Rising Pharma Opportunities IN CHINA

Rick Pauls, President and CEO of DiaMedica, talks about how the Chinese market is poised for growth.


Rick Pauls

PV: Why do you think the Chinese market has potential for the pharmaceutical industry?

PAULS: The westernization of China is leading to increases in many diseases, such as stroke and kidney diseases. Much of the disease incidence is because people are starting to adopt more western diets and lifestyles. As the country becomes even more westernized and more money is put into healthcare and reimbursement, we expect that the pharmaceutical industry will continue to grow. From a patenting perspective, we also think over the coming years there will greater protection on intellectual property than there have been in the past. Additionally, almost every major pharmaceutical company has a presence in China or is actively looking to expand their operations to manage the potential growth. In terms of our focus, we believe that our stroke drug has a strong potential to receive government reimbursement after approval.

PV: What challenges does the Chinese market present for nonlocal companies?

PAULS: From our research and in talking to the pharmaceutical industry in China, one of the critical factors is to engage with a local partner. Local companies have better relationships with the Chinese government and the China Food and Drug Administration (CFDA). It's also important that the manufacturing is done in China as part of receiving regulatory approval. Based on recent news coverage, the China CFDA appears to be going through some challenging times and taking longer than it would take for the U.S. FDA to approve a drug to enter clinical trials.

It's also critical to have a partner that understands how to sell and market a product in China. A local Chinese partner can help drive the process both on the clinical side and on the sales and marketing side as well.

In terms of regulatory challenges, in the last five to 10 years the clinical bar for regulatory approval is higher than it has been and is becoming more similar to FDA-like standards. There also are more clinical trials and larger studies required compared with five to 10 years ago.

It's going to cost more to do clinical research in China and approvals will take a bit longer than they have in the past, but ultimately our sense is that the Chinese government is working towards putting a lot of effort into making the process smoother than it is right now.

PV: Why is your company pursuing the China market?

PAULS: Our program for DM199 is being studied for acute ischemic stroke. The only universally approved stroke treatment outside of China is tissue plasminogen activator (tPA), which can only be administered to patients within 4.5 hours of the stroke. A human urine-derived form of human tissue kallikrein-1 (uKLK1) has been approved in China for administration up to 48 hours post-stroke by promoting cerebral vascular circulation and angiogenesis and inhibiting apoptosis.

We have successfully manufactured a recombinant (synthetic) form of the KLK1 protein. In China, Techpool BioPharma, which is a joint venture between Takeda and Shanghai Pharmaceuticals, has commercialized the same KLK1 protein. Techpool is extracting KLK1 from human urine sourced from schools and from the Chinese army with challenges in sourcing all the human urine, which is not an ideal source of a protein for drug product with its inconsistent source and the risks of endotoxins and impurities. We believe regulatory bodies across the world, including in China, prefer to replace with synthetic versions.

We are completing a bridging study in Australia designed to identify a dose of our drug that matches the approved dosing of a urine-sourced form of the same protein. This is more of a biosimilars opportunity for the Chinese market. In 2017, we plan to move DMD199 into Phase II for stroke.

There is a great need to replace the urine source of the protein. We estimate that a couple hundred liters of human urine is needed to treat a single patient over a 21-day window. We estimate that 30,000 to 40,000 people per year are paying about $1,400 out of pocket in China for the currently available therapy. PV

DiaMedica's Research

DiaMedica recently completed the first of a two part Phase Ib bridging trial of DM199, a novel recombinant tissue kallikrein (rKLK1) protein for the treatment of neurological and kidney diseases. DiaMedica has completed four previous clinical trials with DM199, including single ascending doses, multiple ascending doses, and a pilot study in Type 2 diabetic patients. Additionally, DiaMedica is researching DM199 for kidney disease. Because DM199 activates the bradykinin receptors, the company's researchers believe DM199 could improve kidney function without increasing the risks of increased hyperkalemia.

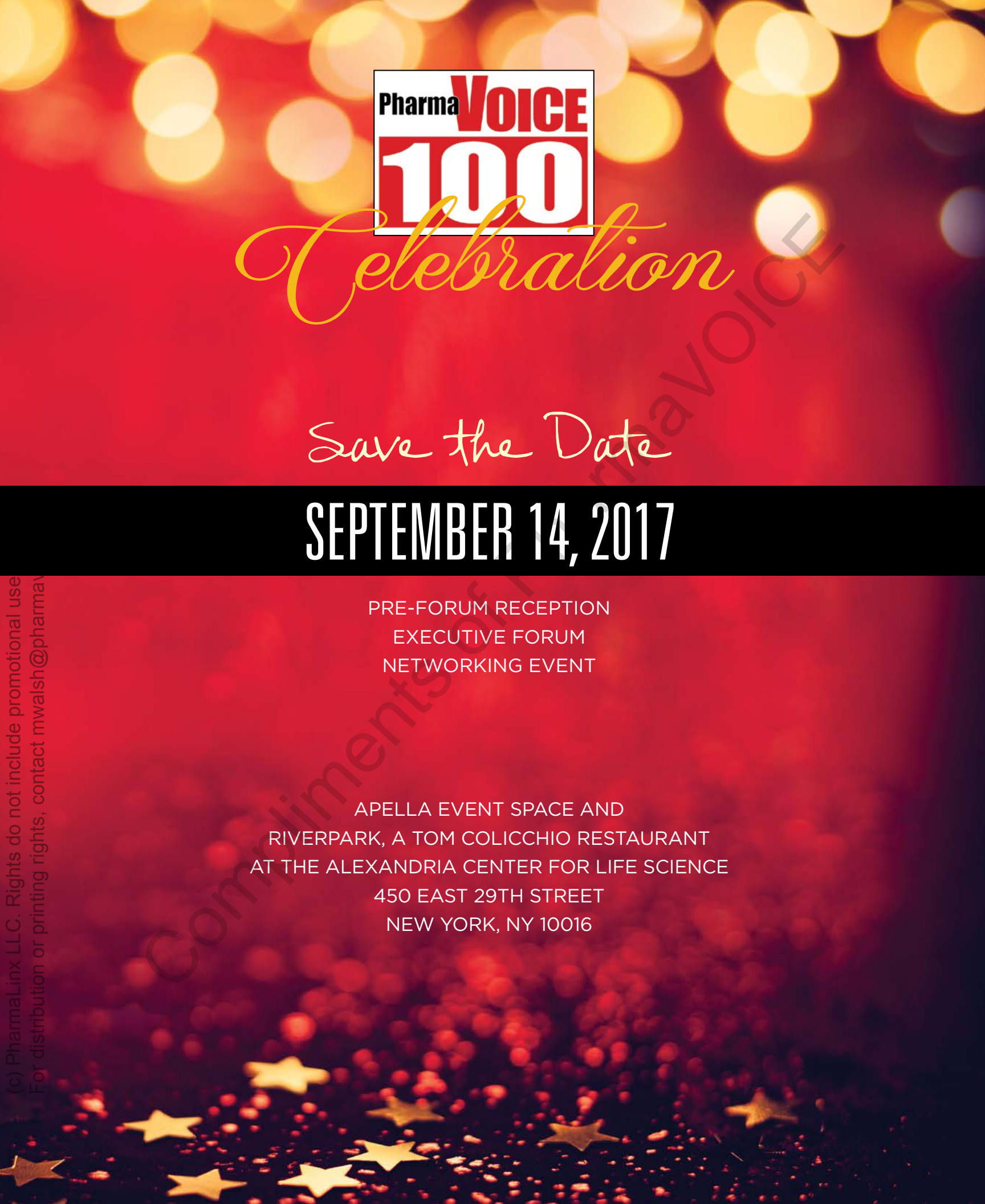
The Chinese Pharmaceutical Market

More than $115 billion in drugs were sold in China in 2015, according to IMS Institute for Healthcare Informatics, making it the world's second largest market after the United States. China's pharmaceutical market shrank by 1% in dollar terms from October to November, according to Barclays Plc., a sharp contrast with the 17% expansion in the second half of 2013.

One of the biggest problems: China's government-run health insurance funds, which are struggling to keep up with an aging population and surging incidence of diseases such as cancer or diabetes. As they grapple with tighter budgets and a slowing economy, many of these funds are capping reimbursements to patients and pushing local authorities to negotiate with companies to lower drug prices. As a result, the world's largest pharmaceutical companies are facing a roadblock in China as a state-led campaign to slash drug prices has triggered a slowdown in sales growth.

In March 2016, Bloomberg reported that China had won price cuts of more than 50% in national-level bargaining with drug companies on about five kinds of costly imported drugs for illnesses, including cancer.

Source: Bloomberg



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