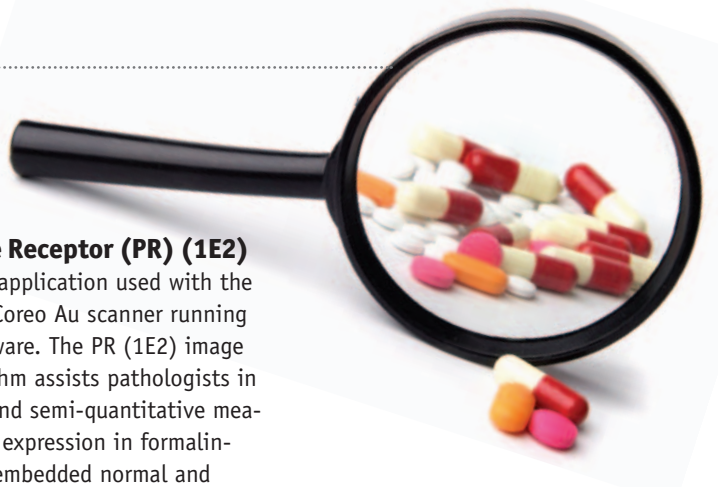
tools



Drugs in the News

- Coronado Biosciences, Inc. *(www.coronadobiosciences.com)* announced submission of an investigational new drug application (INDA) to the Food and Drug Administration (FDA) for **CNDO-109**, a novel biologic that primes natural killer cells without the need for cytokines (IL-2), and is being studied for the treatment of patients with high-risk acute myeloid leukemia (AML) in first complete remission. CNDO-109 activated NK cells have shown early efficacy in an investigator-initiated Phase I clinical trial in patients with AML, and demonstrated pre-clinical activity in multiple myeloma, breast cancer, prostate cancer, and ovarian cancer.

- Marshall Edwards, Inc. *(www.marshalledwardsinc.com)* announced submission of an INDA to the FDA to initiate clinical testing for oncology drug candidate **ME-344**, a mitochondrial inhibitor and an active metabolite of NV-128, a first-generation compound.

Assays, Genetic Tests & Vaccines in the News

- Ventana Medical Systems, Inc. *(www.ventanamed.com),* a member of the Roche Group, announced that the FDA approved the application of its **INFORM HER2 Dual ISH DNA Probe** cocktail assay **(HER2 Dual ISH)** on the Ventana BenchMark ULTRA automated slide staining platform for commercialization in the U.S. The HER2 Dual ISH assay is intended for use in the determination of HER2 gene status in breast cancer tissue as an aid in the assessment of patients that may be considered for treatment with Herceptin (trastuzumab). The HER2 Dual ISH assay detects both HER2 and chromosome 17 on a single slide using a standard light microscope.

  Ventana also received 510(k) clearance from the FDA for the **Ventana Companion Algorithm Progesterone Receptor (PR) (1E2)** image analysis application used with the Ventana iScan Coreo Au scanner running VIRTUOSO software. The PR (1E2) image analysis algorithm assists pathologists in the detection and semi-quantitative measurement of PR expression in formalin-fixed, paraffin-embedded normal and neoplastic breast tissue. This application aids the pathologist in achieving consistency and objectivity in PR interpretation for breast cancer patients.

- The FDA approved Gen-Probe's *(www.gen-probe.com)* **PROGENSA® PCA3 (Prostate Cancer gene 3) assay**, the first molecular test to help determine the need for repeat prostate biopsies in men who have had a previous negative biopsy. The PROGENSA PCA3 assay is indicated for use in conjunction with other patient information to aid in the decision for repeat biopsy in men 50 years of age or older who have had one or more previous negative prostate biopsies and for whom a repeat biopsy would be recommended by a urologist based on the current standard of care, before consideration of PROGENSA PCA3 assay results. A negative PROGENSA PCA3 assay result is associated with a decreased likelihood of a positive biopsy.

- CK Life Sciences International *(www.ck-lifesciences.com)* announced that the FDA has granted clearance for its subsidiary Polynoma LLC *(www.polynoma.com)* to proceed with Phase III clinical testing of its **melanoma vaccine**. Using a combination of antigens from three proprietary melanoma cell lines, Polynoma's melanoma vaccine is intended to stimulate the body's immune system to fight the cancer.

Devices in the News

- Kinoca Minolta *(www.konicaminolta.com/medicalusa/)* announced FDA clearance for the **Aero DR Wireless 17x17 inch Flat Panel Detector (FPD).** It is the first wireless 17x17 inch FPD weighing only 7.92 pounds. The increased imaging area of the 17x17 inch Aero DR FPD improves clinical workflow and patient care by offering users more versatility in positioning patients and allowing for more clinical data on every exposure, which may decrease the number of exposures needed for studies that require imaging a larger region of interest.

- Varian Medical Systems *(www.varian.com)* received FDA 510(k) clearance for a surface beacon transponder to be used with the Varian Calypso system as a real-time tracking device capable of monitoring motion during radiotherapy treatment for indications anywhere in the body. The **Surface Beacon Transponder®** is placed temporarily on the skin for real-time tracking of respiratory and other patient motion during radiotherapy, thereby greatly expanding the number of cancer sites for which the Calypso technology can be used.

- Hospira, Inc. *(www.hospira.com)* announced that the FDA has granted regulatory clearance for the company's **Symbiq™ 3.13 infusion device**, the enhanced version of the company's advanced infusion system platform. The clearance was granted through the new draft FDA regulatory guidance for 510(k) infusion pump submissions. Hospira plans to start working with current customers to upgrade to the enhanced Symbiq device in the first quarter, and expects to begin shipments to previously contracted customers in the second quarter. OI