAP) recently released its new policy and guidelines on cholesterol in children, displaying a sense of urgency due to the current epidemic of childhood obesity with the subsequent increasing risk of type II diabetes, hypertension, and cardiovascular diseases in older children and adults.

When asked about reimbursement, Joiner noted that 35% of children are currently covered by Medicaid. However, the liquid statin, he believes, should not have problem getting reimbursement coverage because there are no other liquid statins available on the market that are FDA approved with proper doses, Joiner added.

The company is currently partnered with clinical research organization Camargo Pharmaceutical Services.

by Viral Gandhi

