Pfizer, Bayer, and BMS Advance Personalized-Medicine Products
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By: Patricia Van Arnum
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Personalized medicine is still an emerging field for the pharmaceutical industry, but several large companies recently reported developments in this area.

Last week Pfizer (New York) entered into an agreement with DxS, a subsidiary of Qiagen (Venlo, The Netherlands), a molecular-diagnostics company. The companies will develop a companion diagnostic test for *PF-O49448568* (CDX-10), an immunotherapy vaccine in development for treating glioblastoma multiforme (GBM), the most common form of brain cancer. Pfizer is licensing *PF-O49448568* (CDX-10) from the biopharmaceutical company Celldex Therapeutics (Needham, MA).

PF-O49448568 (CDX-10) is a peptide vaccine that targets the tumor-specific epidermal growth-factor receptor variant III (EGFRvIII), a mutated form of the EFFR that is only present in cancer cells and occurs in 25–40% of GBM tumors. The therapy is in Phase II clinical development.

The EGFRvIII companion diagnostic will be developed and manufactured at Qiagen's facility in Manchester, UK. The diagnostic will be a real-time polymerase-chain reaction assay used to detect EGFRvIII RNA in tumor tissue.

Bayer (Leverkusen, Germany) has started clinical Phase I studies for a personalized vaccine derived from tobacco plants. Late last month, the US Food and Drug Administration gave the company approval for the Phase I trials to test the idiotype vaccine for treating non-Hodgkin's lymphoma in human subjects.

The patient-specific vaccine is being produced in a pilot plant operated by Icon Genetics (Halle, Germany), a subsidiary of Bayer, using Bayer's magniCON technology. The technology allows for the rapid production of high yields of recombinant proteins. With this technology, the plant source is not genetically modified. Instead, the blueprint for the required product is inserted temporarily into the plant using a species of *Agrobacterium* and distributed through the plant cells, according to a Bayer press release. The protein subsequently is extracted from the plant's leaves with high purity. The process can be carried out in a large-scale closed facility.

"The goal of cancer therapy in the future will be to tailor treatment to the individual patient as far as possible," said John Butler-Ransohoff, project manager for plant-made pharmaceuticals at Bayer, in the Bayer press release. "Hematological tumors such as B-cell lymphomas are a good starting point for the further

development of personalized medicine because the idiotypic antibodies formed by the lymphomas are highly specific tumor markers."

Bristol-Myers Squibb (New York) has broadened its collaboration with KineMed (Emeryville, CA), a translational and personalized-medicine agreement in the area of Alzheimer's disease and other neurodegenerative conditions. The companies first signed a pact in 2009 under which KineMed is using its proprietary translational and personalized-medicine platform to identify and characterize biomarkers in cerebrospinal fluid to facilitate the development of BMS drug candidates to treat Alzheimer's disease.

According to a recent PricewaterhouseCoopers (PwC) report, the market for personalized medicine in the United States is valued at $232 billion and is expected to grow 11% annually. The core diagnostics and therapeutic segment of the personalized health market is estimated at $24 billion and is expected to increase 10% annually to reach $42 billion in 2015. Using a broader definition of the market to include demand for high-technology storage and data sharing, as well as drugs and devices, PwC projects that the market for personalized medicine could reach $452 billion by 2015.