Milestones

■ 10 YEARS AND COUNTING...

Baxter Healthcare Corp. is celebrating the 10th anniversary of its Kidney Patient Educator (KPE) program, a project that has provided credible, timely information on chronic kidney disease (CKD) and treatment options to 80,000 kidney disease patients in more than 30 states since 1997.

Started as a small pilot support program to supplement education by nephrologists, Baxter's KPE program provides kidney disease patients with access to a licensed healthcare professional who can provide unbiased information about the disease and treatments, as well as one-on-one emotional support.

■ SILVER CELEBRATION

The National Organization for Rare Disorders (NORD) and rare-disease patient organizations across the United States are celebrating the 25th anniversary of the signing of the Orphan Drug Act (ODA). In the decade before the ODA was passed by Congress and signed on Jan. 4, 1983, by President Ronald Reagan, only 10 treatments had been developed for rare diseases by the industry. In the 25 years since then, more than 1,100 treatments for rare diseases have entered the research pipeline and more than 300 have been approved by the FDA for marketing.

■ MORE THAN 100 CONVERSIONS

Octagon Research Solutions Inc. has completed the conversion of electronic clinical study data to CDISC SDTM format for more than 100 studies across eight therapeutic areas and 2,500 domains.

CDISC (Clinical Data Interchange Standards Consortium) developed the SDTM (Study Data Tabulation Model) as a standard format for the submission of electronic clinical study data to regulatory authorities. The FDA is currently accepting electronic clinical data in this format and has referenced the SDTM as the recommended format for clinical study data in electronic regulatory submissions.

If your company or organization is celebrating a major anniversary, please send your information to: feedback@pharmavoice.com, subject line Milestones.

TUNING IN...

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THE PRICE IS RIGHT

Drug Pricing Decisions More Critical Than Ever

Worldwide pharmaceutical sales were **$643 billion in 2006, an increase of 6.5% compared with 2005.**

In an era of more competition from generics, expiring patent protection for many top-selling drugs, and a slowdown in new drug discoveries, there is very little margin for error in drug pricing decisions. Kalorama Information's recent report states that pharma sales reached $643 billion worldwide in 2006, increasing by 6.5% compared with 2005, and global pharmaceutical companies have enjoyed a median profitability more than three times the average for all Fortune 500 companies. But companies will be challenged in the coming years.

In addition to the onslaught of generics, which have increased their market penetration from 44% to 51.6% in the last couple of years, shrinking government and corporate healthcare budgets are putting pressure on the pricing strategies of pharmaceutical and biotech companies and reducing their margins. After eight years of double-digit growth, commercial prescription drug costs decreased to the single digits in 2003 and settled at a 4.8% growth rate in 2005.

"The golden years of monopolistic pricing are gone," says Joseph Constance, the report's author. "Medicare Part D initiation, tiered managed care formulary systems, and the increasing clout of generic medicines are challenging margins. Companies will have to adapt to survive, and pricing is one of the few levers they can pull."

SOURCE: KALORAMA INFORMATION, ROCKVILLE, MD.

R&D/REVENUE RATIO

New Products Account for 16% of Sales

According to a recent report from The Centre for Medicines Research International Ltd. (CMR), new products — those launched within the last five years — accounted for 16% of total revenue in 2006.

These findings reflect the industry's continuing exposure to patent expirations of its blockbuster drugs.

And although the cost of R&D continues to rise, there's no sign of a sustained upturn in the number of new products reaching the market.

Also noteworthy is the continuing expansion of clinical development in traditionally noncore countries, that is, countries other than: Canada, France, Germany, Italy, Japan, Spain, U.K., and U.S. In 2005, almost 50% of patients recruited to clinical trials came from noncore regions.

SOURCE: CMR, PHILADELPHIA