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Letter from Editor



Dear TBI readers,

Over the past two years, our hearts are saddened from the news covering worldwide incidence of bird flu, the name for the deadly H5N1 strain of the avian influenza. It has infected more than 170 people and killed 103 by March 16, 2006. The outbreaks have hit Asia, Africa and Europe. It is highly likely that bird flu will arrive to North America this year. Experts fear the virus could change into a form that passes easily among people. The potential effect of an avian influenza pandemic on the global economy and financial systems could be severe. Last

November, President George W. Bush asked congress approval for \$7.1 billion to prepare for a pandemic on belief of that advanced modern technology may give the policymakers new tools to curb or control the next pandemic.

SAPA-West, its members are from Bio/Pharmaceutical industry and Academic universities, has been actively joining the chores for the bird flu awareness. Early this year, our Science and Technology Committee organized a symposium on avian flu research. In this issue, we have four articles dedicated to the avian pandemic flu covering from preparation and prevention strategies to vaccine and drug development. The feature article was written by internationally renowned Prof. Yunde Hou, a member of Chinese Academy of Science and the Director of Chinese Institute of Virology. In the article, Prof. Hou proposed plans for global cooperation to combat avian flu epidemic/pandemic. Those proposal bears importance for China and international strategic policy making. We would suggest you to read thoroughly his articles and other articles if you are interested in learning more about the future direction in this area.

Like most of you, we were thrilled to celebrate the 1st birthday of our Journal, Trends in Bio/Pharmaceutical Industry (TBI). As the new year starts, some of our Editors resigned from the board due to either family or business restrictions. We are very grateful for their faithful services during their term. Their dedication and the great team effort had brought this Journal from a concept to a reality. At the same time, we would like to welcome five new editors to join the board this year. They are from US, Canada and China. I am sure this Journal will be greatly benefited from their scientific expertise and international visions. Please join us to welcome them and let's work together to better serve our members and our community.

In 2005, four timely issues were published and mailed to you recently. As part of SAPA-West member benefit, you will continue to receive all future issues as long as your membership status stays active. For non-members, we encourage you to join the society and the great team of scientists. At the same time, we welcome both members and non-members to contribute to the Journal. We can not fulfill our mission without your participation and contribution. After all, it is a Journal that is from you and for you! Thanks for reading.

Jon Mo, Ph.D.
Editor
April 3, 2006

New Drugs Approved by FDA in 2004-2005

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About the author: Dr. Zhi-Jie Ni is a Senior Scientist and a group leader at Chiron Corporation. His medicinal chemistry interests are in the areas of oncology and infectious diseases (antibacterial and anti-HCV). He received his B.S. in Chemistry from Hangzhou University, M.S. from Shanghai Institute of Organic Chemistry, and PhD in Organic Chemistry from the Chinese University of Hong Kong. He completed his postdoctoral trainings at Ohio State University as well as Emory University.

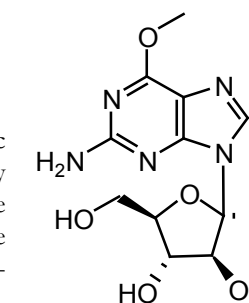
Introduction

A recent study by Tufts Center¹ for the Study of Drug Development found that an average of 8.5 years was required for a compound to move through the clinical and approval phases. That is significantly longer than the average of 7.2 years for drugs approved in the immediately preceding period of 1999-2001. The report also found that longer clinical trial times is a major factor the extended - time that is required to bring new prescription drugs to market in the United States.¹ As a result, the number of new molecular entity approvals by the FDA has been falling in early 2000s. Despite these challenges, a number of important therapeutic agents were brought to the market in the US. In 2004, 30 new chemical entities entered the market for therapeutic use. The number was 15 in 2005². A new drug is defined as a medication containing an active substance that has never before been approved for marketing in any form in the United States. In this review, we will highlight some new drugs that were approved by FDA during last two years for the treatment of cancer, infectious disease, and diabetics.

Anti-Cancer Drugs

Arranon (nelarabine)³ by GlaxoSmithKline

Arranon is a prodrug of cytotoxic deoxyguanosine analog. It is rapidly activated by adenosine deaminase to guanine arabinoside (ara-G). The accumulation of 5'-triphosphate (ara-GTP), the active form of Arranon, disrupts DNA synthesis in rapidly dividing cells, inducing cellular apoptosis. Arranon was approved for the treatment of pediatric and adult patients with T-cell acute lymphoblastic leukemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) who had relapsed or not responded to at least two chemotherapy regimens.



The approval was based the results from a trial of pediatric patients of 21 years and younger, which indicated that 13% of patients achieved complete disease response (bone marrow blast counts <5%) and full recovery of peripheral blood counts, and 10% achieved complete disease response without full hematological recovery. A slight better response (18%) was observed from adult patients. Thus, 18% achieved complete response and hematological recovery. Median overall survival was 20.6 weeks. In October 2005, the FDA granted the drug accelerated approval in patients with T-ALL and T-LBL. The drug was launched in January 2006.