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Israeli Drug Development Companies Are Poised for 505(b)(2) Development Process, Camargo Expert Says

(Cincinnati, Ohio; Dec. 17, 2013) – Many Israeli pharmaceutical executives recently learned that the 505(b)(2) development process is an important tool that can significantly reduce costs and shorten the timeline for approval of new drugs, adding substantially to ROI.

"Israel is known for innovation, and Israeli developers offer a wide range of drug candidates with high market potential and an opportunity to gain U.S. FDA approval through 505(b)(2)," said Ken Phelps, president and CEO of Camargo Pharmaceutical Services and a leading international authority on the development process.

Speaking before an enthusiastic group of more than 40 C-level executives at an invitation-only drug development seminar in Tel Aviv Dec. 9, Phelps said development under 505(b)(2) is ideal for pharmaceutical companies looking to develop drugs based on a change from a previously approved drug because it allows utilizing selected data from studies in the public domain.

"For new indications, drugs that enhance some aspect of an existing drug, drugs with dosage changes or new active ingredients, prodrugs, combination drugs or drug-device combinations, 505(b)(2) can be an attractive alternative," Phelps said.

As head of a full-service organization specializing in 505(b)(2) development, Phelps stressed the importance of careful planning to evaluate both the scientific, regulatory and commercial feasibility of proposed drug products.

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“A step-by-step plan is essential to success,” Phelps said, “but success can mean a differentiated product with three, five or even seven years of market exclusivity and great potential for ROI.”

Phelps’ remarks provoked an enthusiastic response from the audience. “In two hours [our] team got answers to issues they were debating for months,” said Dr. Sharon Cohen-Vered, head of CMC at NeuroDerm.

Dr. Roni Mamluk, COO at Chiasma added, "Even for a very experienced professional in the field, the event was an eye-opener."

About Camargo Pharmaceutical Services

Camargo Pharmaceutical Services is your full-service drug development partner specializing in the 505(b)(2) process. Before development even begins, we verify profit potential by working with your team to develop a comprehensive program and timeline complete with important milestones and cost objectives. We manage every facet of the plan throughout your development continuum, from feasibility assessments, formulation and testing the drug product, to conducting preclinical and clinical studies, to final submission. Connect with Camargo on LinkedIn, the President’s blog or visit www.camargopharma.com for more information.

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