Trends-in-Medicine

Quick Takes

by Maude Campbell

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Trends-in-Medicine
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Check out the new *Trends-in-Medicine* blog on our website (www.trends-in-medicine.com). The latest entry is about rotavirus vaccines.

…Highlights from this week's news affecting drugs and devices in development…

SHORT TAKES

- **ALLOS THERAPEUTICS' pralatrexate –** The FDA has given orphan drug status to pralatrexate, which is currently being used in a clinical trial for the treatment of advanced or metastatic transitional cell carcinoma of the bladder.
- **AMGEN's denosumab –** Amgen has filed a new NDA for denosumab for use in treating bone tumors resulting from metastatic cancers. The FDA is also reviewing denosumab as an osteoporosis treatment.
- **AVANIR's Zenvia (dextromethorphan + quinidine) –** Avanir expects the FDA to make an approval decision by October 30, 2010, on the drug for treatment of pseudobulbar affect.
- **CEPHALON/IMMUPHARMA's Lupuzor (IPP-201101) –** Phase III trials are underway in Europe for this injectable therapy for systemic lupus, and Cephalon expects to start a clinical trial in the U.S. within a few weeks.
- **Technetium-99 shortage –** The Nuclear Research and Consultancy Group of the Netherlands said repairs to the High Flux Reactor are proceeding on schedule, and the restart date is planned for the second half of August 2010.

NEWS IN BRIEF

ACCORD trial mortality analysis – intense glucose control *not* linked to increased mortality

A post hoc analysis of the ACCORD diabetes trial indicates that, contrary to previous reports, rapid lowering of blood glucose and using intensive glucose control regimens to maintain hemoglobin A1c levels did not increase death rates compared with a conventional glucose control strategy. Researchers reported in ***Diabetes Care*** that – after adjusting for baseline characteristics associated with higher mortality risk – higher HbA_{1c} levels during treatment was a better predictor of death than HbA_{1c} levels

measured during follow-up or the decrease of HbA_{1c} levels during the first year of treatment. Intensive glucose control increased the risk of death from 6% to 9%, but the risk of death was higher than that associated with standard treatment when the average HbA_{1c} was maintained and >7%. The researchers concluded that higher HbA_{1c} levels, rather than low HbA_{1c} levels, were the likely contributors to increased mortality seen in the intensive glycemic control group.

AEROCRINE – buys Apieron

Aerocrine has bought all assets of bankrupt Apieron, ending Apieron's litigation against Aerocrine in the U.S. and Germany. Patent infringement claims against Apieron in the U.S. will not be dismissed, though. Patent infringement claims arose after Apieron launched Insight, an exhaled nitric oxide measurement device, in the U.S. in 2008 and Apieron filed bankruptcy in March 2010. Aerocrine, which specializes in management of inflammatory airway disease, said it will not invest to resume production of Insight, which was discontinued after the Apieron bankruptcy filing.

ASTELLAS – to buy OSI Pharmaceuticals

After OSI rejected a previous $3.5 billion unsolicited offer, Astellas agreed to buy OSI for $4 billion. OSI makes Tarceva (erlotinib) for treatment of advanced pancreatic and liver cancer. The OSI acquisition is the largest in Astellas' history. It will give the company its first cancer drug and hopefully will lessen the effects of competing generic versions of current Astellas drugs.

BAXTER – problems increasing?

Baxter recalled all lots of its Hylenex (hyaluronidase human injection) after glass particles were found in vials of the product, though no patient injuries have been reported. Baxter is asking customers to return any of the ~3,500 vials in circulation. This recall comes on the heels of several other serious problems at Baxter: the infusion pump recall, a hepatitis C outbreak, and propofol issues. *The question is whether all of this will have a negative impact on Baxter's relationship with the FDA and its ability to get new products approved.*

JOHNSON & JOHNSON – fallout continues from children's product recall

The House Committee on Oversight and Government Reform asked J&J CEO William Weldon to testify during a May 27, 2010, hearing on the children's medicines recall. Weldon will be asked to explain the company's response to findings of foreign material in the products. Meanwhile, the FDA has expanded its inquiry into the manufacturing of the medications in question. A spokesman for J&J's McNeil Consumer Healthcare unit said the company is conducting a comprehensive quality assessment across its manufacturing operations.

National Cancer Institute – gets new director

President Barack Obama has nominated former NIH chief Dr. Harold Varmus to lead the NCI. Varmus served as director of the NIH under President Clinton between 1993 and 1999 and has been president of Memorial Sloan-Kettering Cancer Center since 2000. In 1989, Varmus won the Nobel Prize in Physiology or Medicine for his research on the genetic basis of cancer.

PFIZER – pays Washington University for research

In an unusual partnership move, Pfizer will pay Washington University in St. Louis $22.5 million to help it discover new uses for more than 500 existing drugs and drug candidates. Pfizer will provide university researchers with its data on the drug compounds through an online portal and will move its discovery unit from the current suburban location to one next door to the Washington University School of Medicine. Don Frail, chief scientific officer of Pfizer's Indications Discovery Unit, said, "By harnessing the scientific expertise at this leading academic medical center, the collaboration seeks to discover entirely new uses for these compounds in areas of high patient need that might otherwise be left untreated."

ROCHE/BIOGEN IDEC – discontinue ocrelizumab arthritis program

After reviewing results of four Phase III clinical studies of ocrelizumab in patients with rheumatoid arthritis (RA), the companies said they are discontinuing development of the drug. The companies said the overall risk:benefit profile of ocrelizumab "was not favorable in RA taking into account the currently available treatment options." An independent Data Safety Monitoring Board (DSMB) concluded that the safety risk outweighed the benefits in RA patients and said there was an infection-related safety signal, with patients developing serious and opportunistic infections, some of which were fatal.

Ocrelizumab is also being assessed as a potential treatment for relapsing-remitting multiple sclerosis (RRMS), and a Phase II clinical MS trial will continue.

ROXRO PHARMA's Sprix (intranasal ketorolac) – receives FDA approval

The FDA approved Sprix, a nasal spray for outpatient, short-term use in managing acute moderate-to-severe pain that requires analgesia normally provided by opioids. Ketorolac is a nonsteroidal anti-inflammatory (NSAID) usually administered by injection in a hospital setting. The intranasal version can be used for up to 5 days and offers a non-opioid option for outpatient pain relief.

ST. JUDE MEDICAL – buys LightLab Imaging

St. Jude Medical will pay $90 million for LightLab Imaging, a subsidiary of Goodman. The deal puts St. Jude into the coronary imaging market. LightLab has been developing optical coherence tomography (OCT), which uses infrared light that can produce high-resolution, real-time images that would be an alternative to current technologies, such as intra-vascular ultrasound (IVUS) imaging. The FDA recently approved LightLab's C7-XR Imaging System and C7 Dragonfly Imaging catheter for imaging during interventional procedures.

TEVA's talampanel – safe but not effective in ALS

Teva reported that talampanel, a treatment in development for amyotrophic lateral sclerosis (ALS), or Lou Gehrig's disease, failed to meet a key efficacy goal in the 559-patient Phase II ALSTAR trial. However, the drug did appear safe, meeting the trials safety goals.

FDA NEWS

The FDA's Center for Drug Evaluation and Research (CDER) will soon start a series of inspections under 21 CFR Part 11 of pharma compliance with electronic recordkeeping require-ments. The audits will be added to routine inspections of manufacturing facilities and clinical trial data. Why is this a big deal? Remember a few years ago how an FDA finding of a computer issue at one Lilly manufacturing site became a systemic problem, spreading throughout the company and holding up Lilly drug approvals.

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